WEEKLY REPORT

01/17/2026

SUPREME COURT COMPLETES NATIONAL HEALTH PLATFORM PROJECT AND HANDS IT OVER TO CNJ

Brazil's Supreme Federal Court (STF) has completed the development of the National Health Platform and formally transferred the system to the National Council of Justice (CNJ) for usability testing and governance structuring. The digital platform is intended to centralize all demands related to access and acquisition of medications within the Unified Health System (SUS) across the country. This step is seen as significant for improving transparency and coordination in administrative and judicial requests. The tool was created based on an interfederative agreement approved in the judgment of Extraordinary Appeal (RE) 1366243, a case with general repercussion (Tema 1.234), concluded in October 2024, and presented publicly in December 2025. Designed with multiple interfaces for physicians, health managers and members of the judiciary, the platform integrates key health databases and automatically indicates whether a requested medication is covered by existing public policies and which level of government is financially responsible. The CNJ will now conduct further testing and work with federal, state, and municipal entities, health regulators, and the Federal Council of Medicine (CFM) to finalize governance. Read more.

BRAZIL CLARIFIES CLINICAL RESEARCH PROTOCOL REVIEW DURING TRANSITION TO NATIONAL ETHICS SYSTEM

Brazil's Ministry of Health's Secretariat of Science, Technology and Health Innovation (SECTICS) has issued a technical note detailing the processing and review of clinical research protocols involving human participants as the country transitions to the National Research Ethics System (Sinep) under the National Research Ethics Instance (Inaep), established by law. The guidance aims to ensure ethical and regulatory compliance and legal certainty for ongoing and new clinical studies during this implementation period. The document provides instructions for accredited Research Ethics Committees (CEPs) on how to assess protocols, with specific procedures depending on the risk classification submitted via Brazil's Plataforma Brasil. For high-risk studies, CEPs must confirm thematic alignment before forwarding approved protocols to Inaep for redistribution to an appropriate accredited committee. Protocols with the Ministry of Health itself as a proponent will undergo review by accredited committees, while the former National Research Ethics Commission (Conep) will serve as an avenue for appeals under the new framework. The technical note also extends CEP accreditation by one year and temporarily suspends new biobank protocol submissions until Inaep clarifies applicable procedures, aiming to protect research participants and institutional review processes. Read more.

BRAZIL'S ANVISA FACES EFFICIENCY CHALLENGE IN 2026 WITH REGULATORY AGILITY AGENDA

Brazil's Brazilian Health Regulatory Agency (Anvisa) is entering 2026 with a strategic priority to improve regulatory efficiency by reducing long backlogs in the analysis of clinical research authorizations, medicine and product registrations, and other health technology approvals. The agency's leadership is set to continue reforms begun in 2025 that focus on streamlining review processes and introducing tools to accelerate decision-making while maintaining scientific and safety standards. Among the measures planned for 2026 are grouping similar products with the same active pharmaceutical ingredient (API) for joint review, broader use of regulatory reliance on trusted foreign evaluations to cut redundant work, and the establishment of working

groups with industry and experts to monitor and refine implemented actions. Anvisa is also expected to address other regulatory priorities such as updating hospital project rules, advancing advanced therapy frameworks, clarifying medical cannabis cultivation regulations, and addressing ongoing debates on advertising standards in the Federal Supreme Court (STF). The leadership transition and changes in the Collegiate Board this year have added urgency to these efficiency goals. Agency meetings scheduled to begin in late January 2026 will help define further implementation steps and priorities, reflecting Anvisa's effort to balance agility with technical rigor in Brazil's evolving regulatory environment. Read more.

ANVISA'S PRESIDENT TARGETS BACKLOG REDUCTION AND NATIONAL INNOVATION

Brazil's health regulatory agency, Anvisa, under new leadership by director-president Leandro Safatle, has announced a strategic push in 2026 to significantly reduce its backlog of regulatory analyses and to prioritize innovations developed within the country. The initiative responds to concerns that the pace of internal approvals has lagged behind the rapid emergence of new health technologies. In an interview with Agência Brasil, Safatle outlined a series of measures approved by the agency to optimize process flows for medicines, vaccines, medical devices, and inspections, aiming to halve the current backlog within six months and normalize review timelines within a year. These include forming internal task forces, leveraging regulatory reliance on trusted foreign data, and enhancing coordinated reviews of similar products, while maintaining scientific rigor and safety standards. Anvisa has also created a Committee of Innovation to monitor priority projects, such as polilaminina (a Brazilian-developed compound for spinal injury), a chikungunya vaccine, methods to control dengue and new endoprostheses, and plans to reinforce its workforce with around 100 new specialists. The agency's long-term goals include consolidating its role as a regional and global reference authority in health regulation. Read more.

ANVISA FINES BRAZIL'S LARGEST PHARMACEUTICAL COMPANY OVER UNAUTHORIZED PRODUCTION

Brazil's Brazilian Health Regulatory Agency (Anvisa) has imposed an administrative fine on EMS, considered the largest pharmaceutical company in the country, after determining that the company produced 154 medicines at a facility that did not have regulatory authorization to operate at the time of production. The case stems from a 2015 inspection in which Anvisa found that EMS transferred manufacturing to a plant in the Manaus Free Trade Zone (Zona Franca de Manaus) without submitting the change for prior approval, in violation of regulatory requirements. The administrative process, which remained under confidentiality for nearly a decade, concluded in late 2025 with the affirmation of the penalty, initially levied at R$48,000 and, when adjusted for inflation, potentially equivalent to about R$73,000. Anvisa officials noted that while the fine does not indicate a current risk to public health, it reinforces the importance of compliance with authorization procedures for pharmaceutical production. EMS stated that all irregularities have since been resolved, that the facility operates with current approvals and that its medicines remain "fully compliant and safe for the public." Read more.

ANVISA RECORDS 13 WEIGHT-LOSS INJECTION PEN REGISTRATION APPLICATIONS AT ANVISA

Brazil's national health regulator, the Brazilian Health Regulatory Agency (Anvisa), has already received 13 registration applications for weight-loss medication injection pens based on active ingredients such as semaglutide and other GLP-1 agonists, according to industry sources. This surge follows the expected expiration of the semaglutide patent in March 2026, which opens the door for generics and similar products to enter the market and intensify competition. The applicants include several domestic and multinational pharmaceutical companies positioning for a share of what analysts project could be a multi-billion-reals market later this year. Firms such as Hypera, Biomm, EMS and Eurofarma are among those with pending dossiers, reflecting industry anticipation of broader demand and potentially lower prices compared with existing branded products. The shift could also influence discussions on access and coverage by the Unified Health System (SUS) in future years. Read more.

BRAZIL SEES LOWER DEMAND FOR BARIATRIC SURGERY AMID RISE IN WEIGHT-LOSS PEN USE

The surge in demand for weight-loss injection pens based on GLP-1 receptor agonists like semaglutide (e.g., Ozempic) and tirzepatide (e.g., Mounjaro) has been linked with a decline in interest in bariatric surgery in Brazil, according to clinical specialists and industry observers. Data from the Brazilian Society of Bariatric and Metabolic Surgery indicate that demand for bariatric procedures fell by about 20 % between 2023 and 2024, a trend coinciding with an 88 % increase in the purchase of medications used as weight-loss pens in 2025, totaling roughly R$ 9 billion according to trade figures. Experts interviewed note that pharmacological treatments are expanding options for obesity care, particularly for patients with moderate obesity, and are often seen as less invasive than surgery. However, specialists caution that surgical intervention remains the gold standard for severe and extreme obesity, especially for patients with a body-mass index (BMI) above 40 kg/m². Read more.

BRAZIL BRACES FOR GENERIC WEIGHT-LOSS PENS AS OZEMPIC PATENT EXPIRES

The Brazilian market for GLP-1 weight-loss injection pens is poised for significant expansion in 2026 following the expiration of the patent on semaglutide, the active ingredient in Ozempic and Wegovy. With the end of exclusivity expected in March, domestic and international pharmaceutical companies are preparing to launch generic and similar products, a move that analysts estimate could nearly double market revenue from approximately R$11 billion in 2025 to around R$20 billion this year. Price reductions projected at 30–50% are expected to drive broader demand, although specialists caution that access may remain limited to higher-income segments in the short term. Companies such as EMS, Eurofarma and Hypera are advancing regulatory strategies with Anvisa, which is currently reviewing at least 11 applications for semaglutide-based products and seven for liraglutide. Despite the expected increase in competition, structural barriers and prescription practices are likely to continue shaping the pace and scale of market expansion. Read more.

GILEAD EXCLUDES BRAZIL FROM GENERIC HIV PREVENTION INJECTION PRODUCTION, RAISING ACCESS CONCERNS

Brazilian health authorities and advocates are raising concern after Gilead Sciences — the patent holder of the long-acting HIV prevention drug lenacapavir — excluded Brazil from its voluntary licensing agreements for generic production, meaning the country will not be able to locally manufacture a generic version of the injectable HIV prophylactic. As a result, access to the medicine through Brazil's Unified Health System (SUS) may be threatened by high prices if imported supplies are not negotiated at affordable rates. Anvisa (the Brazilian Health Regulatory Agency) recently approved the lenacapavir injection for HIV pre-exposure prophylaxis (PrEP) with the aim of reducing risk of transmission, but Brazil's absence from the list of countries covered by Gilead's generic licensing deal — which currently includes about 120 low and middle-income nations — leaves policymakers and public health experts concerned about the drug's pricing and availability under SUS. After regulatory approval, the maximum price must still be set by the Drug Market Regulation Chamber (CMED), and SUS incorporation will be assessed by the National Commission for the Incorporation of Technologies into SUS (Conitec) and the Ministry of Health. Read more.

BRAZIL APPROVES LONG-ACTING HIV PREVENTION DRUG SUNLENCA

Brazil's Brazilian Health Regulatory Agency (Anvisa) has approved the use of Sunlenca (lenacapavir) for HIV-1 prevention as pre-exposure prophylaxis (PrEP), expanding options for people at risk of acquiring the virus. The decision applies to adults and adolescents aged 12 years and older weighing at least 35 kg, who must have a confirmed negative HIV-1 test before initiation. The medication is available in both an oral form and a subcutaneous injection administered every six months, which may improve adherence compared with daily regimens. Anvisa's approval followed clinical studies demonstrating high efficacy, with results indicating up to 100 % reduction in HIV-1 incidence in some subgroups and significantly greater

effectiveness compared with daily oral PrEP. The long-acting profile of lenacapavir — which works by inhibiting multiple stages of the HIV-1 capsid function — positions it as a potentially important tool in Brazil's HIV prevention strategy. Although registration has been granted, **pricing must still be established by Brazil's Drug Market Regulation Chamber (CMED), and inclusion in the Unified Health System (SUS) will be evaluated by the National Commission for the Incorporation of Technologies into SUS (Conitec) and the Ministry of Health. Read more.

BRAZIL BLOCKS INCLUSION OF HERPES-ZOSTER VACCINE IN SUS OVER HIGH COST

Brazil's Ministry of Health has vetoed the incorporation of the newer recombinant herpes-zoster vaccine into the Unified Health System (SUS) after a cost-effectiveness assessment found that the financial impact would be unsustainable for public budgets. The decision, formalized in a decree published on January 12, 2026, follows a recommendation from the National Commission for the Incorporation of Technologies into SUS (Conitec) that the vaccine's benefits did not justify its projected cost under current pricing. According to official estimates, incorporating the vaccine — intended for adults aged 80 and older and immunocompromised individuals aged 18 and above — would cost approximately R$5.2 billion over five years, exceeding what policymakers consider affordable relative to its expected public health impact. The Ministry noted that negotiations with the manufacturer on price reductions may continue, and a new application could be considered if compelling new data or pricing proposals emerge. The vaccine remains available exclusively in the private healthcare market at significantly higher cost. Read more.

BRAZIL'S HEALTH MINISTRY REJECTS FIOCRUZ-TAKEDA DENGUE VACCINE PRODUCTION PROJECT

Brazil's Ministry of Health has rejected a proposal from the Butantan Institute's unit Bio-Manguinhos and Japanese pharmaceutical company Takeda to establish a Productive Development Partnership (PDP) to manufacture the Takeda dengue vaccine Qdenga in Brazil. The federal health authority said the project did not meet the minimum requirements of the PDP program because it failed to ensure full access to the technical knowledge needed to produce the active pharmaceutical ingredient (API), a requirement for national vaccine production. The vaccine, currently used in the Unified Health System (SUS) for adolescents aged 10 to 14, would have benefited from local manufacturing by shortening dependence on imports and potentially expanding coverage to other age groups. However, the Ministry of Health noted that without technology transfer and API production capability in Brazil, the proposal could not strengthen domestic vaccine production capacity. Takeda said it remained technically prepared to support the partnership and is open to dialogue with the ministry and federal government to advance access and national immunization capabilities, but Fiocruz indicated it will not re-submit the proposal. Read more.

BRAZIL'S BUTANTAN FOCUSES ON NEW VACCINE DEVELOPMENT, DIRECTOR SAYS

The Butantan Institute is strengthening its focus on the development of new vaccines following the regulatory approval of Brazil's first single-dose dengue vaccine. According to director Esper Georges Kallás, the institute is leveraging its scientific capacity and manufacturing infrastructure to advance additional immunization projects targeting diseases such as yellow fever, Zika and avian influenza, alongside ongoing studies of recently approved products for the Brazilian public health system. The Butantan-DV dengue vaccine, registered by the Brazilian Health Regulatory Agency (Anvisa) in December 2025, has already entered the production phase, with initial stock available and larger batches planned. The institute expects to scale up manufacturing throughout 2026 to support incorporation into the Unified Health System (SUS). Beyond dengue, the vaccine pipeline reflects Brazil's broader strategy to strengthen domestic innovation and reduce dependence on imported immunobiological products. Read more.

BRAZIL MET VACCINATION COVERAGE GOALS FOR ONLY TWO VACCINES IN 2025

Brazil achieved the national immunization coverage target (95 % or above) in 2025 for only two vaccines administered through the National Immunization Program (PNI): BCG, which

protects infants against tuberculosis, and the hepatitis B vaccine for newborns. These figures are based on preliminary data from the Ministry of Health, indicating a partial recovery after years of declining coverage rates. Despite these gains at birth, coverage for other routine immunizations—such as the measles-mumps-rubella (MMR) vaccine, polio, and COVID-19 vaccines—remains well below national targets. Experts point to broader challenges including vaccine hesitancy driven by misinformation, logistical barriers to completing multi-dose schedules, and the need for stronger public awareness and outreach to improve vaccination adherence across age groups. Read more.

BRAZIL OPENS PUBLIC CALL TO BOOST DIGITAL HEALTH SOLUTIONS FOR SUS

Brazil's Ministry of Health has published Public Call No. 1/2026 to identify innovative digital health partners and technologies aimed at strengthening the Unified Health System's (SUS) digital transformation, including the SUS Digital Program and the Agora Tem Especialistas initiative. The call seeks proposals from the health innovation ecosystem that can help expand access to specialized care and improve digital services across the public health network. Selected solutions may be integrated into the Inova SUS Digital Lab, an interinstitutional environment created to foster cooperation, technological development, and the adoption of digital tools in SUS. This effort aligns with broader policy goals to advance digital health services such as electronic medical records, data interoperability, and telehealth, as well as user-oriented platforms like Meu SUS Digital, which provides patients access to their health information and clinical history. Read more.

BRAZIL SEES AVERAGE 15.57% INCREASE IN CORPORATE HEALTH PLAN COSTS IN 2025

Corporate health plan contracts in Brazil experienced a notable average adjustment of 15.57 % in 2025, significantly above the general inflation rate and the authorized benchmark for individual and family plans established by the National Supplementary Health Agency (ANS) of 6.06 %. This figure reflects negotiated increases by health plan operators in the employer-sponsored (corporate) segment, driven by rising medical and hospital care costs, higher utilization of services and broader coverage demands in the supplementary health market. Although ANS regulates maximum adjustments for individual and family plans, corporate plans do not follow a fixed annual cap, allowing operators to apply market-driven increases. The relatively high adjustment in the corporate segment adds pressure on companies' benefit expenses and underscores ongoing challenges in controlling healthcare cost inflation within the private health system. Read more.

BRAZIL NEWS

Brazil's health authorities approve ordinance redefining supplementary SUS transfers

Brazil expands OncoBrasil project to strengthen pediatric oncology mapping

Brazilian women's awareness of HPV vaccination remains low despite vaccine's cancer prevention benefits

Majority of Brazilians use Google for health information but trust remains low

Brazil enacts law regulating professional practice of acupuncture

Brazil highlights leprosy awareness in "Purple January" campaign

Brazil launches inaugural national mental health survey to map well-being

MORE HIGHLIGHTS

EU and Mercosur sign trade deal after 25 years of negotiations

Trump administration to suspend immigrant visa processing for 75 nations

Trade with Iran makes Brazil a target for more US tariffs, data shows

Brazil billionaire Batista shuttles between DC and Caracas, eyeing oil deals

Brazil to hand back Argentine diplomatic representation in Venezuela

Global grain traders' green pledges face skepticism as deal to protect Brazil's rainforest unravels

Brazil police serve warrants on businessmen in Banco Master probe

Banco Master probe in Brazil may take up to six months, source says

Brazil central bank liquidates REAG for 'serious rule violations'

Brazil shuts down Sigma Lithium waste piles over safety concerns