

WEEKLY REPORT



08/16/2025

BRAZIL TO CHALLENGE U.S. DATA ON ROYALTIES AND PATENTS IN RESPONSE TO TRUMP ADMINISTRATION

The Brazilian government, under President Luiz Inácio Lula da Silva, plans to dispute intellectual property data presented by the Office of the United States Trade Representative (USTR) in the commercial investigation opened during Donald Trump's administration. According to Folha de S. Paulo, Brazil's response, being prepared by the Ministry of Foreign Affairs (Itamaraty), will argue that patent issuance timelines in the country are significantly shorter than those claimed by the U.S. and could be further reduced. In addition, the government intends to highlight that the large U.S. surplus in intellectual property royalties paid by Brazil demonstrates that the country maintains strict rules in this sector and respects American copyright and industrial property rights. [Read more.](#)

BRAZIL'S REGULATORY AGENCIES FACE STRUCTURAL CHALLENGES LEADING TO 'OPERATIONAL SUFFOCATION', SAYS ANVISA MANAGER

The House of Representatives' Committee on Public Administration and Civil Service held a hearing on Tuesday (12) to discuss the strengthening of regulatory agencies. Danitza Passamai Rojas, Anvisa's general manager for Human Resources, highlighted that the challenges faced by regulatory agencies are structural, not isolated, and generate what she called an "operational suffocation." She stressed that these institutions perform essential state functions, crucial to protecting society and upholding the rule of law. Regarding Anvisa specifically, Rojas emphasized its strategic role in sanitary control of products and services, which account for an estimated 30% of Brazil's GDP. The agency operates nationwide, as well as in ports, airports, and border crossings, extending its scope beyond national territory. Rojas warned about a significant decline in staffing levels: in 2007, the agency had 2,360 active employees, but by 2023 this number dropped to 1,468, including 260 from a special staff corps in extinction. After the 2024 nominations, Anvisa currently has 1,533 employees. According to industry estimates, this shortage compromises operations, with a backlog of registrations valued at around BRL 17.8 billion. [Read more.](#)

BRAZIL'S SENATE COMMITTEE APPROVES ANVISA PRESIDENT AND TWO DIRECTORS; NOMINATIONS MOVE TO PLENARY

The Senate's Social Affairs Committee (CAS) approved on Wednesday (13) the nominations of three directors of the Brazilian Health Regulatory Agency (Anvisa), including its new president, Leandro Pinheiro Safatle. After their confirmation hearings and a secret vote, the nominations of Safatle, Thiago Lopes Cardoso Campos, and Daniela Marreco Cerqueira will now proceed to a full Senate vote. Safatle, an economist, will replace Antônio Barra Torres, whose mandate ended in December, as president of Anvisa. A career federal public servant since 2011, he has worked at Anvisa, Fiocruz, and the Ministry of Health, where he currently serves as deputy secretary of Science, Technology and Innovation and the Health Economic-Industrial Complex. Thiago Campos, a lawyer with specializations in health policy and sanitary law, is currently legal coordinator at the Brazilian Company of Hospital Services (Ebserh) and a board member of Bahia's State Health Council. Daniela Cerqueira, a career Anvisa official since 2006, holds a PhD in molecular biology and currently serves as executive secretary of the Drug Market Regulation Chamber (CMED), the interministerial body responsible for pharmaceutical pricing. [Read more.](#)

ANVISA'S ANNOUNCEMENT ON DRUG QUEUES PROVOKES IMMEDIATE REACTION IN THE MARKET

The announcement made by the director of the National Health Surveillance Agency (Anvisa), Daniel Meirelles, of the publication of a notice to change the logic of medicine queues provoked an immediate reaction in the market. The proposal allows a company to forgo a product in the registration queue and replace it with another one that will require a longer wait time. This exchange, the director believes, can help reduce the wait for new products to enter the market and ensure that companies have strategic products evaluated more quickly. Meirelles also believes this instrument could also reduce potential wasted energy from the agency's technical team. Since there is currently a long time between the filing of an application and its review, Meirelles argues that, in some cases, products may no longer be of interest to companies when registration is finally granted. One group believes that the measure proposed by Meirelles could help their businesses. This perception is particularly prevalent among companies with multiple product orders awaiting review. In these cases, there's greater scope for maneuver and, consequently, business opportunities. This assessment, however, is not unanimous. For some companies, a measure like this will cause a significant change in the business environment, generating instability and harming competition. Sindusfarma's executive director, Nelson Mussolini, told JOTA that some members have already expressed opposition to the idea of publishing the notice. The organization is currently conducting an evaluation among all members to issue a formal statement. [Read more.](#)

BREAST CANCER DRUGS WILL BE AVAILABLE IN BRAZIL'S SUS IN OCTOBER, SAYS MINISTER

Health minister Alexandre Padilha announced on Tuesday (12) that drugs used in the treatment of breast cancer will be available to patients through the Unified Health System (SUS) starting in October. The Clinical Protocol and Therapeutic Guidelines (PCDT), published eight months ago, recommend the use of cyclin inhibitors and trastuzumab emtansine to help prolong survival, delay chemotherapy, and reduce hospitalizations. The announcement comes after a wait of more than three years, as the drugs were incorporated into the SUS in December 2021 and September 2022. According to the National Cancer Prevention and Control Policy (PNPC), after the publication of an incorporation decision, a drug should reach patients within 180 days. Padilha explained that the process is in its final negotiation stage with the industry, states, and municipalities to secure fair pricing and proper registration of the medicines. "Our goal is to begin Pink October with the most modern and updated treatments for women. We are very dedicated to ensuring a historic Pink October," said the minister during an event organized by Esfera Brasil. He also announced the creation of a nationwide mammography quality control plan, noting that although Brazil has more mammography devices than necessary, many are malfunctioning, under maintenance without replacement, or out of service. [Read more.](#)

EXPERTS ADVOCATE FLEXIBILITY IN SHARED-RISK CONTRACTS FOR BRAZIL'S HEALTH MINISTRY

Specialists called for greater flexibility in the design of shared-risk agreements between Brazil's Health Ministry and pharmaceutical companies. These agreements, currently under discussion in the House of Representatives through Bill 667/2021, allow experimental use of treatments that have not yet completed all clinical trial phases. These contracts aim to share clinical and budgetary risks between the public sector and manufacturers, enabling patient access to advanced therapies — especially for rare diseases or cases where other treatments have failed. Cássio Ide Alves, technical director at Abramge, noted that agreements may include features like volume-based discounts or confidentiality clauses, and in some cases, tying payment to treatment results. [Read more.](#)

BRAZIL LACKS POLICIES FOR ADULTS WITH RARE DISEASES, SENATE COMMITTEE SAYS

Specialists highlighted the urgent need for dedicated policies for Brazilian adults living with rare diseases during a Senate Social Affairs Committee (CAS) hearing on Monday (11). Conditions like multiple sclerosis, neuromyelitis optica, and amyotrophic lateral sclerosis (ALS) were cited as examples of diseases that significantly impair patient autonomy, work capacity, and social interaction, especially when diagnosis and treatment are delayed, burdening both public and private health systems. Senator Damares Alves (Republicanos-DF), one of the organizers of the debate, emphasized that the issue must not remain "forgotten or shelved." She noted the public's strong engagement in the discussion, with over 250 contributions submitted through the Senate's e-Citizenship platform. [Read more.](#)

BRAZIL'S SENATE COMMITTEE APPROVES WADIH DAMOUS FOR ANS PRESIDENCY; NOMINATION HEADS TO PLENARY

The Senate's Social Affairs Committee (CAS) approved the nomination of Wadih Damous for president of the National Supplementary Health Agency (ANS) on Wednesday (13). The approval came with 16 votes in favor and 5 against, with a report recommending approval by Senator Sérgio Petecão (PSD-AC). The nomination now moves to the full Senate Plenary for final decision. Wadih Damous is currently the National Consumer Secretary and previously served as a federal deputy for the PT. He will replace Paulo Roberto Vanderlei Rebello Filho, whose term ended in December 2024. [Read more.](#)

SUS WILL HAVE ROBOTIC SURGERY FOR PROSTATE CANCER AFTER CONITEC'S DECISION

The National Commission for the Incorporation of Technologies into the SUS (Conitec) approved the incorporation of robot-assisted radical prostatectomy (PRAR) into the public health network for the treatment of prostate cancer. The procedure, which involves the complete removal of the prostate, is the main treatment for localized or locally advanced cancer. It is considered curative. Prostate cancer is the most common malignancy among men, with the National Cancer Institute (INCA) estimating 77,000 new cases in Brazil by 2025. [Read more.](#)

ORDINANCE PUBLISHED DEFINES RULES FOR QUALIFICATION AND REGISTRATION OF GENE THERAPY SERVICES IN THE UNIFIED HEALTH SYSTEM

Ordinance SAES/MS No. 3,080, dated July 29, 2025, was published in the Official Gazette of the Union this Thursday (14). It establishes rules for the qualification and registration of services that perform Gene Therapy in the National Registry of Health Establishments (CNES) and includes procedures in the SUS Table of Procedures, Medications, Orthoses, Prostheses, and Special Materials. The regulation defines the technical and administrative criteria for health establishments to be qualified to perform gene therapy infusions, following the SUS Clinical Protocols and Therapeutic Guidelines (PCDT). [Read more.](#)

BRAZIL'S SUS LAUNCHES NATIONAL HPV TEST TO PREVENT CERVICAL CANCER

Starting this Friday (15), Brazil's Unified Health System (SUS) will offer a 100% nationally developed molecular biology DNA-HPV test for the early detection of cervical cancer. The innovative method can identify 14 genotypes of the human papillomavirus (HPV), allowing detection before lesions or early-stage cancer appear, including in asymptomatic women. According to the Ministry of Health, the test will initially be available in 11 Brazilian states, in addition to the Federal District: Rio de Janeiro, São Paulo, Minas Gerais, Ceará, Bahia, Pernambuco, Pará, Rondônia, Goiás, Rio Grande do Sul, and Paraná. [Read more.](#)

MAIS MÉDICOS WAS A 'DIPLOMATIC COUP' AND THE US WILL HOLD EVERYONE INVOLVED IN THE 'SCHEME' ACCOUNTABLE, SAYS THE EMBASSY

The day after the United States decided to revoke the visas of two Brazilians who worked on implementing the Mais Médicos program, the country's embassy in Brazil said the program was a "diplomatic coup" designed to exploit Cubans. He also said he will continue to hold "everyone" involved in the initiative accountable. Allies of former President Jair Bolsonaro (PL) expect that former President Dilma Rousseff and Health Minister Alexandre Padilha may have their access

to the United States restricted in the future. Padilha, according to a person with access to the discussion, is on the list of those whose visas were restricted, although the State Department did not disclose the minister's name. Dilma's status, however, is uncertain. But the strategy is to maintain pressure on Brazil. Mais Médicos was created in 2013, during Dilma's administration, when Padilha was also the minister. The State Department told Folha that it would not disclose details about other individuals who will be punished. [Read more](#).

PADILHA SAYS TRUMP'S SANCTIONS AGAINST FAMILY MEMBERS ARE A 'COWARDLY ACT' TO INTIMIDATE

Health Minister Alexandre Padilha (PT) said this Friday (15) that the cancellation of his wife and 10-year-old daughter's visas to the United States is a cowardly act and unrelated to the now-defunct partnership of the Mais Médicos program with Cuba. Padilha stated that the sanction "has to do with an attempt to intimidate those who do not bow their heads to Trump, who do not salute the American flag." [Read more](#).

HOW GOIÁS STATE IS REDESIGNING HEALTHCARE WITH AI INITIATIVES IN BRAZIL

Artificial intelligence is emerging as a promising technology in healthcare. In Brazil, one example is the healthcare ecosystem of Goiás state, which has multiple initiatives in this area. Among them is the Conecta SUS dashboard, from the state's Health Secretariat, which uses AI to analyze indicators across different areas for decision-making — from primary care to resource management. The Secretariat also operates a predictive platform for dengue outbreaks in municipalities, developed by Predict.AI. With over 80% accuracy, the tool uses climate data to help design preventive actions. In state hospitals, the AI tool Caren assesses the risk of complications in newborns. These solutions are just the tip of an ecosystem that has positioned Goiás as a national reference in AI in healthcare. [Read more](#).

MORE HIGHLIGHTS

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[Experts call for more debate on public-private partnerships in health in Brazil](#)

[Anvisa modernizes import and export procedures for controlled products](#)

[Anvisa opens directed consultation to update Brazil's list of recognized radiopharmaceuticals](#)

[Health Committee approves proposal to include immunotherapy in the SUS for cancer treatment](#)

[Public Hearing at the Minas Gerais State Legislative Assembly discusses access to treatment for Duchenne Muscular Dystrophy and Elevidys medication](#)

[Requests at Minas Gerais State Legislative Assembly seek to improve diagnosis, treatment, and access to medication for Duchenne Muscular Dystrophy](#)

[Bill is sponsored to establish Week of Information and Dissemination of Clinical Trials in Rio Grande do Sul state](#)

[ALMG Committee approves requests for women's health care during menopause](#)

BRAZIL NEWS

[Brazil's Supreme Court to start Bolsonaro coup trial on September 2](#)

[Brazil lawmaker Eduardo Bolsonaro warns of more US sanctions, maybe tariffs](#)

[Brazil-US meeting canceled amid tariff dispute, says finance minister](#)

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[Brazil in talks with Canada to revive Mercosur trade deal](#)

[Brazil's Lula, China's Xi discuss BRICS, bilateral opportunities](#)

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[Brazil inflation likely stayed high in July, but some signs of deceleration](#)

[Brazil's Lula says proposal to regulate social media platforms is ready](#)