WEEKLY REPORT

11/15/2025

BRAZIL UPDATES CONITEC'S STRUCTURE AND DECISION-MAKING PROCESS, ADDING VOTING CIVIL SOCIETY REPRESENTATIVES

The federal government has issued Decree No. 12,716/2025, reshaping the structure and decision-making flow of the National Committee for Health Technology Incorporation (Conitec). The measure aligns the committee with Law No. 15,120/2025, expanding social participation and modernizing governance. Each Conitec committee will now have 17 voting members, including a rotating civil-society representative linked to the condition under review, the Secretariat of Information and Digital Health, and the Health Technology Assessment Center (HTA Center). For the first time, civil-society representatives gain deliberative voting rights, not merely consultative participation. The decree also updates meeting procedures, establishing monthly sessions from February to December, with both in-person and virtual formats allowed and quorum requirements defined. After a committee issues its final recommendation, the process moves to the Secretariat of Science, Technology, and Innovation in Health (SECTIS/MS), which becomes the formal decision-maker for technology incorporation into the SUS. The Executive Secretariat of Conitec is now housed within SECTIS, and partnerships with REBRATS institutions are authorized to support technical and scientific assessments. Extraordinary meetings may be convened to expedite urgent evaluations. Read more.

BRAZIL SUPREME COURT SETS 1 DECEMBER 2025 DEADLINE FOR GOVERNMENT ACTION PLAN ON PRICING AND ACCESS TO NON-INCORPORATED MEDICINES

The Brazilian Federal Supreme Court has determined that the federal government must present, by 1 December 2025, a comprehensive action plan addressing the pricing and provision of medicines that are not incorporated into the SUS. The measure responds to growing judicialization pressures and seeks to ensure greater clarity on how the state will handle high-cost therapies and treatments outside established incorporation pathways. The Court's order reflects a broader movement to align legal, regulatory and policy frameworks in the health sector, particularly in disputes involving access to non-incorporated drugs. The decision may also influence budget planning and create new obligations for the Ministry of Health and regulatory bodies as they define guidelines for financing and patient access. Read more.

BRAZIL'S JUDICIARY RELEASES NEW CNJ GUIDE TO STANDARDIZE RULINGS ON ACCESS TO MEDICINES

The National Council of Justice (CNJ) has published a new guide aimed at standardizing judicial rulings on access to medicines, a recurrent legal issue involving therapies not incorporated into the SUS. The document outlines principles and criteria intended to support judges in evaluating evidence, health-technology assessments, and regulatory status, reducing variability in decisions. The guide is part of a broader effort by the judiciary to address rising litigation in the health sector, which places pressure on public budgets and often results in unequal access. By providing clearer guidance, the CNJ seeks to harmonize decisions across courts, strengthen legal certainty, and support institutional dialogue between the judiciary and health authorities. Read more.

BRAZIL PREPARES NEW DRUG PRICING RULE EXPECTED IN DECEMBER

The Brazilian government is finalizing a new regulatory framework for drug pricing, expected to be released in December. The rule is anticipated to update criteria for maximum sale prices,

revise public purchasing parameters and strengthen links between pricing decisions and health-technology assessments conducted for the SUS. The upcoming regulation reflects ongoing discussions within the federal government about improving transparency, predictability, and alignment with international best practices. It may also reshape how pharmaceutical companies plan market entry and pricing strategies in Brazil, with potential effects on competition and patient access. Read more.

ANVISA OFFICIALLY PUBLISHES NEW RULES TO ACCELERATE REGULATORY REVIEWS AND LAUNCHES HEALTH INNOVATION COMMITTEE

The Brazilian Health Regulatory Agency (Anvisa) has formally published new rules designed to accelerate regulatory reviews and reduce bottlenecks in the evaluation of medicines and health technologies. The package of measures includes updated procedures, clearer timelines and expanded mechanisms for prioritizing submissions, positioning regulatory efficiency as a central institutional objective. Alongside the regulatory changes, Anvisa has launched the Health Innovation Committee, which will guide strategic priorities, promote coordination across technical areas and support modernization initiatives. The combined measures aim to speed patient access to innovative therapies, strengthen Brazil's regulatory environment, and enhance the country's attractiveness for clinical research and product development. Read more**.**

ANVISA'S DRUG EVALUATION OFFICE IMPLEMENTS NEW PROCEDURES TO COMPLY WITH ANVISA'S RDC 997/2025

Brazil's Drug Evaluation Office has implemented new internal procedures to operationalize Anvisa's RDC 997/2025, which establishes exceptional and temporary measures to optimize the regulatory queue for medicines and biological products. The new protocol creates a dedicated "optimized-analysis" pathway and requires companies to reclassify eligible petitions under the updated subject-code system to access the priority track. The procedural shift is designed to reduce bottlenecks in Anvisa's review pipeline and accelerate decisions for both clinical-trial authorizations and marketing applications. While the changes are expected to increase efficiency, stakeholders are watching how the new process will be applied in practice, particularly regarding prioritization criteria and consistency across therapeutic areas. Read more**.**

INTERFARMA RAISES TRANSPARENCY CONCERNS ON ANVISA MOVES TO CUT REVIEW TIMES

Anvisa has advanced a new set of measures aimed at shortening regulatory review times, including dedicated queues, reliance mechanisms, and the grouping of similar dossiers for joint analysis. The agency highlights that the initiative is part of its broader modernization plan intended to reduce backlog and improve predictability for companies submitting both new registrations and post-approval changes. Interfarma, while supportive of efforts to improve efficiency, has expressed concerns about transparency, arguing that accelerated pathways must maintain clarity on criteria and equal treatment across companies. The debate underscores the balance Anvisa must strike between faster access to innovation and preserving regulatory fairness and visibility for all market participants. Read more.

BRAZIL REACHES 93.7% COMPLETION IN ANVISA'S OPTIMIZED ONLINE REVIEW PROJECT FOR BIOLOGICAL PRODUCTS

Anvisa has reported that its Optimized Online Review Project for biological products has reached 93.7% completion, marking a significant achievement in the digitization and modernization of regulatory workflows. The project aims to transition biological-product submissions into a fully digital, streamlined environment capable of reducing redundancies and improving evaluation timelines. The near-completion milestone demonstrates the agency's continued prioritization of efficiency and digital transformation. The next phase will focus on ensuring uniform application across all biological categories, training technical teams, and expanding interoperability with other regulatory modernization initiatives currently under implementation. Read more.

BRAZIL STILL HAS DRUGS APPROVED FOR THE SUS THAT REMAIN UNAVAILABLE AFTER MORE THAN TWO YEARS

Several medicines incorporated into the SUS continue to face delays of more than two years before reaching actual patient access, even after meeting regulatory and HTA requirements. The gap reflects structural issues in procurement, distribution, contracting, and financing that can prevent approved therapies from arriving in public-health facilities. The persistent delay highlights an ongoing disconnect between incorporation decisions and real-world availability. It also raises concerns about planning, coordination among federal and state authorities, and the predictability of access for high-cost or complex therapies that depend on specialized logistics and budgeting flows. Read more.

BRAZIL SETS REIMBURSEMENT VALUE FOR CYCLIN INHIBITOR THERAPIES IN THE SUS BUT ACCESS CONCERNS REMAIN

The federal government has established the official reimbursement value for cyclin-dependent kinase inhibitor therapies within the SUS, marking a relevant milestone for the incorporation of these oncology treatments. The decision signals financial commitment and sets the basis for public procurement and protocol alignment. Despite the advance, concerns remain regarding actual access, as budget allocation, supply chains, and local implementation may still limit availability for patients. Stakeholders emphasize that reimbursement definitions are only the first step, and that real-world access depends on coordinated actions across procurement systems, oncology networks, and clinical-protocol updates. Read more.

BRAZIL'S ANS STRESSES THAT HUMAN LIFE CANNOT BE TREATED AS A DETAIL IN DEBATE OVER HIGH-COST DRUGS

Brazil's National Supplementary Health Agency (ANS) emphasized that discussions on high-cost medicines must not overlook the central principle that human life is not a negotiable detail. The agency highlighted the need for balanced decision-making that considers financial sustainability while ensuring timely and equitable access to therapies within the private health system. The statement reflects growing tensions around reimbursement obligations, judicialization, and the impact of high-cost treatments on operators' budgets. ANS reinforced that regulatory stability depends on transparent criteria, evidence-based decisions, and mechanisms capable of protecting both beneficiaries and the long-term viability of health plans. Read more.

BRAZIL ADVANCES BILL REMOVING REQUIREMENT FOR GMP CERTIFICATION IN COUNTRY OF ORIGIN

Brazil's Congress is advancing a bill that removes the requirement for a Good Manufacturing Practice (GMP) certificate issued by the country of origin for imported medicines. The proposal seeks to streamline regulatory processes, reduce duplication and allow Anvisa to rely on its own inspections and evaluations when assessing manufacturing quality abroad. Supporters argue that the change could expedite imports, reduce costs, and align Brazil with international reliance practices. Critics, however, warn that removing the origin-country certification could increase pressure on Anvisa's inspection capabilities and may require additional safeguards to maintain product quality and patient safety. Read more.

BILL PROPOSES PATENT TERM ADJUSTMENT MECHANISM IN CASES OF ADMINISTRATIVE DELAY AT INPI IN BRAZIL

A new bill proposes creating a patent-term adjustment mechanism for cases in which excessive administrative delays occur at Brazil's National Institute of Industrial Property (INPI). The measure aims to protect innovators from shortened effective patent life caused by prolonged examination timelines, which continue to pose challenges across multiple sectors, including pharmaceuticals. If approved, the mechanism would introduce a formal system to compensate for delays, aligning Brazil with practices adopted in other jurisdictions. The proposal has sparked debate on how to balance innovation incentives with access to technologies,

particularly in the health sector, where patent extensions may influence competition and pricing. Read more.

SINDUSFARMA LAUNCHES FIRST PHARMACEUTICAL INDUSTRY CENSUS TO INFORM PUBLIC POLICY

Sindusfarma has launched its first Pharmaceutical Industry Census to gather comprehensive data on manufacturing, innovation, workforce, investment, and supply-chain capacity. The initiative will collect data from around 230 member companies between November 2025 and March 2026, targeting at least 80 % participation. The survey will map leadership structures, production capacity, innovation, human resources, and financial performance across the sector. The results will form the basis of a government program proposal for the pharmaceutical industry, to be presented at an event in Brasília in April 2026. Read more.

BRAZIL REACHES RECORD LEVEL OF HEALTH SPENDING DRIVEN BY PARLIAMENTARY AMENDMENTS, STUDY SHOWS

A new study indicates that Brazil's public health spending has reached a record level, heavily driven by parliamentary amendments that have expanded resources flowing to local health services and infrastructure. The increase reflects both political priorities and structural pressures within the Unified Health System (SUS), including growing demand for specialized care and high-cost procedures. Researchers note that although the additional funding contributes to regional improvements, it also raises concerns about fragmentation, dependence on amendments, and uneven distribution across states and municipalities. The findings highlight the need for long-term budget planning and governance reforms to ensure sustainability and strategic allocation of health expenditures. Read more.

BRAZIL REVISITS THE QUALITY OF MEDICAL EDUCATION; GOVERNMENT PLANS INSPECTIONS OF ALL MEDICAL SCHOOLS IN 2026 AND CONSIDERS CLOSING VACANCIES

The federal government is revisiting concerns over the quality of medical education and has announced that all medical schools in Brazil will undergo inspections throughout 2026. The measure responds to persistent challenges related to uneven training standards, infrastructure limitations, and the rapid expansion of medical-program offerings across the country. Authorities are also considering the possibility of closing vacancies or suspending new course openings if institutions fail to meet quality thresholds. The initiative seeks to strengthen professional training, improve patient safety and ensure that the health system is supported by adequately prepared medical professionals. Read more.

BRAZIL APPROVES NEW NATIONAL POLICY AND AWARENESS WEEK FOR MEN'S HEALTH

Brazil has approved a new national policy focused on men's health promotion, accompanied by the creation of an annual Men's Health Awareness Week. The initiative aims to strengthen early detection, prevention and treatment of conditions that disproportionately affect men, including cardiovascular diseases, metabolic disorders, and certain cancers. The policy places emphasis on improving access to primary care services, expanding outreach efforts, and addressing cultural barriers that often delay men's engagement with the health system. It also outlines coordinated actions between federal, state, and municipal governments to build a more structured and proactive approach to men's health. Read more.

BRAZIL FACES ACCELERATED AGING AS CHRONIC AND NEUROLOGICAL DISEASES RISE AMONG ELDERLY

Brazil is experiencing accelerated demographic aging, with new data showing a sharp increase in chronic and neurological diseases among the elderly population. The trend poses growing challenges for the health system, which must adapt to rising demand for long-term care, rehabilitation services, and specialized treatment pathways. Experts warn that without structural reforms and expanded investment in geriatric care, the country may struggle to

manage the health and social impacts of aging. Policymakers are urging the expansion of home-based care models, improved coordination across health networks and initiatives to address caregiver shortages. Read more.

MORE HIGHLIGHTS

Brazil secures US$300 million donation for climate-health plan

Brazil tests AI project to speed up health-related court cases, but expansion depends on stable funding

Brazil's Anvisa issues call for scientific evidence on medical cannabis cultivation to support future regulation

Brazil updates health plan mandatory coverage with new lung cancer drug

BRAZIL NEWS

Brazilian coffee, beef, and tropical fruit will still be tariffed 40%, says Brazil's vice president

Brazil foreign minister meets Rubio to assess tariff talks, source says

China finds bigger role as US sidesteps Brazil climate summit

COP30 Indigenous protesters defend summit incursion as climate talks roll on

COP30 highlights growing need of countries for resilience to storms, flood, and fires

Indigenous leader Raoni calls Brazil infrastructure plans a threat to Amazon forest

Brazil trims 2025 growth, inflation forecasts amid slowdown

Brazil meal voucher rule changes to save $1.5 billion a year, Finance Ministry says

Brazil's fiscal discipline crucial post-2026 election, warns Goldman Sachs

Brazil finmin says room for rate cuts, cenbank chief doing 'good job'

Brazil central bank tightens rules for virtual assets, cryptocurrency

Brazil's deadliest police raid failed to capture or kill gang leaders

Eduardo Bolsonaro to face trial in Brazil for seeking Trump help in his father's legal case