

WEEKLY REPORT



04/18/2026

BRAZIL LAUNCHES NATIONAL CLINICAL TRIAL PROGRAM WITH BRL 120 MILLION TO BOOST SUS INNOVATION

The Ministry of Health has launched the National Clinical Trial Program (PPClin), announcing an initial investment of BRL 120 million to strengthen clinical research and accelerate the development of innovative therapies within the Unified Health System (SUS). The initiative, presented during the SUS Inova Brasil event in Rio de Janeiro, aims to integrate research institutions, regulators, and industry to translate scientific knowledge into practical healthcare solutions. The program will fund projects through a public call involving federal hospitals, universities, and research institutes, focusing on improving research infrastructure, training professionals, and expanding decentralized clinical trial capacity across the country. Authorities highlight that the strategy seeks to increase patient access to innovative treatments, reduce regional disparities, and strengthen Brazil's role in global trial and development while supporting the Health Economic-Industrial Complex. [Read more.](#)

BRAZIL BEGINS REGIONAL MEETINGS TO STRENGTHEN ETHICS POLICY IN HUMAN RESEARCH

Brazil has launched a series of regional meetings to strengthen governance and implementation of the National System for Ethics in Research with Human Beings (Sinep), starting with a training event for Research Ethics Committees (CEPs) in the Southeast region. Organized by the National Research Ethics Authority (Inaep) in partnership with the Ministry of Health, the initiative aims to improve coordination, update technical knowledge, and reinforce protection standards for trial participants. The meetings will take place across all five regions of the country throughout 2026, focusing on key topics such as system modernization, integration between stakeholders, and capacity building for ethics committees. Authorities highlight that the initiative supports the implementation of Brazil's updated regulatory framework for human research, ensuring scientific development aligned with ethical standards and participant safety. [Read more.](#)

BRAZIL PLANS TO LAUNCH NEW DRUG PROCUREMENT MODEL IN 2026 TO REDUCE COSTS

The federal government is preparing to implement a new model for the procurement of drugs within the Unified Health System (SUS) starting in 2026, aiming to increase efficiency and reduce costs through more strategic purchasing mechanisms. The proposal includes leveraging Brazil's large purchasing volume to negotiate lower prices, particularly for high-cost and complex therapies. The model under discussion also seeks to simplify procurement processes and expand competition among suppliers, while exploring instruments such as centralized purchasing and innovative contracting strategies. Officials indicate that the initiative is part of a broader effort to modernize pharmaceutical assistance and strengthen the sustainability of the SUS, amid rising pressure from high-cost technologies and growing demand for access. [Read more.](#)

BRAZIL EXPLORES CONFIDENTIAL PRICING MODEL FOR HIGH-COST CANCER DRUGS PROCUREMENT

A federal working group discussing the regulation of oncology pharmaceutical assistance is evaluating the adoption of confidential pricing mechanisms ("price silencing") in the

procurement of high-cost cancer drugs within the Unified Health System (SUS). The strategy would allow negotiated discounts offered by pharmaceutical companies to remain undisclosed, aiming to secure lower prices in centralized purchasing processes. The model, already used in countries such as the United Kingdom, is being analyzed by the Ministry of Health and has been submitted for consultation with the Federal Court of Accounts (TCU). While proponents argue that confidentiality could enhance bargaining power and reduce costs, uncertainties remain regarding transparency, oversight, and the actual fiscal impact. The discussions are part of broader efforts to define responsibilities across federal, state, and municipal levels and to modernize procurement frameworks for complex oncology treatments. [Read more.](#)

BRAZIL HIGHLIGHTS PREVENTABLE BLINDNESS AS 75% OF CASES COULD BE AVOIDED

Experts warned that up to 75% of blindness cases in Brazil could be prevented with early diagnosis and timely treatment, during a public hearing at the House of Representatives marking the April Brown awareness campaign. Specialists emphasized that limited access to primary care and chronic underfunding of the Unified Health System (SUS) remain key barriers to early detection and intervention. Conditions such as glaucoma and diabetic retinopathy were identified as leading causes of preventable vision loss, with high rates of underdiagnosis due to late symptom onset. Stakeholders also highlighted delays in incorporating new technologies and the need to strengthen ophthalmology services within primary care to reduce waiting times and improve outcomes. [Read more.](#)

BRAZIL COURT ORDERS PROVISION OF HIGH-COST DRUG AMID IMMINENT BLINDNESS RISK

A state court in Goiás has ordered public authorities to provide a high-cost ophthalmologic drug to a patient diagnosed with age-related macular degeneration, citing the imminent risk of irreversible blindness. The injunction requires both the state and municipal governments to supply aflibercept and ensure intravitreal administration within five days, following medical evidence of severe disease progression. The ruling highlights the constitutional right to health and recognizes the urgency of treatment, given the risk of permanent central vision loss if intervention is delayed. The case also underscores ongoing challenges in access to specialized therapies within the Unified Health System (SUS), as the patient had exhausted administrative pathways before seeking judicial relief. Treatment costs were estimated between BRL 6,500 and BRL 10,000 per application, reinforcing affordability barriers. [Read more.](#)

BRAZIL STRENGTHENS CONCILIATION STRATEGY TO REDUCE HEALTHCARE JUDICIALIZATION

Brazil's National Council of Justice (CNJ) has established new cooperation agreements with the Ministry of Health and the Office of the Attorney General (AGU) to expand the use of conciliation and mediation in healthcare-related disputes. The initiative aims to reduce the volume of lawsuits in the Unified Health System (SUS) by promoting institutional coordination and resolving demands through consensual mechanisms rather than litigation. The agreements prioritize cases involving medicines already incorporated into the SUS, enabling their provision through regular healthcare channels instead of court orders. Authorities highlight that the strategy seeks to improve predictability in public management, reduce legal uncertainty, and alleviate pressure on the judiciary, while maintaining access to justice through more efficient and cooperative solutions. [Read more.](#)

BRAZIL PATIENT GROUPS CHALLENGE CONITEC RULES ON CIVIL SOCIETY PARTICIPATION

Patient organizations in Brazil are preparing legal action against current rules of the National Committee for Health Technology Incorporation (Conitec), arguing that recent regulations fail to ensure effective participation of civil society in decision-making on technology incorporation into the public health system. The initiative is led by Casa Hunter, which claims that restrictions on eligibility, representation, and conflict-of-interest declarations create unequal conditions

compared to other stakeholders. Despite recent measures by the Ministry of Health to streamline participation (such as governance manuals, training initiatives, and a selection panel), associations argue that key barriers remain, including strict selection criteria and limitations on who can represent organizations. The Ministry states that efforts are ongoing to improve engagement, noting that civil society has already contributed to multiple technology assessments across disease areas within the Unified Health System (SUS). [Read more.](#)

ANVISA LAUNCHES ACTION PLAN TO CUT DRUG APPROVAL BACKLOGS

The Brazilian Health Regulatory Agency (Anvisa) has presented an action plan aimed at reducing backlogs in the analysis of medicines and other health products, as part of a broader effort to improve regulatory efficiency and accelerate access to innovation. The initiative targets accumulated queues in drug registration, post-registration changes, clinical trials, and inspections, which have increased in recent years due to growing demand and structural constraints. The plan includes a combination of temporary and structural measures, such as process prioritization based on risk, adoption of reliance mechanisms using decisions from international regulators, use of artificial intelligence tools, and reinforcement of technical staff. Authorities aim to reduce waiting times by up to 50% within six months and normalize processing timelines by the end of 2026, with early results already indicating significant reductions in some areas. [Read more.](#)

ANVISA POSTPONES DEBATE ON RULES FOR COMPOUNDED WEIGHT-LOSS INJECTABLES

The Brazilian Health Regulatory Agency (Anvisa) has postponed discussions on new regulations for the compounding of GLP-1-based weight-loss injectables in pharmacies, amid increasing scrutiny over safety and quality concerns. The agency had been expected to advance regulatory measures targeting the manipulation of substances such as semaglutide and tirzepatide, widely used in obesity and diabetes treatments. The delay occurs as Anvisa intensifies inspections and enforcement actions across the supply chain, including importers and compounding pharmacies, following the identification of irregular practices and quality failures. Authorities have highlighted discrepancies between imported raw materials and market demand, as well as risks associated with large-scale compounding outside the intended individualized prescription model. [Read more.](#)

ANVISA PREPARES ACTION PLAN TO ADDRESS RISKS FROM GLP-1 WEIGHT-LOSS INJECTABLES

The Brazilian Health Regulatory Agency (Anvisa) is preparing an action plan to mitigate health risks associated with the growing use of GLP-1 receptor agonists, widely known as weight-loss injectables. According to Anvisa leadership, the initiative responds to a surge in demand accompanied by irregularities across the supply chain, including the importation of active pharmaceutical ingredients and the large-scale compounding of these products outside regulated standards. The strategy includes strengthening regulatory oversight, enhancing pharmacovigilance, and improving control over imports and compounding practices, as well as promoting coordination with professional councils and other authorities. Measures under discussion also involve educational campaigns, stricter monitoring of adverse events, and the creation of working groups to support implementation. Authorities warn that the expansion of unregulated products and inappropriate use may expose patients to significant safety risks, reinforcing the need for a more robust governance framework. [Read more.](#)

CMED SETS PRICE FOR NEW ALZHEIMER DRUG AT UP TO BRL 11,000 PER MONTH

Brazil's Drug Market Regulation Chamber (CMED) has approved the price of lecanemab, a new therapy for early-stage Alzheimer's disease, with monthly treatment costs ranging from approximately BRL 8,100 to BRL 11,000 depending on state taxes. The drug, developed by Eisai in partnership with Biogen and marketed as Leqembi, was approved by the Brazilian Health Regulatory Agency (Anvisa) in late 2025 and is expected to reach the market in mid-2026. Lecanemab is a monoclonal antibody targeting beta-amyloid protein and is indicated for

patients with mild cognitive impairment or mild dementia due to Alzheimer's disease. Clinical studies show the therapy can slow disease progression, although it does not reverse existing damage. Experts highlight that the high cost and need for specialized administration (via intravenous infusion every two weeks) pose challenges for broad access, with no current expectation of coverage by the Unified Health System (SUS) or private insurers. [Read more.](#)

BRAZIL DEBATES INCLUSION OF SEMIANNUAL HIV INJECTION AS HIGH COST LIMITS SUS ADOPTION

The potential incorporation of lenacapavir, a long-acting injectable for HIV prevention administered twice a year, faces significant barriers in Brazil due to high costs and pharmaceutical market dynamics. During a public hearing at the Chamber of Deputies, officials from the Ministry of Health, experts, and civil society representatives highlighted that pricing and patent-related constraints currently limit the feasibility of offering the therapy through the Unified Health System (SUS). Lenacapavir is considered a breakthrough in HIV prevention, as it may improve adherence and reduce stigma compared to daily oral prophylaxis. However, the drug is still undergoing price definition by the Drug Market Regulation Chamber (CMED), after which the National Committee for Health Technology Incorporation (Conitec) will assess its cost-effectiveness for public coverage. Stakeholders emphasized the need for strategies such as local production or compulsory licensing to expand access, warning that without affordability, the innovation may have limited public health impact. [Read more.](#)

ANS PRESIDENT CALLS FOR STRUCTURAL REFORM IN SUPPLEMENTARY HEALTH MODEL

The president of the National Supplementary Health Agency (ANS), Wadih Damous, has called for a structural shift in Brazil's private health system, advocating a transition from a procedure-based model to one centered on care pathways, prevention, and clinical outcomes. Speaking at the 17th Unidas Seminar in Brasília, Damous stated that the current system shows signs of exhaustion and fails to adequately place the patient at the center of care. He described the sector as facing a structural crisis rather than a temporary disruption, emphasizing that the challenge goes beyond financial sustainability and involves ensuring equitable and effective care. The proposed regulatory shift includes greater focus on primary care, early risk identification, and the responsible use of artificial intelligence, while avoiding practices that could indirectly exclude beneficiaries. Damous also highlighted governance reforms and warned that judicialization reflects systemic shortcomings rather than being a root cause. [Read more.](#)

ANS DROPS LIMITED COVERAGE HEALTH PLAN PROPOSAL AND SHIFTS FOCUS TO DISCOUNT CARDS REGULATION

The National Supplementary Health Agency (ANS) has decided to discontinue the proposal for simplified health plans that would exclude emergency care and hospitalizations, redirecting its efforts toward regulating the growing market of healthcare discount cards. The abandoned model, introduced in 2025, would have covered only consultations and basic exams, leaving more complex care to the Unified Health System (SUS). The agency has launched a public call for data from companies operating discount card services, aiming to establish clearer rules and improve transparency for consumers. ANS officials argue that the lack of regulation in this segment creates confusion, as such products are often marketed similarly to traditional health insurance plans. The initiative includes the creation of an internal working group to develop regulatory guidelines for the sector. [Read more.](#)

ANS EVALUATES COST-EFFECTIVENESS THRESHOLDS FOR TECHNOLOGY INCORPORATION

The National Supplementary Health Agency (ANS) is assessing the adoption of cost-effectiveness thresholds to guide decisions on the incorporation of new technologies into private health plans. The initiative, currently under internal evaluation, aims to provide a structured economic parameter to support health technology assessment (HTA) and mitigate the financial impact of high-cost treatments on the supplementary health system. The agency is working in

partnership with the Pan American Health Organization (PAHO) and is expected to commission a study with Argentina's Institute for Clinical Effectiveness and Health Policy (IECS). Officials indicate that the model may draw on benchmarks used by the National Committee for Health Technology Incorporation in the SUS (Conitec), while adapting the methodology to the specificities of the private sector. Despite potential gains in predictability and sustainability, stakeholders highlight concerns that fixed thresholds could limit access to innovative therapies, particularly in high-cost or rare disease areas. [Read more.](#)

ANS PLANS TO EXPAND ARTIFICIAL INTELLIGENCE USE WHILE TIGHTENING OVERSIGHT ON INSURERS

The National Supplementary Health Agency (ANS) plans to expand the use of artificial intelligence (AI) as a strategic tool to improve governance, reduce administrative backlogs, and enhance the technical capacity of its workforce. According to ANS leadership, the initiative is still in the planning phase and will depend on resource allocation but is considered essential for modernizing regulatory activities in the supplementary health sector. At the same time, the agency intends to strengthen oversight of how health insurers deploy AI, amid concerns about potential misuse of predictive tools for risk selection, contract cancellations, or targeted premium increases. Officials highlight that AI may also support monitoring of beneficiaries, early identification of health risks, and preventive care strategies, but stress the need to avoid reinforcing existing distortions in the system. [Read more.](#)

ANS EXPANDS COVERAGE WITH NEW CANCER AND ATOPIC DERMATITIS TREATMENTS

The National Supplementary Health Agency (ANS) has approved the inclusion of new therapies for cancer and severe atopic dermatitis in the mandatory coverage list for private health plans. The update includes osimertinib mesylate in combination with chemotherapy for first-line treatment of advanced or metastatic non-small cell lung cancer with specific EGFR mutations, as well as lebrikizumab for adult patients with severe atopic dermatitis who are intolerant or unresponsive to ciclosporin. The decision follows technical assessments, public consultations, and pricing negotiations, including a price reduction agreement for lebrikizumab to ensure cost-effectiveness. In addition, ANS approved the incorporation of a quantitative RT-PCR test for detecting the Philadelphia chromosome, supporting diagnosis and monitoring of leukemia. Coverage for the new technologies will become mandatory between May and July 2026 under specific regulatory resolutions. [Read more.](#)

BRAZIL'S EMS PARTNERS WITH US BIOTECH TO DEVELOP HIGH-COMPLEXITY THERAPIES

Brazilian pharmaceutical company EMS has entered into a partnership with a US-based biotech firm to develop high-complexity and disruptive therapies, with an initial focus on rare diseases and conditions lacking effective treatment options. The initiative aligns with the company's broader strategy to expand its innovation pipeline and strengthen capabilities in advanced therapeutic platforms. The collaboration is being led by Rio Biopharmaceuticals, EMS's US-based arm responsible for structuring global partnerships with biotech companies at the frontier of scientific innovation. In Brazil, industrial execution will be supported by the company's peptide manufacturing facility in Hortolândia, São Paulo, which has the capacity to produce up to 20 million units annually and is part of recent investments totaling approximately BRL 1.2 billion in high-complexity technologies. [Read more.](#)

BRAZIL FACES INSULIN SUPPLY UNCERTAINTY AS NOVO NORDISK SEEKS CONTRACT WITH SUS

Denmark-based pharmaceutical company Novo Nordisk has signaled it may resume supplying human insulin to Brazil's Unified Health System (SUS), contingent on the signing of a new contract with the Ministry of Health by the end of May. The proposal includes the delivery of between 100 million and 125 million insulin pens from July 2026 to March 2028, potentially covering the entire national demand for the product. The move comes amid ongoing supply

challenges, as the company has reduced deliveries in recent years while shifting its portfolio toward higher-growth products such as Ozempic. The Ministry of Health has indicated it will proceed with a public tender in the coming months, emphasizing that procurement decisions follow technical and pricing criteria. If no agreement is reached, Novo Nordisk plans to discontinue production of this type of insulin by the end of 2026, raising concerns over long-term supply stability within the SUS. [Read more.](#)

BRAZIL FACES CYCLOPHOSPHAMIDE SHORTAGE THREATENING ONCOLOGY AND TRANSPLANT TREATMENTS

Brazil is facing a shortage of cyclophosphamide, a key chemotherapy and immunosuppressive drug, raising concerns among medical societies and patient groups about disruptions in cancer care and advanced therapies. The shortage, linked to manufacturing issues affecting supply chains, has led to reduced availability of injectable formulations across the country. Healthcare authorities and medical organizations warn that the lack of the drug may compromise high-complexity treatments, including hematopoietic stem cell transplants and protocols for leukemia and lymphoma. The Ministry of Health has issued technical guidance recommending prioritization of critical cases and more stringent stock management, while stakeholders call for emergency measures such as exceptional imports. Supply normalization is currently expected only by mid-2026. [Read more.](#)

BRAZIL TO INVEST BRL 1.1 BILLION IN NEW ONCOLOGY COMPLEX IN RIO DE JANEIRO

The Ministry of Health has announced a BRL 1.1 billion investment to build a new integrated campus of the National Cancer Institute (National Cancer Institute – INCA) in Rio de Janeiro, marking the first federal public-private partnership (PPP) in Brazil's healthcare sector. The project is expected to expand radiotherapy and chemotherapy capacity by 40% and consolidate services currently spread across multiple units into a single, modern complex. The initiative includes the creation of up to 450 hospital beds, a 20% increase in surgical rooms, and expanded access to clinical research, with participation rates projected to rise significantly. The new facility will integrate care, research, and professional training, strengthening Brazil's oncology infrastructure and supporting efforts to reduce waiting times for specialized services within the Unified Health System (SUS). [Read more.](#)

BRAZIL SUPERMARKET DRUG SALES RULES FALL SHORT OF EXPECTATIONS FOR RETAIL SECTOR

The recently enacted law allowing the sale of medicines in supermarkets has failed to meet expectations from the food retail sector, as strict regulatory requirements limit the model's scalability and commercial appeal. Although initially perceived as opening shelf sales for over-the-counter drugs, the legislation instead mandates the installation of fully compliant pharmacy units within supermarkets, including dedicated physical space and the mandatory presence of a licensed pharmacist. Industry stakeholders from both the supermarket and pharmaceutical sectors have expressed dissatisfaction with the final framework, citing operational complexity, workforce constraints, and uncertainty over viable business models. Large retail chains may expand through in-store pharmacy formats or partnerships, while smaller operators are more likely to rely on franchising or agreements with established pharmacy networks. Experts note that the regulation effectively preserves the traditional pharmacy model, limiting disruptive impact on the broader retail landscape. [Read more.](#)

BRAZIL TO EXPAND INTERNET ACCESS TO 2,700 PRIMARY CARE UNITS TO ACCELERATE SUS SERVICES

The federal government plans to expand broadband connectivity to up to 2,700 primary healthcare units (UBS) across Brazil, aiming to accelerate service delivery and strengthen digital health capabilities within the Unified Health System (SUS). The initiative, led by the Ministry of Communications in partnership with the Ministry of Health, will be supported by approximately BRL 100 million from the Universal Telecommunications Services Fund (Fust) and is expected to reach facilities in more than 1,000 municipalities. The project focuses on enabling electronic medical records, data integration, and the expansion of telehealth services, particularly in underserved and remote areas, including rural, Indigenous, and peripheral communities. Authorities highlight that improved connectivity will support faster diagnoses, reduce unnecessary patient travel, and help address regional disparities in access to healthcare services. [Read more.](#)

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[Brazil advances prostate cancer screening with higher detection of clinically significant tumors](#)

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[Ministry of Health declines inclusion of meningococcal B vaccine in SUS for infants](#)

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