WEEKLY REPORT

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BRAZIL DEBATES REFORM OF PRIMARY HEALTHCARE POLICY

Brazil is reviewing its National Primary Care Policy (PNAB) as mounting pressure on the country's primary healthcare network exposes persistent challenges, including shortages of healthcare professionals, recurring medicine stockouts at public clinics, and growing demand driven by population aging, chronic diseases, and mental health conditions. The updated policy, expected by the end of 2026, aims to modernize the organization of primary care while reinforcing the role of the Family Health Strategy (ESF) as the cornerstone of Brazil's Unified Health System (SUS). The proposed reform includes measures to improve the recruitment and retention of family physicians and multidisciplinary teams, revise financing mechanisms, and restore the territorial, community-based model that has historically guided primary care in Brazil. Specialists also advocate reducing the number of patients assigned to each healthcare team to improve continuity of care, prevention, and disease management, while strengthening coordination between primary care and specialized services to increase the efficiency and sustainability of the public health system. Read more.

ANS EXTENDS DATA COLLECTION ON HEALTH DISCOUNT CARDS AFTER LOW INDUSTRY PARTICIPATION

Brazil's National Regulatory Agency for Private Health Insurance and Plans (ANS) has extended the deadline for companies offering health discount cards to submit operational information after low participation in the agency's public data collection process. According to ANS President Wadih Damous, many companies expressed concerns that the questionnaire could lead regulators to classify their business models as private health plans, subjecting them to a stricter regulatory framework. The agency has revised and simplified the questionnaire and reopened the consultation period to gather more representative data on a market estimated to serve millions of Brazilians. The initiative is part of ANS's broader effort to define the regulatory boundaries for health discount cards, prepaid healthcare services, and similar products, following guidance from Brazil's Superior Court of Justice (STJ). The information collected will support future regulatory decisions aimed at distinguishing these products from private health insurance while increasing transparency and consumer protection. The outcome of the process could have significant implications for companies operating in the supplementary healthcare market and for the regulation of alternative healthcare access models in Brazil. Read more.

BRAZIL'S PRIVATE HEALTH INSURANCE MARKET SURPASSES 53 MILLION BENEFICIARIES

Brazil's private health insurance sector has surpassed 53 million beneficiaries, continuing a growth trend driven primarily by employer-sponsored health plans. According to data from the National Regulatory Agency for Private Health Insurance and Plans (ANS), collective corporate plans remain the main engine of expansion, reflecting the resilience of the formal labor market and the increasing role of supplementary healthcare in meeting the country's healthcare needs. The sector also continues to record strong growth in dental coverage, reinforcing the steady expansion of private healthcare services. The milestone underscores the growing importance of supplementary healthcare within Brazil's healthcare system, where private coverage complements the Unified Health System (SUS) for more than one-quarter of the population. Industry analysts note that while enrollment continues to rise, the market faces ongoing challenges related to affordability, medical inflation, regulatory oversight, and the sustainability of healthcare financing. The expansion also highlights the strategic importance of the private health sector for pharmaceutical companies, healthcare providers, and investors seeking opportunities in Latin America's largest healthcare market. Read more.

PATENT TERM ADJUSTMENT DEBATE RETURNS TO BRAZIL'S HEALTH INNOVATION AGENDA

The debate over reintroducing a Patent Term Adjustment (PTA) mechanism has returned to Brazil's health policy agenda, as lawmakers consider proposals to compensate patent holders for administrative delays in patent examinations by the National Institute of Industrial Property (INPI). Supporters, including research-based pharmaceutical companies, argue that the measure would restore legal certainty, improve the predictability of intellectual property protection, and strengthen Brazil's ability to attract investments in research and development. The discussion follows the Brazilian Supreme Court's 2021 decision to strike down the automatic patent term extension previously provided under the Industrial Property Law. The proposal has sparked strong opposition from manufacturers of generic and biosimilar medicines, academic institutions, and public health stakeholders, who argue that extending patent protection could delay market competition, increase pharmaceutical spending, and postpone patient access to more affordable medicines. Bills currently under discussion in the National Congress seek to establish a limited compensation mechanism for delays attributable to the government, reflecting the broader challenge of balancing incentives for pharmaceutical innovation with competition and the sustainability of Brazil's healthcare system. Read more.

ANVISA APPROVES FIVE NEW SEMAGLUTIDE PENS FOR DIABETES TREATMENT

The Brazilian Health Regulatory Agency (Anvisa) has approved five new semaglutide injection pens for the treatment of type 2 diabetes, further expanding competition in Brazil's rapidly growing GLP-1 market. The approvals follow the expiration of the original semaglutide patent and include synthetic versions developed by different manufacturers, increasing the number of therapeutic alternatives available to patients. The move is expected to broaden supply and, over time, contribute to lower prices for one of the country's most sought-after classes of diabetes medicines. The new products must still receive maximum price authorization from the Drug Market Regulation Chamber (CMED) before reaching pharmacies, and manufacturers will determine their commercial launch dates. The approvals build on Anvisa's strategy to accelerate the review of GLP-1 therapies while maintaining standards of safety, efficacy, and quality, reinforcing Brazil's position among the first regulatory agencies worldwide to authorize synthetic semaglutide products and paving the way for greater access to innovative diabetes treatments. Read more.

SANDOZ ENTERS BRAZIL'S SEMAGLUTIDE MARKET THROUGH PARTNERSHIP WITH ADALVO

Sandoz has entered Brazil's fast-growing GLP-1 market through a partnership with European pharmaceutical company Adalvo, following the Brazilian Health Regulatory Agency's (Anvisa) approval of Owozy®, a synthetic semaglutide pen indicated for the treatment of type 2 diabetes. Brazil will be the first country to launch the product globally, reflecting its position among the earliest markets to open following the expiration of Novo Nordisk's semaglutide exclusivity. Owozy will be manufactured by Adalvo in Canada and commercialized by Sandoz, with the companies targeting a launch in the second half of 2026 after maximum price approval by the Drug Market Regulation Chamber (CMED). The launch marks Sandoz's expansion beyond its traditional focus on generics and biosimilars into the rapidly growing market for complex follow-on medicines. Company executives said the product will be priced competitively against the originator and is expected to increase patient access to GLP-1 therapies in a market where more than 16.5 million Brazilians live with diabetes. The company is also evaluating future indications, including obesity, and potential discussions with the government regarding access through the Unified Health System (SUS), underscoring the strategic importance of Brazil in the evolving global semaglutide market. Read more.

BRAZIL DEFINES LIST OF ULTRA-HIGH-COST ONCOLOGY MEDICINES FOR SUS FUNDING

Brazil's Ministry of Health has published the first official list of 18 ultra-high-cost oncology medicines to be financed under the Unified Health System (SUS), marking another milestone in the implementation of the Oncology Pharmaceutical Assistance Component (AF-Onco). The list includes therapies for breast, lung, gastric and ovarian cancers, multiple myeloma, and leukemia, among other conditions, and establishes the medicines that will be centrally financed by the federal government due to their exceptionally high budget impact. The measure is part of the broader restructuring of oncology care and pharmaceutical assistance announced earlier this year. The new regulation provides greater clarity on the financing and procurement of innovative cancer therapies, supporting more predictable access across the country while helping states and healthcare providers plan treatment delivery. According to the Ministry of Health, the ordinance will take effect in 120 days and complements recent initiatives to expand access to high-cost oncology medicines through the SUS, reinforcing the federal government's strategy to standardize funding and reduce regional disparities in access to advanced cancer treatments. Read more.

BRAZIL TO BUILD FIRST PROTON THERAPY CENTER FOR CANCER TREATMENT

Brazil will establish its first proton therapy center, introducing one of the world's most advanced forms of radiation therapy for cancer treatment. The facility, to be built in Rio de Janeiro with federal support and technology supplied by Belgium's IBA, will provide highly precise radiation that minimizes damage to surrounding healthy tissues, making it particularly beneficial for pediatric tumors and cancers located near critical organs. The project represents a major milestone for Brazil's oncology infrastructure and is expected to strengthen research, professional training, and access to cutting-edge radiotherapy technologies. Despite the announcement, patients treated through Brazil's Unified Health System (SUS) are not expected to benefit immediately. Construction of the center is still underway, with the first treatments projected to begin only in 2030, while future incorporation into the SUS will depend on regulatory and reimbursement decisions. Once operational, the facility is expected to position Brazil among the limited number of countries offering proton therapy and reduce the need for patients to seek this highly specialized treatment abroad. Read more.

ANVISA EXPANDS ACCESS TO INNOVATIVE THERAPIES FOR CANCER, RARE DISEASES, AND PULMONARY HYPERTENSION

The Brazilian Health Regulatory Agency (Anvisa) has approved three new innovative therapies, broadening treatment options for patients with serious diseases and significant unmet medical needs. The agency authorized Datroway® (datopotamab deruxtecan) for adults with locally advanced or metastatic EGFR-mutated non-small cell lung cancer (NSCLC) who have previously received EGFR-targeted therapy and platinum-based chemotherapy. Anvisa also approved a new indication for Ilaris® (canakinumab) to treat rare autoinflammatory diseases and granted marketing authorization for Winrevair® (sotatercept), the first activin signaling inhibitor approved in Brazil for the treatment of pulmonary arterial hypertension (PAH), a rare and progressive cardiovascular condition. The approvals reinforce Anvisa's ongoing efforts to accelerate access to innovative medicines while addressing unmet clinical needs in oncology, rare diseases, and cardiovascular care. Datroway offers an additional option for lung cancer patients who progress after standard targeted therapies, while canakinumab expands access to targeted biologic treatment for severe autoinflammatory disorders. Meanwhile, sotatercept introduces a first-in-class therapy that targets the underlying vascular remodeling associated with pulmonary arterial hypertension, representing a significant advance over treatments focused primarily on symptom management. Together, the three approvals reflect continued progress in precision medicine and the expansion of Brazil's regulatory framework for high-value innovative therapies.

PHARMACY COUNCIL SEEKS INVESTIGATION INTO SALE OF MEDICINES THROUGH VENDING MACHINES

The Regional Pharmacy Council of São Paulo (CRF-SP) has asked the São Paulo Public Prosecutor's Office (MPSP) to investigate the sale of medicines through automated vending machines installed in residential condominiums. The council argues that the practice violates Brazil's pharmaceutical legislation by dispensing medicines without the mandatory supervision of a licensed pharmacist, potentially encouraging self-medication, improper use, and compromising patient safety. The request comes amid broader discussions on the modernization of pharmaceutical retail regulations and access to over-the-counter medicines. According to the CRF-SP, Brazilian law recognizes pharmacies as healthcare establishments rather than conventional retail outlets, requiring pharmaceutical assistance and professional guidance during medicine dispensing. The council maintains that vending machines cannot comply with these legal and sanitary requirements and is seeking regulatory action to prevent the expansion of the model. The case highlights the ongoing debate between expanding consumer convenience and preserving the safeguards designed to ensure the rational and safe use of medicines in Brazil. Read more.

BRAZIL ADVANCES ON HIV TARGETS BUT FACES RISING NEW INFECTIONS, UNAIDS REPORTS

Brazil continues to rank among the global leaders in the HIV response, having achieved two of the three 95-95-95 targets established by the Joint United Nations Programme on HIV/AIDS (UNAIDS). According to the agency's latest report, the country has met the goals for HIV diagnosis and viral suppression while significantly expanding access to pre-exposure prophylaxis (PrEP) and increasing domestic public investment in HIV programs. These achievements reinforce Brazil's longstanding policy of universal access to prevention, testing, and antiretroviral treatment through the Unified Health System (SUS). Despite this progress, Brazil remains one of 21 countries that recorded an increase of more than 20% in new HIV infections between 2010 and 2025, underscoring persistent challenges in prevention and treatment coverage. UNAIDS notes that the country has yet to meet the target for antiretroviral treatment uptake, while emphasizing that expanding access to innovative prevention tools—including long-acting PrEP—and ensuring affordable access to new technologies will be essential to reversing transmission trends and achieving the global goal of ending AIDS as a public health threat by 2030. Read more.

BRAZIL EXPANDS STRATEGY FOR NEXT-GENERATION HIV PREVENTION

Brazil is advancing a comprehensive strategy to expand access to next-generation HIV prevention technologies through the Unified Health System (SUS). The Ministry of Health has confirmed plans to incorporate long-acting injectable PrEP with cabotegravir, administered every two months, while negotiating with Gilead Sciences to acquire lenacapavir, the first twice-yearly injectable HIV prevention therapy. Although Anvisa has already approved lenacapavir, the product remains under pricing negotiations and will require evaluation by the National Commission for the Incorporation of Technologies into the SUS (Conitec) before becoming available in the public health system. The initiatives are part of Brazil's broader effort to improve adherence, expand prevention options, and reduce new HIV infections. In parallel, Fiocruz and MSD have signed a memorandum of understanding to explore the future local production of alimatravir (MK-8527), an investigational once-monthly oral PrEP currently in Phase 3 clinical trials. The agreement includes technology transfer and the possibility of domestic manufacturing if the product receives regulatory approval, reinforcing Brazil's strategy to strengthen the Health Economic-Industrial Complex (CEIS). Together, these initiatives position Brazil among the countries leading the adoption of long-acting HIV prevention technologies while combining expanded access through the SUS with investments in local pharmaceutical innovation and manufacturing capacity.

SÃO PAULO'S HIV PREVENTION STRATEGY GAINS GLOBAL RECOGNITION

São Paulo has become the only city in the world to offer HIV prevention medications through subway stations, an initiative that has attracted international attention as a model for expanding access to pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP). By integrating HIV prevention into high-traffic public spaces, the city's health system has reduced barriers to testing, counseling, and treatment, helping normalize preventive care while reaching populations at greater risk of infection. The strategy has contributed to a steady increase in PrEP uptake and reinforced São Paulo's position as a global leader in innovative HIV prevention policies. The program builds on Brazil's longstanding commitment to universal access to HIV prevention and treatment through the Unified Health System (SUS). Health experts highlight that combining easy access to preventive medication with expanded testing, public awareness campaigns, and specialized healthcare services has been instrumental in reducing new HIV infections and tackling stigma. As Brazil prepares to introduce long-acting injectable PrEP nationwide, São Paulo's experience is increasingly viewed as a blueprint for scaling comprehensive HIV prevention strategies in other countries. Read more.

MORE HIGHLIGHTS

Anvisa to Reassess Combustion-Free Nicotine Products Amid Global Regulatory Shift

Brazilian Study Shows HPV Vaccination Has Halved Virus Prevalence Among Young People

Brazil Creates Technical Committee to Oversee Development of Portable Tuberculosis Diagnostic Test

Cristália Invests R$54 Million in Clinical Development of Novel Overdose Therapy

BRAZIL NEWS

Lula unifies Brazil's left, but questions remain about its future without him

Major Brazil conservative party to stay neutral in presidential race, hurting Bolsonaro bid

Lula leads Flavio Bolsonaro in potential Brazil runoff, poll shows

Brazil household debt barely budges despite Lula debt-relief push

Lula's payroll loans boom, but Brazilian defaults spike too

Risk-averse investors push Brazil debt deeper into interest rate exposure

Brazil inflation nears target band, supporting more monetary easing

Brazil implements temporary 32% ethanol blend in gasoline from Saturday

Brazil withholds approval of Trump's ambassador pick, deepening rift with US

Lula says Brazil denied visas to US officials over election meddling concerns

Brazil requests WTO consultations over US tariffs

Xi tells Lula China backs Brazil in rejecting external interference, Xinhua reports

Brazil, South Korea agree to advance talks for Mercosur trade deal

Brazil recalls ambassador to Argentina after Milei attacks Lula, sources say

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