WEEKLY REPORT

07/04/2026

BRAZIL SELECTS FIRST HIGH-COST MEDICINES FOR CONFIDENTIAL PRICING NEGOTIATIONS

Brazil's Ministry of Health has defined the first list of high-cost medicines eligible for confidential pricing negotiations, marking a new step toward implementing the country's "silent procurement" model. According to JOTA, the strategy will initially focus on selected therapies where confidential discounts are expected to improve affordability and facilitate access through the Unified Health System (SUS), while preserving commercial confidentiality for negotiated prices. The initiative is part of the government's broader effort to introduce confidential pricing agreements for innovative medicines, following discussions with oversight bodies and drawing on international procurement practices. The model is expected to support future health technology incorporations by enabling larger discounts on ultra-high-cost medicines while maintaining transparency over procurement processes, except for the negotiated net prices. Read more.

MINISTRY OF HEALTH LAUNCHES DASHBOARD TO MONITOR USE OF HIGH-COST MEDICINES IN THE SUS

Brazil's Ministry of Health has launched a new dashboard to monitor the use of specialized medicines provided through the Unified Health System (SUS), strengthening oversight of one of the country's highest-cost pharmaceutical programs. The platform consolidates data on medicine dispensing, patient treatment and healthcare services, enabling managers to track utilization patterns, support planning and improve decision-making for the Specialized Component of Pharmaceutical Assistance (CEAF). According to the Ministry, the dashboard is expected to improve transparency, optimize resource allocation and support more efficient management of high-cost medicines across the country. The initiative is part of the government's broader digital health strategy, which seeks to expand the use of data-driven tools to strengthen pharmaceutical assistance and monitor access to medicines within the SUS. Read more.

BRAZIL'S PHARMACEUTICAL IMPORTS SURGE AMID RISING DEMAND FOR GLP-1 DRUGS AND AGING POPULATION

Brazil's pharmaceutical imports rose 14.4% year over year to US$ 6.53 billion between January and May 2026, driven by growing demand for GLP-1 weight-loss medicines, an aging population and expanded access to high-cost therapies through the Unified Health System (SUS). Medicines now account for 5.6% of the country's total imports, reflecting sustained growth fueled by increasing demand for innovative therapies that are not manufactured domestically. Industry representatives argue the trend highlights Brazil's technological gap in pharmaceutical innovation and manufacturing, particularly for biologics and other advanced therapies. While imports have expanded for three consecutive years at double-digit rates, pharmaceutical exports have remained broadly stagnant, widening the sector's trade deficit and reinforcing calls for stronger industrial, innovation and financing policies to boost domestic production of high-value medicines. Read more.

MOST RARE DISEASE TECHNOLOGIES ASSESSED BY CONITEC IN 2025 WERE NOT INCORPORATED INTO THE SUS

Nearly two-thirds of the technologies evaluated by Brazil's National Commission for the Incorporation of Technologies into the Unified Health System (Conitec) for rare diseases in 2025 were not recommended for incorporation into the Unified Health System (SUS), according to an analysis by Futuro da Saúde. Conitec assessed 24 medicines and procedures for rare diseases during the year—up from 15 in 2024—but only eight received positive recommendations, while 16 were rejected. The report points to high budget impact, limited clinical evidence due to small patient populations and uncertainty regarding long-term outcomes as the main barriers to incorporation. Patient organizations and industry representatives argue that the current assessment framework remains challenging for rare disease therapies and have called for greater flexibility in health technology assessment methodologies for treatments targeting small populations. Read more.

CNJ BEGINS TESTING NATIONAL PLATFORM TO STREAMLINE HEALTH LITIGATION

Brazil's National Council of Justice (CNJ) has begun the testing phase of the National Health Platform, a digital system designed to standardize and accelerate the processing of healthcare-related lawsuits. The platform is a key measure implementing the Theme 1234 decision of the Supreme Federal Court (STF) and will connect courts, federal, state and municipal health authorities, enabling the exchange of technical information and administrative data before judicial decisions are issued. The system is expected to improve coordination between the judiciary and the public healthcare system by providing judges with standardized information on treatment requests, patient eligibility and administrative reviews, while reducing procedural delays and inconsistencies in health-related litigation. The CNJ will conduct usability tests with judges, healthcare professionals, public officials and other stakeholders before the platform is rolled out nationwide. Read more.

TRF1 APPLIES SUPREME COURT PRECEDENT TO DENY COVERAGE OF HIGH-COST RARE DISEASE MEDICINE

Brazil's Federal Regional Court of the 1st Region (TRF1) has applied the Supreme Federal Court's (STF) binding precedent on the judicial provision of high-cost medicines to reject a request requiring the state of Bahia to supply inotersen, a treatment for hereditary transthyretin amyloidosis. The court concluded that the case did not meet the criteria established by the STF for compelling the public health system to provide medicines that have not been incorporated into the Unified Health System (SUS). The reporting judge also noted that supplying the therapy would cost the SUS approximately BRL 1.59 million for each quality-adjusted life year (QALY) gained. The decision reinforces the growing influence of the STF's framework for pharmaceutical judicialization, which requires courts to assess factors such as clinical evidence, cost-effectiveness, budget impact and the availability of therapeutic alternatives within the SUS before ordering public funding of non-incorporated medicines. The ruling may serve as an important precedent for future litigation involving high-cost therapies for rare diseases. Read more.

STUDY FINDS MOST MEDICINES INVOLVED IN LAWSUITS SHOULD ALREADY BE AVAILABLE THROUGH THE SUS

More than half of the medicines requested in healthcare lawsuits in Brazil had already received a favorable recommendation for incorporation into the Unified Health System (SUS) and should have been available to patients, according to an Interfarma study presented at the 2026 HTAi Annual Meeting in Istanbul. The analysis of 3,049 lawsuits filed between 2022 and 2025 found that 57.5% of the medicines demanded in court had already been recommended by the National Commission for the Incorporation of Technologies in the SUS (Conitec), suggesting that judicialization is increasingly driven by delays in implementation rather than by demands for unassessed therapies. The study estimates that the average time between a positive incorporation recommendation and actual patient access can exceed two years, despite legislation establishing a significantly shorter implementation period. Delays in updating Clinical Protocols and Therapeutic Guidelines (PCDTs), procurement processes and distribution were identified as the main bottlenecks. Oncology was among the therapeutic areas most affected,

with some medicines reportedly remaining unavailable to patients years after incorporation into the SUS. Read more.

AF-ONCO IMPLEMENTATION ADVANCES, BUT OPERATIONAL CHALLENGES REMAIN

Brazil's Ministry of Health has begun implementing new operational flows for the Oncology Pharmaceutical Assistance Component (AF-Onco), including exclusive oncology authorization forms (APACs), prior authorization procedures, dilution centers and the rollout of the e-SUS AF information system. The measures are intended to improve the financing, monitoring and distribution of oncology medicines within the Unified Health System (SUS), although key regulatory steps remain pending before the model becomes fully operational. Health authorities expect to launch pilot projects in the second half of 2026 while continuing work on technology prioritization, procurement and the publication of the remaining implementing regulations. Industry representatives and patient organizations have welcomed the progress but caution that the success of AF-Onco will depend on timely execution, clear operational guidance and effective coordination among federal, state and local health authorities. Read more.

GEOPOLITICAL TENSIONS REINFORCE BRAZIL'S PUSH TO EXPAND DOMESTIC API PRODUCTION

The conflict involving Iran has intensified concerns over Brazil's heavy dependence on imported active pharmaceutical ingredients (APIs), reinforcing government and industry efforts to strengthen domestic production. The disruption of logistics routes linking Asia to global markets has highlighted vulnerabilities in pharmaceutical supply chains, prompting renewed investment in Brazil's fine chemicals and API manufacturing capacity as part of the country's strategy to enhance health sovereignty and reduce external dependence. Industry leaders argue that expanding domestic API production has become not only an industrial policy priority but also a matter of national security, given that Brazil imports most of the APIs used by its pharmaceutical industry. The initiative aligns with broader policies under the Health Economic-Industrial Complex (CEIS) and the New Industry Brazil program, which seek to increase local manufacturing of strategic health products and improve the resilience of the country's pharmaceutical supply chain. Read more.

BRAZIL LAUNCHES RESEARCH CENTER TO REDUCE DEPENDENCE ON IMPORTED PHARMACEUTICAL INGREDIENTS

Brazil has launched a new research center dedicated to developing active pharmaceutical ingredients (APIs) from the country's biodiversity, aiming to reduce long-term dependence on imported raw materials used in medicine production. The initiative, led by the National Center for Research in Energy and Materials (CNPEM) with BRL 60 million in funding from the Ministry of Health and Embrapii, will focus initially on oncology and infectious diseases as part of the government's strategy to strengthen the Health Economic-Industrial Complex. Despite the strategic objective, the project does not establish concrete targets for reducing imports or a timeline for bringing new products to market. The first four years will be dedicated to early-stage research and preclinical development, with human clinical trials and regulatory approval expected only in subsequent phases. Brazil currently imports more than 90% of the APIs used by its pharmaceutical industry, primarily from China and India. Read more.

LAW REMOVES REQUIREMENT FOR PRIOR REGISTRATION IN COUNTRY OF ORIGIN FOR ANVISA APPROVAL

Brazil has enacted Law No. 15,440/2026, eliminating the requirement that medicines be previously registered in their country of origin before obtaining marketing authorization from the Brazilian Health Regulatory Agency (Anvisa). Originating from Bill No. 2,142/2025, the legislation amends Brazil's Pharmaceutical Products Health Surveillance Law (Law No. 6,360/1976) and replaces the former requirement with proof of compliance with Good Manufacturing Practices (GMP), as defined by Anvisa's regulations. The change brings Brazil's legislation into line with Anvisa's current regulatory practice, which already prioritizes manufacturing quality and regulatory compliance over prior foreign approval. The new law

revokes provisions that required foreign products to demonstrate registration in their country of origin—or, in exceptional cases, in another jurisdiction or by an international regulatory authority—potentially facilitating earlier access to innovative medicines while maintaining manufacturing quality standards. Read more.

ANVISA UPDATES GUIDANCE ON PHARMACOKINETIC STUDIES FOR BIOSIMILARS

The Brazilian Health Regulatory Agency (Anvisa) has issued Informative Note No. 1/2026/GGBIO, updating the regulatory pathway for the assessment of comparative pharmacokinetic (PK) studies supporting biosimilar registration and clinical development. Under the new guidance, responsibility for reviewing these studies will be centralized within the Office for the Evaluation of Biological Products (GPBIO/GGBIO), aligning the assessment process with RDC 875/2024, which allows comparative efficacy studies to be waived under certain conditions. As a result, comparative PK data assume an even more important role in demonstrating biosimilarity. The guidance also clarifies submission procedures for PK studies during both the clinical development phase and the marketing authorization process, confirming that previously reviewed PK data do not need to be resubmitted at the time of registration. Anvisa said the revised framework is intended to improve regulatory consistency, accelerate the review of biosimilars and provide greater predictability for developers while maintaining standards of quality, safety and efficacy. Read more.

ANVISA ADVANCES REVIEW OF STANDARD DRUG LEAFLETS AND REMOVES 57% OF PENDING APPLICATIONS

The Brazilian Health Regulatory Agency (Anvisa) has completed another stage of its initiative to streamline the review of standard drug leaflets, defining the next steps for 353 pending applications submitted under Public Call No. 16/2025. Of the total, 60 applications will be closed due to lack of interest from applicants, 140 will be withdrawn at the companies' request, and 153 will proceed to structured technical review after being grouped by reference medicine. The agency estimates that the process will eliminate 200 cases from its regulatory backlog, resolving 57% of the petitions covered by the initiative. According to Anvisa, the initiative is intended to improve the quality and consistency of information provided in standard package leaflets for generic and similar medicines while increasing regulatory efficiency. The remaining applications will undergo technical assessment by the General Office for Drug Safety and Efficacy Assessment (GESEF), as part of the agency's broader strategy to reduce historical backlogs, standardize medicine information and strengthen regulatory predictability. Read more.

ANVISA REVIEWS 16 SEMAGLUTIDE APPLICATIONS AS POST-PATENT COMPETITION ACCELERATES

Brazil's Health Regulatory Agency (Anvisa) is reviewing 16 applications for semaglutide-based medicines following the expiration of the Ozempic patent in March, paving the way for increased competition in one of the country's fastest-growing pharmaceutical markets. Six applications are currently under technical review and another ten remain in the regulatory queue. Ozivy, developed by Brazilian pharmaceutical company EMS, became the first synthetic semaglutide approved after the patent expiration, while additional candidates—including Hypera's Semavy—are awaiting regulatory clearance. The growing pipeline is expected to increase competition and put downward pressure on prices, potentially expanding patient access to GLP-1 therapies for diabetes and obesity. However, Anvisa stressed that the products under review are complex synthetic analogs or biosimilars that require rigorous assessments of quality, safety and efficacy. Regulatory approval will not automatically lead to incorporation into the Unified Health System (SUS), which depends on separate health technology assessment and reimbursement decisions. Read more.

WEIGHT-LOSS DRUGS EXPECTED TO DRIVE DOUBLE-DIGIT GROWTH IN BRAZIL'S PHARMACEUTICAL MARKET

Brazil's pharmaceutical industry expects to increase revenue by around 10% in 2026, driven largely by the rapid expansion of the GLP-1 market for obesity and diabetes treatments. According to industry estimates, demand for weight-loss injections such as Ozempic, Wegovy and Mounjaro, together with the arrival of lower-cost competitors following the expiration of semaglutide's patent, is expected to sustain robust growth across manufacturers, distributors and pharmacy chains. Industry executives also expect broader access to GLP-1 therapies to accelerate market expansion while reshaping competition in Brazil's pharmaceutical sector. Although weight-loss medicines currently account for a relatively small share of total prescription volumes, analysts project they will become one of the industry's fastest-growing segments, boosting pharmacy revenues and increasing investment in innovative therapies over the coming years. Read more.

RECORD SEIZURE HIGHLIGHTS SURGE IN ILLEGAL IMPORTS OF WEIGHT-LOSS INJECTIONS FROM PARAGUAY

Brazilian customs authorities seized 2,707 weight-loss injection pens containing tirzepatide and experimental retatrutide hidden inside a vehicle near the Paraguayan border, in one of the country's largest seizures this year. The operation also uncovered 786 additional vials of peptides and other injectable products, with the total cargo valued at more than BRL 320,000. Authorities report that seizures of illegal weight-loss medicines in the Foz do Iguaçu region have increased by more than 1,350% in 2026, reflecting the rapid expansion of cross-border trafficking. The case underscores growing concerns over the parallel market for GLP-1 therapies, fueled by significant price differences between Brazil and Paraguay and the availability of products without medical prescriptions. Manufacturers and health authorities warn that medicines acquired outside authorized distribution channels may not comply with required storage and transportation conditions, posing risks related to quality, efficacy and patient safety, particularly for products that have not received regulatory approval. Read more.

REGULATORY AUTONOMY SEEN AS KEY TO ATTRACTING INVESTMENT IN BRAZIL

Brazilian regulatory authorities and industry leaders argue that stronger institutional and financial autonomy for regulatory agencies is essential to improve legal certainty and attract long-term investment. During a forum hosted by Valor Econômico, officials warned that recurring budget cuts, staff shortages and delays in appointing agency directors have weakened the capacity of institutions such as the Brazilian Health Regulatory Agency (Anvisa) and the National Supplementary Health Agency (ANS) to regulate strategic sectors effectively. Participants also defended measures to shield regulatory agencies from budget contingencies, arguing that predictable funding and independent technical decision-making are critical for fostering innovation, infrastructure development and business confidence. The debate comes as Congress advances legislation to exempt regulatory agencies' budgets from federal spending freezes, a proposal widely supported by business groups to strengthen Brazil's regulatory environment and improve the country's competitiveness. Read more.

BRAZILIAN SENATE APPROVES NATIONAL STRATEGY TO STRENGTHEN DOMESTIC PRODUCTION OF MEDICINES AND VACCINES

Brazil's Senate has approved legislation creating the National Health Strategy for the Health Economic-Industrial Complex, a framework designed to strengthen domestic production of medicines, vaccines, medical devices and strategic health inputs. The bill, which now awaits presidential sanction, establishes long-term policies to reduce Brazil's dependence on imported health technologies through incentives for innovation, public procurement, financing and industrial development. The legislation also creates the status of "Strategic Health Company," granting eligible manufacturers priority in regulatory procedures, easier access to financing from the Brazilian Development Bank (BNDES) and preferential treatment in public initiatives related to strategic health products. The proposal aims to reinforce the resilience of the Unified Health System (SUS), expand national manufacturing capacity and improve preparedness for future public health emergencies. Read more.

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STUDY SUGGESTS QDENGA SHOULD BE ADMINISTERED ONLY IN HEALTHCARE FACILITIES AFTER SEVERE ALLERGIC REACTIONS

A Brazilian study has found a higher-than-expected incidence of severe allergic reactions following administration of Takeda's dengue vaccine Qdenga, leading researchers to recommend that the vaccine be administered exclusively in healthcare facilities equipped to manage anaphylaxis. Among 146,115 doses administered to children in Belo Horizonte, researchers identified 28 hypersensitivity cases, including nine cases of anaphylaxis and two of anaphylactic shock. All patients recovered fully within 48 hours. The researchers emphasized that the findings do not alter Qdenga's overall favorable benefit-risk profile or support changes to current vaccination recommendations. Takeda noted that anaphylaxis is already described in the product label and reiterated that vaccination should occur in settings prepared to provide immediate medical care if needed. The study reinforces the importance of post-vaccination observation, particularly after the first dose, while maintaining that immunization remains a key tool for reducing the burden of dengue in Brazil. Read more.

NEWBORN SCREENING REMAINS CRITICAL TO PREVENTING IRREVERSIBLE DAMAGE FROM PHENYLKETONURIA

Health experts are reinforcing the importance of Brazil's newborn screening program after highlighting that phenylketonuria (PKU), a rare genetic disorder affecting approximately one in every 25,000 births, can be effectively controlled when diagnosed through the heel prick test during the first days of life. Without early treatment, the inability to metabolize the amino acid phenylalanine can lead to irreversible neurological damage, impairing cognitive and motor development. Although there is no cure, lifelong dietary management and nutritional supplementation allow affected children to develop normally when treatment begins soon after birth. The awareness campaign, held in conjunction with International Phenylketonuria Day on June 28, underscores the importance of expanding access to newborn screening and specialized follow-up care. Specialists emphasize that early diagnosis remains the most effective strategy for preventing severe complications from PKU, reinforcing the role of neonatal screening as one of Brazil's most important public health initiatives for rare diseases. Read more.

CONGRESS HIGHLIGHTS WORLD PHENYLKETONURIA DAY WITH SPECIAL ILLUMINATION

Brazil's National Congress was illuminated in green and blue to mark World Phenylketonuria (PKU) Day, drawing attention to the rare genetic disorder and the importance of early diagnosis through newborn screening. PKU affects approximately one in every 15,000 newborns in Brazil and, although it has no cure, severe neurological complications can be prevented when the condition is identified during the first weeks of life through the heel prick test and followed by appropriate dietary treatment. The awareness initiative aims to increase public understanding of rare diseases and reinforce the importance of timely diagnosis and lifelong treatment. People with PKU are unable to properly metabolize the amino acid phenylalanine, making strict dietary

management essential to prevent intellectual disability, seizures and other serious neurological complications. Read more.

BRAZIL'S PRIVATE HEALTH PLANS RECORDED 2 BILLION HEALTHCARE PROCEDURES IN 2025

Private health plans in Brazil performed nearly 2 billion healthcare procedures in 2025, a 3.7% increase compared with the previous year, according to new data released by the National Supplementary Health Agency (ANS). The sector also expanded its beneficiary base by 1.96%, reaching 52.9 million people covered by medical plans, reflecting continued growth in demand for private healthcare services. Consultations, diagnostic tests, therapies and hospital admissions all increased during the year, underscoring the sustained utilization of healthcare services in the supplementary health sector. The figures were released as part of the ANS's annual Healthcare Map (Mapa Assistencial), which monitors service utilization and provides key indicators for healthcare providers, insurers and policymakers assessing trends in Brazil's private health market. Read more.

MEDICAL STUDENTS SUPPORT BRAZIL'S LICENSING EXAM BUT FEAR WEAKER PRACTICAL TRAINING

Brazilian medical students broadly support the introduction of the National Medical Examination (Enamed) as a mandatory licensing requirement, viewing it as an important mechanism to ensure minimum standards of professional competence. However, many also warn that medical schools may shift their focus toward improving students' performance on the written exam at the expense of hands-on clinical training, potentially weakening practical education during undergraduate programs. Students and medical educators argue that while a national competency exam can improve quality assurance, it does not address structural problems such as the rapid expansion of medical schools and uneven educational standards across institutions. Experts emphasize that safeguarding practical training, supervised clinical experience and patient-centered education will be essential for ensuring that the Enamed strengthens—rather than narrows—the quality of medical education in Brazil. Read more.

BRAZIL'S AGING POPULATION CALLS FOR A SHIFT TOWARD PREVENTION AND INTEGRATED CARE

Brazil's rapidly aging population is expected to place growing pressure on the healthcare system, requiring a transition from an acute care model to one focused on prevention, primary care and the long-term management of chronic diseases. The number of Brazilians aged 60 and older increased from 20.5 million in 2010 to 35.2 million in 2025, and is projected to exceed 65 million by 2050, representing nearly one-third of the country's population. Specialists argue that strengthening primary healthcare will be essential to maintain quality of care and the sustainability of the Unified Health System (SUS). Experts also emphasize the need for integrated care pathways, multidisciplinary teams and expanded home-based and community care to address the growing prevalence of chronic conditions, frailty and functional decline among older adults. They argue that investments in healthy aging, digital health and coordinated care will be critical to reducing avoidable hospitalizations and ensuring that Brazil's health system is prepared for the country's demographic transformation. Read more.

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