

WEEKLY REPORT



11/22/2025

ANVISA CREATES COMMITTEE TO MONITOR IMPLEMENTATION OF ITS REGULATORY BACKLOG ACTION PLAN

Anvisa has established a dedicated Monitoring Committee to oversee the execution of its Regulatory Backlog Action Plan, approved earlier this month as part of a broader institutional effort to modernize regulatory operations. The new body will track progress across all directorates involved in clinical-trial evaluations, marketing authorizations, post-approval changes, and GMP-related processes. The committee's mandate includes monitoring performance indicators, identifying structural bottlenecks, proposing corrective adjustments, and ensuring alignment with the temporary measures adopted to reorganize workflows. By creating a formal governance mechanism, Anvisa seeks to guarantee that the backlog-reduction plan is implemented consistently and transparently, strengthening predictability for regulated sectors and reinforcing Brazil's convergence with international regulatory-efficiency standards. [Read more.](#)

BRAZIL TO LAUNCH NATIONAL PLATFORM FOR MEDICATION-RELATED JUDICIAL HEALTH CASES

The Ministry of Health is preparing to launch a unified national platform that will consolidate judicial cases involving medicines across federal and state systems. Today, data related to litigation is dispersed among courts, public defenders, state health secretariats, and NAT-Jus units. The new system will centralize these records, allowing the government to map prescribing patterns imposed by court orders, track expenditure pressures, and identify therapeutic classes that consistently generate demand for judicial access. By integrating databases and standardizing analytical outputs, the platform is expected to support more informed policy decisions, improve procurement planning, and strengthen evidence-based responses to judicialization. Officials also expect the tool to highlight systemic gaps, such as absence of clinical guidelines, supply failures, or technologies not yet assessed by Conitec. [Read more.](#)

BRAZILIAN HEALTH COUNCIL URGES PARITY AND STRONGER SOCIAL OVERSIGHT IN HUMAN-RESEARCH REGULATION

The National Health Council (CNS) issued a public statement calling for equal representation between government and civil society in Brazil's ethical-oversight framework for clinical trials. The position responds to ongoing discussions in the Executive Branch about restructuring the CEP/Conep system, including proposals that would alter how ethical review is governed, how decisions are escalated, and how responsibilities are distributed. CNS argues that civil-society parity is not merely a procedural feature, but a constitutional safeguard grounded in Brazil's health-democracy principles. According to the Council, reducing participatory oversight could weaken protections for vulnerable populations, diminish transparency in clinical-research decisions, and undermine international confidence in Brazil's governance model, particularly at a time when the country is expanding its role in global trials, advanced therapies and public-private innovation partnerships. [Read more.](#)

BRAZILIAN STATES DISCUSS ONCOLOGY CHALLENGES AND DRUG-MANAGEMENT GAPS

State health secretariats met this week to examine persistent structural barriers within Brazil's oncology-care network. Authorities highlighted recurrent problems, including delays in diagnostic confirmation, unequal distribution of radiotherapy and chemotherapy services, insufficient integration between outpatient and hospital-based care, and fragmented drug-management processes. Many states reported difficulties maintaining stable supplies of oncology medicines, citing procurement challenges, inconsistencies in federal transfers, and limited visibility into national inventories. Participants also pointed to major disparities in patient pathways, with some regions experiencing prolonged referral times and limited availability of specialized teams. The discussion reinforced the need for stronger federal coordination, expanded data integration, and clearer performance indicators to reduce inequities and strengthen continuity of oncology care across the SUS. [Read more.](#)

INDUSTRY GATHERS AT CADIFA 2025 TO DISCUSS REGULATORY ALIGNMENT AND API DOSSIER CHALLENGES

Anvisa's national seminar on CADIFA 2025 attracted more than 1,000 participants, highlighting the strong and growing interest in the regulatory framework for Active Pharmaceutical Ingredient (API) registration in Brazil. The event brought together regulators, industry representatives, technical experts, and international guests to discuss the evolution of CADIFA, the impact of recent normative updates, and the agency's plans to advance regulatory convergence. Speakers emphasized the importance of CADIFA in increasing transparency, improving predictability for manufacturers, and aligning Brazil with international quality standards for APIs. The seminar also highlighted ongoing challenges such as dossier quality, process standardization, and the need for greater industry preparedness to support more efficient regulatory reviews. [Read more.](#)

BRAZIL WARNS OF RISING COUNTERFEIT RISKS AS HIGH-VALUE MEDICINES TOP FALSIFICATION LIST

Authorities issued an alert on the growing risk of counterfeit high-value medicines circulating in both legal and illegal channels. Oncology drugs, immunobiologics and weight-loss treatments now top Brazil's falsification list, driven by strong demand, global supply pressures and rapidly expanding online sales. Regulators reported an increase in seizures, criminal investigations and reports of diversion schemes involving digital marketplaces and informal distribution networks. The alert underscores the need for stronger surveillance, improved authentication technologies, and expanded public awareness initiatives to protect patients from unsafe or ineffective products. [Read more.](#)

BRAZIL STUDY SHOWS DECLINE IN PREVENTIVE WOMEN'S HEALTH PROCEDURES IN SUPPLEMENTARY HEALTH

A new study from the National Supplementary Health Agency (ANS) shows a concerning decline in preventive women's health procedures within Brazil's private health-insurance sector. The data reveals reductions in screenings such as Pap smears, mammograms, and other routine exams essential for early detection of cervical and breast cancer. Researchers suggest multiple factors behind the decline, including reduced adherence to care pathways, service delays, pandemic-related backlogs, and varying levels of provider engagement across insurance networks. The findings reinforce the need for targeted programs to expand access, improve preventive-care strategies, and encourage earlier diagnosis to reduce long-term health burdens. [Read more.](#)

BRAZIL ADVANCES DOMESTIC PRODUCTION WITH 2.1 MILLION UNITS OF INSULIN GLARGINE DELIVERED TO SUS

Brazil has delivered 2.1 million units of insulin glargine to the SUS, marking a significant milestone in the government's strategy to expand domestic pharmaceutical production through public-private partnerships and technology-transfer agreements. The deliveries reflect progress

in nationalizing high-cost biologics and reducing dependency on imported medicines. The initiative is part of a broader industrial-health policy aimed at strengthening local manufacturing capabilities, increasing supply security, and lowering long-term procurement costs. Officials highlighted that sustained investment in complex biologics production is essential to expand access and improve continuity of care for chronic-disease patients across the country. [Read more.](#)

EMS SECURES R\$107.6 MILLION IN BNDES FUNDING TO EXPAND ITS R&D CENTRE

EMS, Brazil's largest pharmaceutical company, secured R\$107.6 million in financing from BNDES to expand its research and development center, strengthening national capabilities in drug innovation, clinical development, and advanced manufacturing. The investment will support infrastructure upgrades, expansion of laboratory capacity, acquisition of high-complexity analytical technologies and the creation of new R&D units focused on biologics and high-value therapies. According to EMS, the expanded facility will deepen Brazil's participation in global innovation chains, increase the competitiveness of local production, and accelerate the development of medicines tailored to domestic public-health priorities. The financing aligns with the federal strategy to stimulate industrial revitalization, reduce dependency on imported technologies and promote higher value-added activities in the pharma sector. [Read more.](#)

BRAZIL ADVANCES PARTNERSHIP TO DEVELOP FIRST TARGETED TREATMENT FOR YELLOW FEVER

Brazilian research institutions and international partners are advancing a collaborative project to develop what could become the world's first targeted therapeutic for yellow fever. Current care relies solely on supportive treatment, and no specific antiviral therapy exists for the disease, which continues to pose recurrent risks in endemic regions and periodically generates severe outbreaks. The initiative integrates high-throughput screening, molecular modelling, and preclinical testing to identify compounds capable of inhibiting viral replication. Researchers highlight that a successful therapy could drastically improve clinical outcomes, reduce mortality in severe cases and strengthen outbreak-response capacity in Latin America. The partnership also reinforces Brazil's strategic positioning in the global landscape of neglected-disease research. [Read more.](#)

BRAZILIAN RESEARCH INSTITUTIONS ADVANCE PLAN TO DELIVER CAR-T THERAPY BY 2026

Brazilian scientific institutions are advancing an ambitious plan to deliver domestically developed CAR-T cell therapy by 2026, marking a potential milestone in national capacity to produce advanced therapies. The initiative integrates public research centers, university laboratories, and clinical specialists to develop a locally manufactured product capable of offering a lower-cost alternative to imported CAR-T treatments. The project focuses on optimizing manufacturing protocols, expanding GMP-compliant cell-processing capacity, and conducting the clinical evaluations required for regulatory submission. If successful, Brazil could become the first country in Latin America to deliver a fully national CAR-T platform. [Read more.](#)

BRAZIL'S AGRICULTURAL RESEARCH AGENCY GETS CANNABIS RESEARCH GREENLIGHT

Brazilian agricultural research agency Embrapa has received the greenlight from health agency Anvisa to research the cannabis plant, a landmark move that puts farming powerhouse Brazil a step closer towards authorizing its cultivation. In an interview on Friday, Embrapa researcher Daniela Bittencourt welcomed Anvisa's decision this week, which gives the agency unprecedented permission to build its first-ever cannabis seed bank and develop projects to genetically improve the plant for various applications. Embrapa will also research hemp used to produce fibers, Bittencourt said. "This is only the beginning," Bittencourt said by telephone from Brasilia. "Our plan is to carry out research for 12 years but it may possibly go on forever, like what happens with soy and corn". [Read more.](#)

MORE HIGHLIGHTS

[Brazil's Anvisa alerts on prohibition of unregistered weight-loss injection pens](#)

[Brazil's drugstore market sees R\\$13.2 billion in sales driven by diabetes and obesity treatments](#)

[Brazil advances with construction of first intelligent hospital within the SUS health system](#)

[Brazil's regulator reclassifies omeprazole 20 mg as over-the-counter medicine](#)

[STF suspends Brazil's review of advertising rules for medicines and foods](#)

BRAZIL NEWS

[Brazil's Bolsonaro detained over flight risk, damaged ankle monitor](#)

[Lula taps Brazil's solicitor general for Supreme Court seat](#)

[Brazil central bank shuts Banco Master as police detain top investor](#)

[Brazil judge flags BRB role in Banco Master fraud; losses may top \\$1.9 bln](#)

[Brazil eyes taxing crypto for cross-border payments](#)

[Trump signs order to remove tariffs from Brazilian beef, coffee](#)

[Global coffee prices plunge after Trump removes tariffs on Brazil](#)

[COP30 deal exposes fragile climate unity as US steps back](#)

[Takeaways from the COP30 climate summit in Brazil](#)

[What the COP30 climate summit in the Amazon delivered for forests and Indigenous people](#)

[COP30 host city Belem, Brazil, tries to stoke economy while preserving Amazon rainforest](#)

[Germany to contribute 1 billion euros to Brazil's forest fund, Brazil environment minister says](#)

[EU-Mercosur trade deal still needs work to be acceptable for France, says government](#)