WEEKLY REPORT

CONSULTORES
Relações Governamentais

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BRAZIL SUPREME COURT UPHOLDS AGREEMENT ON FUNDING OF ONCOLOGY MEDICINES IN SUS

Brazil's Supreme Federal Court unanimously endorsed an interfederative agreement that reorganizes how oncology medicines provided by court order will be financed under the Brazilian Unified Health System (SUS). The agreement, established within the Tripartite Inter-Manager Commission (CIT), maintains that the federal government reimburses 80 % of the cost incurred by states and municipalities that supply high-cost cancer drugs following judicial decisions. The ruling also updates rules on jurisdiction for legal disputes over oncological treatments after the Ministry of Health's new oncology policy (AF-ONCO), aiming to reduce legal uncertainty and prevent disruption to ongoing cases. The Supreme Court applied the changes with modulation to protect existing judicial proceedings. Read more.

BRAZIL ONCOLOGY REGISTRY "OBSERVA ONCO" LAUNCHES PANEL FOR CANCER DATA MONITORING

Observa ONCO, a national initiative to consolidate and monitor cancer data, has launched a public-facing panel that aggregates epidemiological, care and outcome indicators related to oncology in Brazil. The platform aims to support health professionals, researchers, and policymakers with real-world information on incidence, mortality, clinical practices, and access to treatments across regions. The developers of the panel said the tool will enable analysis of trends over time and comparisons across states, contributing to evidence-based planning and evaluation of cancer control strategies. By improving data transparency and accessibility, Observa ONCO is positioned as a resource to inform public-health decision-making in Brazil's cancer care ecosystem. Read more.

BRAZIL PHARMACEUTICAL INDUSTRY WARNS THAT BILL TO EXTEND OZEMPIC PATENT COULD DRIVE UP HEALTH SPENDING

The association FarmaBrasil, which represents major pharmaceutical companies in Brazil, criticized Bill 5 810/2025 — known as the "Ozempic bill" — for proposing changes to the Industrial Property Law that would allow patent terms to be extended beyond the standard 20 years when administrative delays occur. FarmaBrasil says that by delaying competition from cheaper generics when a blockbuster drug like Ozempic loses exclusivity, the bill would extend monopoly pricing and pressure public and private health expenditures. FarmaBrasil also argued that the proposal creates legal uncertainty and could hinder access to lower-cost medicines, noting that semaglutide patents are due to expire in March 2026 and that generics could enter the market without delay under current rules. The debate reflects broader industry concerns about balancing intellectual property protections with access and affordability in Brazil's healthcare system. Read more.

BRAZIL ANVISA REPORTS 65 SUSPECTED DEATHS LINKED TO WEIGHT-LOSS PENS

The National Health Surveillance Agency (ANVISA) says it is monitoring 65 suspected deaths potentially associated with use of injectable GLP-1-based weight-loss medications — known as "weight-loss pens" — reported in Brazil between December 2018 and December 2025, according to data from the agency's pharmacovigilance system, VigiMed. The overall tally also includes 2,436 notifications of suspected adverse reactions, ranging from nausea and vomiting to pancreatitis and other serious events, underscoring ongoing safety monitoring of these

products. ANVISA emphasizes that reports of suspected deaths do not confirm a causal relationship between the medicines and the outcomes, and that risk-benefit profiles for the approved indications remain unchanged. The agency's monitoring includes active ingredients such as semaglutide, tirzepatide, liraglutide and dulaglutide, which are used in diabetes and obesity treatment. Read more.

BRAZIL ANVISA IMPLEMENTS NEW CADIFA MODEL TO STREAMLINE ACTIVE INGREDIENT CERTIFICATION

The National Health Surveillance Agency (ANVISA) has introduced a new model for issuing the Letter of Suitability for the Active Pharmaceutical Ingredient Dossier (CADIFA), part of its broader digital transformation efforts. Under the updated approach, the final step of the CADIFA issuance process now uses a renewed visual identity and more automated features that make issuance faster, safer, and more standardized for applicants. The modernized CADIFA document presentation includes a revised layout and repositioned signature block, but ANVISA emphasizes that the changes are administrative and internal, with no regulatory or operational impact for companies that request or use CADIFA in drug registration processes. The underlying information contained in CADIFA remains unchanged, though automation aims to reduce errors and improve efficiency. Read more.

BRAZIL REGULATOR APPROVES NEW MEDICATION TO TREAT PHENYLKETONURIA

The National Health Surveillance Agency (ANVISA) has approved the registration of Sephience™, a new medication indicated for the treatment of phenylketonuria (PKU), a rare genetic metabolic disorder in which the body cannot properly break down the amino acid phenylalanine. The decision allows the product to be marketed in Brazil for both pediatric and adult patients, potentially expanding therapeutic options beyond dietary management alone. Phenylketonuria is detected through newborn screening and requires lifelong control of phenylalanine levels to prevent severe neurocognitive impairment and other complications. According to ANVISA, Sephience works by enhancing the breakdown of phenylalanine in the bloodstream, which may broaden dietary possibilities and improve quality of life for affected individuals. Read more.

BRAZIL ANVISA COMPLETES OPTIMIZED REVIEW AND REGISTERS NEW RADIOPHARMACEUTICALS

The National Health Surveillance Agency (ANVISA) announced that it has completed an optimized analysis process and granted marketing authorization for new radiopharmaceutical products in Brazil, enhancing the country's portfolio of diagnostic and therapeutic nuclear medicines. The streamlined review is part of ANVISA's efforts to accelerate access to advanced radiopharmacy technologies while maintaining established safety and quality standards. According to the regulator, the optimized assessment framework supports more efficient evaluation of complex dossiers and aims to reduce timelines for innovative radiopharmaceutical registrations, potentially benefiting patients requiring nuclear diagnostic imaging and targeted therapies. Read more.

BRAZIL ANS PUBLISHES QUALITY INDICATORS FOR PRIVATE HOSPITALS FOR FIRST TIME

For the first time in Brazil, the National Supplementary Health Agency (ANS) has made public quality indicators for private hospitals that serve beneficiaries of health plans, enabling comparison of hospital performance in the supplementary health sector through the Hospital Quality Monitoring Program (PM-QUALISS). The data, consolidated for the 2024 base year, are accessible through the agency's online monitoring panel and include institutions that voluntarily reported selected metrics throughout the year. The panel allows users to view performance by hospital and assess which facilities reported a full set of indicators over all 12 months of 2024, promoting transparency in assisted care outcomes and aligning Brazilian practice with international quality monitoring standards. Hospitals participating in the program include those with national quality certification or accreditation, and the initiative is aimed at enhancing

access to information and encouraging continuous quality improvement across the private hospital network. Read more.

BRAZIL REPORT FINDS NEARLY 60 % OF RESIDENTS DROPPED HEALTH PLANS BECAUSE OF COST

A survey published by Valor Econômico shows that almost 60 % of Brazilians with private health insurance have given up their plans due to high costs, highlighting affordability pressures in the supplementary health sector. Respondents cited rising premiums and out-of-pocket expenses as key factors driving cancellations or downgrades of coverage, particularly among lower- and middle-income households. The analysis also indicates that cost concerns are shaping consumer decisions about healthcare access, with many individuals opting for public-system care or delaying elective services when plan costs become unsustainable. The findings underscore ongoing debate about pricing, benefits, and regulatory frameworks in Brazil's private health insurance market. Read more.

BRAZIL'S BAHIA GOVERNMENT PARTNERS WITH INDIA TO CUT ANNUAL DRUG COSTS OF R$17 BILLION

The government of the state of Bahia announced a strategic partnership with India to seek lower prices for medicines that currently cost around R$17 billion per year in the state's public health programs, aiming to expand access and reduce budget pressure. The collaboration is intended to explore procurement of generics and biosimilars, technology transfer and regulatory cooperation with Indian pharmaceutical suppliers known for competitive pricing. State health officials said the initiative could help improve affordability of essential medicines and strengthen supply sustainability, although details on specific products, timelines and regulatory steps are still being defined. Read more.

MORE HIGHLIGHTS

Brazil ANVISA chief reappointed as vice president of ICMRA

Brazil highlights people-centered AI strategy in global health event in India

Brazil study finds four in ten cancer deaths are preventable

Brazil health ministry blocks inclusion of kidney-protecting drug in SUS

BRAZIL NEWS

US Supreme Court tariff ruling restores competitiveness to Brazil, says VP Alckmin

India, Brazil sign mining pact as Modi targets $20 billion trade in five years

EU should be ready to enact Mercosur deal despite resistance, trade chief says

Brazil's Petrobras to look into Venezuela opportunities, says head of E&P

Brazil's Lula says Maduro should be tried in Venezuela, not abroad

Brazil's government considers easing airlines' access to public aviation fund

Brazil central bank shuts Banco Pleno in extrajudicial liquidation after Banco Master failure