WEEKLY REPORT

CONSULTORES
Relações Governamentais

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AGU CLEARS CONFIDENTIAL PRICING AGREEMENTS FOR HIGH-COST MEDICINES IN SUS

Brazil's Office of the Attorney General (AGU) has concluded that the Ministry of Health may use confidential pricing agreements to purchase high-cost medicines for the Unified Health System (SUS) in exceptional cases. A legal opinion states that the mechanism can be adopted without prior authorization from the Supreme Federal Court (STF) or the Federal Court of Accounts (TCU), provided it is temporary, justified on a case-by-case basis and subject to oversight. The government is preparing a pilot procurement under this model later in 2026. According to the opinion, confidential pricing should be limited to non-competitive procurements, such as patented medicines, orphan drugs and products supplied by a single manufacturer, where disclosure of negotiated prices could undermine the government's bargaining position. The AGU recommends classifying negotiated prices as restricted information for up to five years, while keeping contracts accessible to oversight bodies. It also suggests creating a dedicated negotiation committee within the Ministry of Health and considering specific legislation to provide greater legal certainty for the use of confidential pricing agreements. Read more.

HEALTH MINISTER OUTLINES STRATEGY FOR OBESITY DRUGS, DOMESTIC PRODUCTION AND SPECIALIZED CARE IN SUS

Health Minister Alexandre Padilha said Brazil's Ministry of Health will launch a pilot study to evaluate the use of GLP-1 medicines for obesity treatment within the Unified Health System (SUS), signaling that the government is considering future incorporation of the therapies while seeking evidence on their cost-effectiveness. The study will enroll 250 patients eligible for bariatric surgery and will be conducted by the Conceição Hospital Group in Porto Alegre. According to Padilha, the initiative aims to assess whether treatment with GLP-1 medicines can reduce the need for surgery, improve health outcomes and lower long-term healthcare costs. Any decision on nationwide adoption, however, will still depend on an assessment by the National Health Commission for Technology Incorporation (Conitec). In the interview with O Globo, Padilha also said the government is working to reduce the cost of GLP-1 therapies by encouraging domestic production and increasing competition as patents expire. He highlighted broader efforts to expand access to specialized care through the Agora Tem Especialistas program, including partnerships with private providers to reduce waiting lists and investments in diagnostic and treatment infrastructure. The minister also defended the use of innovative procurement mechanisms, such as risk-sharing agreements and confidential pricing for high-cost medicines, arguing that these tools can help expand patient access while improving the sustainability of public healthcare spending. Read more.

STUDY FINDS MOST HEALTH LAWSUITS IN BRAZIL SEEK ACCESS TO TREATMENTS ALREADY INCORPORATED INTO SUS

A study by Interfarma found that 57.5% of lawsuits seeking medicines through Brazil's Unified Health System (SUS) involve treatments that have already been incorporated or recommended for incorporation into the public healthcare system. Presented at the Health Technology Assessment International (HTAi) 2026 conference, where it received the award for best poster, the analysis suggests that judicialization is often driven not by a lack of technology assessment, but by delays in making approved treatments available to patients. The study analyzed 3,049 lawsuits filed between January 2022 and April 2025, covering 4,637 medicine requests

involving 1,402 molecules. According to Interfarma, patients wait an average of 37 months between a positive recommendation by the National Health Commission for Technology Incorporation (Conitec) and effective access through SUS—approximately 22 months for the publication of clinical guidelines and another 15 months for procurement and distribution. The association argues that shortening these implementation timelines could significantly reduce litigation and improve access to treatment. Read more.

ANVISA SETS RARE DISEASES, CLINICAL TRIALS, AND GLP-1 REGULATION AMONG SECOND-HALF PRIORITIES

Updating Brazil's regulatory framework for rare diseases will be one of the Brazilian Health Regulatory Agency's (Anvisa) main priorities during the second half of 2026, according to Director Daniela Marreco, who oversees medicines, biologics, active pharmaceutical ingredients (APIs), clinical trials, and advanced therapies. In an interview with Futuro da Saúde, Marreco said the agency plans to launch a public consultation to revise the 2017 regulation governing expedited pathways for rare disease medicines and clinical trials, aiming to improve pre-submission requirements, quality standards, and patient access. She also said Anvisa has been engaging with patient organizations and industry representatives to identify opportunities for regulatory improvements. Marreco said the agency also expects to move forward with regulations implementing Brazil's new Clinical Trials Law, including rules for continuous submission of clinical trial applications, which could be submitted to Anvisa's Board of Directors as early as July. Other priorities include defining the regulatory framework for compounded GLP-1 products, advancing policies for biologics, advanced therapies and APIs, and continuing efforts to reduce review backlogs through optimized assessment procedures and greater use of regulatory reliance. She said the agency's broader goal is to improve efficiency, increase predictability for applicants and accelerate access to innovative health technologies while maintaining safety and quality standards. Read more.

BRAZIL RISES TO 12TH IN GLOBAL CLINICAL RESEARCH RANKING

Brazil climbed from 18th to 12th place in the global ranking of newly initiated clinical trials during the first quarter of 2026, accounting for 2.9% of all studies registered worldwide, according to an Interfarma study presented at the BIO International Convention in San Diego. The report attributes the improvement to the implementation of Brazil's Clinical Trials Law and subsequent regulatory changes, which have streamlined approval processes and increased the country's attractiveness for research investments. The study, developed in partnership with IQVIA, found that 51 clinical trials were initiated in Brazil during the first quarter of 2026, compared with the country's 18th-place ranking at the end of 2025. Interfarma projects that Brazil could reach the top 10 globally in the coming years, attracting BRL 2.1 billion in annual direct investments and benefiting up to 286,000 patients, if the current regulatory environment continues to improve. Read more.

CIT APPROVES MEASURES TO ADVANCE ONCOLOGY PHARMACEUTICAL CARE AND MODERNIZE SUS MANAGEMENT

Brazil's Tripartite Intermanagerial Commission (CIT) approved a new package of measures to strengthen the Unified Health System (SUS), including key steps to implement the Oncology Pharmaceutical Assistance Component (AF-Onco). The agreements establish the operational framework for oncology pharmaceutical care, including rules for the new oncology-specific High-Complexity Outpatient Procedure Authorization (APAC), prior authorization mechanisms and other measures aimed at organizing access to and financing of cancer medicines. The meeting also approved initiatives to modernize health information systems, improve user registration, and streamline the regulation of specialized care. Beyond AF-Onco, the CIT approved the creation of a Minimum Healthcare Data Set (CMD) to standardize health information nationwide, measures to improve the SUS user registry by reducing administrative barriers, and new investments to strengthen pharmaceutical services. According to the Ministry of Health, the package is part of a broader effort to modernize SUS management, improve data quality and expand equitable access to healthcare services across the country. Read more.

SENATE COMMITTEE ADVANCES BILL EXPANDING ACCESS TO GENETIC TESTING FOR HEREDITARY BREAST CANCER

Brazil's Senate Human Rights Committee (CDH) approved a bill expanding access to genetic counseling and testing for hereditary breast cancer within the Unified Health System (SUS). The proposal (PL 265/2020) guarantees access to genetic risk assessment, counseling by qualified specialists and tests to identify hereditary mutations associated with breast cancer, with patient eligibility and prioritization to follow clinical protocols established by the Ministry of Health. The bill now moves to the Senate's Social Affairs Committee (CAS). The proposal comes shortly after the Ministry of Health incorporated BRCA1 and BRCA2 genetic sequencing into SUS for eligible patients, reinforcing Brazil's strategy to improve early identification of women at high hereditary risk of breast cancer. The legislation also extends the right to beneficiaries of private health insurance plans and establishes that genetic data must be handled in accordance with Brazil's General Data Protection Law (LGPD). Read more.

ANS PROPOSES BROADER PORTABILITY RULES FOR PRIVATE HEALTH INSURANCE PLANS

The National Supplementary Health Agency (ANS) has proposed changes to Brazil's portability rules for private health insurance plans, aiming to make it easier for beneficiaries to switch insurers without serving new waiting periods. Among the main proposals are reducing the minimum waiting period for people with pre-existing conditions from three to two years, allowing portability for corporate plans with up to 30 beneficiaries, extending the right to plans signed before the 1998 Health Plans Law, and permitting policyholders to transfer together with their dependents. The proposals were presented during a public hearing and will be subject to further regulatory review. The ANS also proposes simplifying price-band rules to expand the number of eligible plans, requiring digital channels for portability requests, and improving communication between insurers and beneficiaries, including mandatory explanations when requests are denied. While the agency argues the changes would make portability more transparent and accessible, health insurers have expressed concerns about the potential impact on costs and requested further discussion of the proposed measures. Read more.

BRAZIL'S PRIVATE HEALTH INSURANCE MARKET CONTINUES TO AGE, IESS SAYS

The number of older adults enrolled in Brazil's private health insurance plans continues to grow faster than younger age groups, according to the latest Beneficiary Monitoring Report released by the Institute for Health Studies (IESS). Between April 2025 and April 2026, the number of beneficiaries aged 59 and older increased 3.1%, while enrollment among individuals aged 0 to 18 remained virtually unchanged (-0.1%). Overall, the medical-hospital insurance market reached 52.96 million beneficiaries, up 1.6% year over year. The report highlights an ongoing demographic shift in Brazil's supplementary health sector, with older beneficiaries accounting for an increasing share of coverage. IESS said the trend reflects broader population aging and is expected to influence healthcare demand, particularly for continuous care and chronic disease management. Collective health plans remained the dominant segment, representing 84% of all medical-hospital plans. Read more.

ILLEGAL MARKET FOR PARAGUAYAN MOUNJARO GROWS AMID SOARING DEMAND IN BRAZIL

The illegal trade in Mounjaro imported from Paraguay has become a multimillion-dollar market fueled by lower prices, easy cross-border access, and strong demand for obesity treatments in Brazil, according to a report by O Globo. The investigation found that products purchased in Paraguay can cost a fraction of the Brazilian price and are frequently resold through social media, messaging apps, and informal distributors, despite lacking authorization from the Brazilian Health Regulatory Agency (Anvisa). Health authorities warn that medicines entering Brazil through illegal channels may not meet quality, safety or storage standards and can expose patients to counterfeit or contaminated products. In response to the growing market, Anvisa and the Federal Police have intensified joint enforcement actions targeting the illegal

importation and commercialization of GLP-1 medicines, including seizures of thousands of unregistered injectable products and inspections of pharmacies, importers, and online sellers. Read more.

MOUNJARO PRICE CUTS EXPECTED TO PRESSURE BRAZIL'S PHARMACY RETAIL SECTOR

Recent price reductions for Mounjaro (tirzepatide) are expected to weigh on the performance of Brazil's pharmacy chains, according to a Santander analysis. The bank estimates that the combination of Eli Lilly's discounts of up to 35% on the drug and the arrival of lower-priced semaglutide competitors could reduce the sector's revenue by around 3% in 2026, as GLP-1 therapies have become one of the main growth drivers for retail pharmacies. Santander estimates that Mounjaro currently accounts for about 80% of GLP-1 sales in Brazil, making its price reduction particularly significant for pharmacy margins. While the bank expects increasing competition from domestic semaglutide products to intensify pricing pressure, it maintains a positive long-term outlook for the sector, citing the expansion of obesity treatments, an aging population and rising demand for chronic disease therapies as key growth drivers. Read more.

HYPERA PREPARES TO LAUNCH BRAZIL'S SECOND SYNTHETIC SEMAGLUTIDE PEN

Hypera Pharma is preparing to enter Brazil's fast-growing GLP-1 market with Semavy, a synthetic semaglutide injectable pen for the treatment of type 2 diabetes. The company has submitted the product's pricing dossier to the Drug Market Regulation Chamber (CMED), a regulatory step that precedes marketing authorization by the Brazilian Health Regulatory Agency (Anvisa). If approved, Semavy will become the second Brazilian-developed synthetic semaglutide to reach the market, following EMS's Ozivy, which was approved in May after the expiration of Novo Nordisk's semaglutide patent in Brazil. Unlike Ozempic and Wegovy, Semavy is initially being developed only for diabetes, with no regulatory application yet submitted for obesity treatment. Although Hypera has not disclosed pricing, increased competition is expected to put downward pressure on the cost of GLP-1 therapies in a market estimated to generate at least BRL 5 billion annually. The launch also aligns with the federal government's strategy to expand domestic production of semaglutide as the Ministry of Health evaluates the potential future incorporation of GLP-1 medicines into Brazil's Unified Health System (SUS). Read more.

HEALTH MINISTRY LAUNCHES SEMAGLUTIDE PILOT PROGRAM IN FEDERAL HOSPITAL

Brazil's Ministry of Health has launched a pilot program to evaluate the use of semaglutide for patients with severe obesity treated by the Unified Health System (SUS). The Real-Bari study will follow 250 patients at the Conceição Hospital Group (GHC) in Porto Alegre over two years to assess the drug's effectiveness, safety and cost-effectiveness in patients with severe obesity or obesity associated with comorbidities who are eligible for bariatric surgery. The initiative marks the first use of semaglutide in a federal hospital as part of a structured research protocol within SUS. The study will evaluate weight loss, quality of life, clinical outcomes, post-surgical conditions, and treatment costs to generate real-world evidence for future public policy decisions. Participants must have failed conventional obesity treatment and be able to self-administer the medication or rely on a caregiver. According to the Ministry of Health, the findings will help determine whether GLP-1 therapies can be incorporated into SUS in a clinically effective and financially sustainable manner, while also supporting Brazil's broader strategy to expand domestic production of these medicines. Read more.

IPEA STUDY CALLS FOR STRUCTURAL REFORMS IN BRAZIL'S PHARMACEUTICAL ASSISTANCE SYSTEM

Pharmaceutical assistance in Brazil's Unified Health System (SUS) extends far beyond medicine procurement and distribution but continues to face structural weaknesses that limit its effectiveness, according to a new study by the Institute for Applied Economic Research (Ipea), developed in partnership with the National Council of State Health Secretaries (Conass) and

the National Council of Municipal Health Secretariats (Conasems). The report identifies persistent challenges related to financing, governance, management, integration with healthcare services and the lack of clear prioritization criteria, arguing that these shortcomings hinder timely access to medicines and their rational use. The study, "Prioriza SUS: Diagnosis and Proposals for Improving Pharmaceutical Assistance," recommends strengthening governance, expanding investment in pharmaceutical services, improving workforce capacity, and better integrating pharmaceutical assistance into healthcare networks. It also emphasizes that pharmaceutical assistance should be viewed as a strategic component of comprehensive healthcare rather than solely as a logistics function, with the potential to improve patient outcomes, enhance resource allocation and reduce health-related litigation. Read more.

CNJ'S AI TOOL COULD IMPROVE CONSISTENCY IN HEALTH-RELATED COURT DECISIONS, EXPERT SAYS

The National Justice Council's (CNJ) new artificial intelligence platform, EvidênciaJud, has the potential to improve the consistency of judicial decisions in healthcare cases by giving judges faster access to scientific evidence and technical opinions, according to legal experts. In an interview with Migalhas, attorney Fabiana Miranda Leão said the tool could help reduce divergent rulings in similar cases, a longstanding challenge in Brazil's healthcare litigation, where judges often need to decide urgent and highly technical disputes involving medicines, treatments, and medical procedures. Leão argued that broader access to qualified scientific information could lead to more evidence-based and legally consistent decisions, benefiting both patients and the healthcare system by reducing legal uncertainty. She stressed, however, that artificial intelligence should serve strictly as a decision-support tool rather than replace judicial reasoning. Read more.

MORE HIGHLIGHTS

Brazil unveils national plan to modernize medical equipment in the public system

Anvisa consults medical device industry on overhaul of post-market surveillance

Anvisa bans weight management platform over unregistered medical software

Senate hearing calls for better access to pulmonary hypertension care

Senate hearing highlights unequal access to hemophilia care in the public system

BRAZIL NEWS

Brazil senator, Lula ally Wagner resigns from leadership amid corruption probe

Why some young Brazilian voters are abandoning Lula

Brazil's Flavio Bolsonaro plans to testify against proposed US tariffs

EU courts Brazil as strategic partner in global race for critical minerals

Brazil posts narrower-than-expected current account deficit in May

Brazil central bank says policy horizon unchanged after market confusion

Brazil inflation slightly below expectations in mid-June

Brazil plans to expand support for micro-entrepreneurs

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