

# WEEKLY REPORT



09/27/2025

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## **BRAZIL'S SUPREME COURT TO REVIEW LAW ON CLINICAL TRIALS REGULATION**

The Brazilian Society of Bioethics (SBB) filed Direct Action of Unconstitutionality (ADI 7,875) before the Supreme Federal Court (STF), challenging the constitutionality of Law 14,874/2024, which created a new regulatory framework for clinical trials in Brazil. According to the petition, the law violates the constitutional right to health by restricting continued access to beneficial treatments after clinical studies. The SBB also argues that the legislation usurps Executive competencies by creating an entity under the Ministry of Health, imposes financial burdens on the Unified Health System (SUS) without proper budget allocation, and limits social participation in the oversight of research ethics. The law, sanctioned in May 2024 with partial presidential vetoes, established the National System of Ethics in Clinical Research. One of its most controversial provisions limits post-study access to experimental drugs to a five-year period, a measure considered unconstitutional by the SBB. The case has been assigned to Justice Cristiano Zanin, who will report on the action. [Read more.](#)

## **NEW ANVISA HEAD VOWS TO ACCELERATE DRUG APPROVAL PROCESS**

Leandro Safatle, the newly appointed director-president of Anvisa, has pledged to tackle the backlog of drug registrations and streamline regulatory review as one of his top priorities. During the IV Brazilian Health Innovation Summit, Safatle emphasized that resolving the agency's registration queues will be his first focus, followed by measures to strengthen innovation. According to him, Anvisa must act as a facilitator of technological development in the country. Long approval times have long been a major complaint from pharmaceutical companies. Delays in both new registrations and post-approval changes are seen as barriers to market entry and innovation in Brazil. Safatle takes office at a time when the agency faces the dual challenge of ensuring rigorous regulatory standards while responding more quickly to industry needs. His statements align with commitments already made by other Anvisa directors to accelerate drug registration without compromising safety and efficacy. [Read more.](#)

## **ANVISA DIRECTOR DANIELA MARRECO OUTLINES PRIORITIES ON BACKLOG REDUCTION AND INNOVATION**

Daniela Marreco, now serving as director at Anvisa, emphasized that her mandate will focus on reducing regulatory backlogs and positioning the agency as a driver of innovation in health technologies. A career official at Anvisa since 2006, with experience as executive secretary of CMED, Marreco highlighted that strategies such as regulatory reliance, regulatory sandbox, and the use of artificial intelligence will be key to improving analysis timelines and aligning Anvisa with innovation policies. She also pointed to the need to revise regulations for AI-based software and medical devices, incorporating international benchmarks to guide the agency's approach. On clinical trials, Marreco underscored that Anvisa actively participated in drafting Law 14.874/2024 and will work with relevant bodies to ensure deadlines are compatible with the agency's operational capacity. [Read more.](#)

## **GOVERNMENT TO OPEN NEW REGULATORY AND SURVEILLANCE POSITIONS AT ANVISA VIA PROVISIONAL MEASURE RECENTLY APPROVED**

Congress has converted Provisional Measure (MP) 1,301/2025 into law, enabling the creation of new federal positions within Anvisa by transforming currently vacant technical and health-related roles across ministries. The transformation will involve 70 vacant technical-

administrative roles within Anvisa and other vacant posts in the Ministries of Health, Social Security, and Labor — all without increasing overall government expenditure. In the first phase, 129 specialist roles in regulation and sanitary surveillance may be filled using candidates from the 2024 reserve register. The move is part of a coordinated effort by the Agency and the Ministry of Health to rebuild staffing capacity and accelerate regulated processes. [Read more.](#)

### **AGENCY CONSOLIDATION IN HTA STILL UNRESOLVED, EXPERTS SAY**

The proposal to establish a single agency for health technology assessment (HTA/ATS) lacks consensus, despite intense debate during the 9th ISPOR Brazil Congress. Proponents argue that centralizing HTA evaluations could streamline decision-making and reduce duplication between CMED, Conitec and other regulatory bodies. Critics, however, caution that the concept is still underdefined, highlighting concerns about governance, funding independence, and structural complexity. During the event, key topics included governance and transparency reforms, use of real-world data, artificial intelligence to speed assessments, and potential integration across the public and private sectors. Government representatives stated that discussion must evolve beyond academic debate toward political and regulatory alignment. [Read more.](#)

### **BRAZIL'S JUDICIARY TO ADOPT GENERATIVE AI TOOL FOR JUDGES STARTING DECEMBER**

The National Justice Council (CNJ) has announced that, as of December, magistrates will have access to a generative AI platform designed to support the review of health-related cases, providing technical opinions and references from prior judicial decisions. The initiative, called Project GenAI, was developed domestically by the Hospital das Clínicas at the University of São Paulo (InovaHC) in partnership with USP's Institute of Mathematics and with support from Amazon. The platform will be integrated into CNJ's systems to strengthen analysis in health litigation. According to the CNJ, the tool is expected to reduce judicial workload and improve consistency in rulings on health sector lawsuits. Experts, however, point out challenges around transparency, bias mitigation, and the need for strong oversight in applying AI within the judiciary. [Read more.](#)

### **HEALTH JUDICIALIZATION COST BRAZIL R\$ 9.6 BILLION BETWEEN 2020 AND 2024**

Data obtained via the Access to Information Law reveal that the federal government spent R\$ 9.6 billion to comply with judicial decisions in the health area over the 2020–2024 period, covering medications, surgeries, hospitalizations, and other services. Among the most demanded therapies, eculizumab led in judicial claims, with 2,871 acquisitions totaling about R\$ 1.77 billion. Alfa-galactosidase, used in Fabry disease, accounted for R\$ 408 million, while treatments for cystic fibrosis (elexacaftor + tezacaftor + ivacaftor) represented around R\$ 551 million across 1,246 requests. Specialists warn that this unpredictability in judicial expenses disturbs health system planning and may divert resources from collective programs, undermining broader public health strategies. [Read more.](#)

### **HEALTH COMMITTEE APPROVES SUBSTITUTE BILL ESTABLISHING GUIDELINES FOR COMPREHENSIVE CARE FOR WOMEN'S HEALTH DURING CLIMACTERIC AND MENOPAUSE IN SUS**

The Health Committee of the House of Representatives approved on Wednesday (24) the substitute report by Congresswoman Iza Arruda (MDB-PE) to Bill 5602/2019. The proposal establishes guidelines for comprehensive care for women in climacteric and menopause within the Unified Health System (SUS) and creates the National Awareness Day on the subject, to be marked on October 18. The new draft emphasizes principles of integrality, equity, multiprofessionality, and health education, while leaving implementation to SUS technical areas. It requires the creation and periodic updating of clinical protocols with the participation of medical societies and civil society. The text also provides for access to different therapeutic modalities — including hormonal and non-hormonal treatments, psychological care, and integrative practices — based on scientific evidence. Additional provisions include data

collection, epidemiological monitoring, permanent training of health professionals, and coordination with states and municipalities. The creation of the National Awareness Day on Climacteric and Menopause, on October 18, was maintained as a tool for social and scientific mobilization, supported by educational campaigns and training activities. [Read more.](#)

### **HEALTH COMMITTEE APPROVES REQUEST TO EXPAND GUEST LIST FOR HEARING ON MENOPAUSE POLICY**

Health Committee of the House of Representatives approved on Wednesday (24) Request No. 248/2025, authored by Congressman Romero Rodrigues (PODE-PB), to include new participants in the public hearing on the "National Policy for Comprehensive Health and Quality of Life of Women in Menopause: Challenges and Paths for Implementation." The debate, also proposed by the congressman, will take place on October 16. The approved request expands the list of invited speakers to include: - Representatives of the National Policy for Comprehensive Women's Health (PNAISM), the Ministry of Health, and the Unified Health System (SUS); - Adriana Ferreira, president of Instituto Menopausa Feliz; - Fabiana Gomes, city councilor of Campina Grande (PB); - Dr. Raphael Câmara, Federal Council of Medicine (RJ); - Dr. André Vinícius, gynecologist, lecturer and author; - Dr. Juliana Risso, gynecologist, specialist in nutrology and female longevity, head of the climacteric and intimate laser clinic at Hupe/UERJ; - Dr. André Malavasi Longo de Oliveira, gynecologist and obstetrician, University of São Paulo; - Dr. Lizandra Paravidine Sasaki, president of the Brasiliense Society of Gynecology. [Read more.](#)

### **BRAZIL HIGHLIGHTS INNOVATION IN HPV DIAGNOSIS AND REAFFIRMS PRIORITY IN CERVICAL CANCER ELIMINATION**

At the "Advancing Women's Health" meeting at the United Nations, Brazil's Deputy Health Minister, Mariângela Simão, highlighted recent advances in early HPV detection and reiterated Brazil's commitment to eliminating cervical cancer. She announced that Brazil is replacing cytology testing with a molecular DNA-HPV test, capable of detecting 14 genotypes, as part of a new screening protocol. Produced domestically, the test is expected to broaden screening intervals to five years and be available across all states by the end of 2025. Simão also emphasized the need for global cooperation to guarantee sustainable funding, technology transfer, and equitable access to vaccines and diagnostic innovations, aligning Brazil's strategy with the WHO's goals for cervical cancer elimination. [Read more.](#)

### **BRAZIL LAUNCHES PUBLIC CONSULTATION FOR MEN'S HEALTH PRIMARY CARE GUIDELINES**

The Ministry of Health has opened a public consultation for Primary Care Guideline – Men's Health, with contributions accepted until October 16, 2025. The upcoming guideline will be the first CAB focused specifically on men's health in the Brazilian public health system. It builds upon the National Policy for Integral Men's Health (PNAISH) and aims to deliver recommendations for men aged 20 to 59 across five strategic axes: access and welcoming; sexual and reproductive health; paternity and care; prevalent diseases; and violence and accident prevention. Officials emphasized the importance of social participation, inviting health professionals, managers, researchers, and the public to contribute so that the content properly reflects the needs and specificities of men in diverse contexts. Once finalized, the CAB will support primary health care professionals in delivering integral care that considers masculinities as social determinants of health and allows for adaptations to local realities. The consultation was announced during the National Forum of State Men's Health Coordinators, held in Brasília, where the Agenda Nacional de Saúde do Homem 2025/2026 was also presented. [Read more.](#)

### **MINISTRY OF HEALTH ANNOUNCES NEW BREAST CANCER PROTOCOLS, RESTRUCTURING OF THE DEPARTMENT OF CANCER CARE, AND DEADLINE FOR PHARMACEUTICAL ASSISTANCE REGULATION IN ONCOLOGY**

The National Cancer Institute's Advisory Council (CONSINCA) held its 2nd Ordinary Meeting on Tuesday (23), marked by strategic announcements from Brazil's Ministry of Health for the

national oncology policy. Health Minister Alexandre Padilha confirmed that the regulation of the National Cancer Policy, focused on pharmaceutical assistance in oncology, will be finalized by October. The meeting also brought advances for early diagnosis and treatment of breast cancer, the leading cause of cancer deaths among women in Brazil. Another highlight was the restructuring of the Department of Cancer Care (DECAN), which will gain greater institutional strength and operational capacity within the Secretariat of Specialized Health Care (SAES). Measures include expanded population screening, incorporation of new medicines into SUS, and deployment of 27 mobile health units to provide consultations, exams, and treatments. The Ministry also confirmed investments in radiotherapy, with 121 new linear accelerators expected by 2026, along with the creation of the Brazil Supercenter for Cancer Diagnosis in partnership with A.C. Camargo. [Read more.](#)

### **BRAZIL'S COLORECTAL CANCER MORTALITY JUMPS 47% OVER TWO DECADES**

Colorectal cancer mortality in Brazil rose about 47 % from 2003 to 2023, with men experiencing a steeper increase than women. Health analysts point out that much of this rise is linked to lifestyle changes, aging population, and delays in early detection. Men's mortality climbed around 61 % in the period, while for women the increase was approximately 36 % — reflecting gender disparities in risk, awareness, and access to care. Experts warn that the upward trend signals gaps in screening programs, public health outreach, and the capacity of the health system to manage growing cancer burdens. Without effective interventions, the disease may place increasing pressure on oncology services, diagnostic infrastructure, and public health budgets. [Read more.](#)

### **BRAZIL FACES RISK OF RADIOPHARMACEUTICAL SHORTAGES**

Medical and regulatory stakeholders have raised concerns about a growing risk of radiopharmaceutical shortages in Brazil, following the end of the state monopoly on production and rising cost pressures. During a recent public hearing at the Chamber of Deputies' Health Committee, experts highlighted that since the repeal of the state monopoly on radiopharmaceutical manufacturing in 2022, supply has decreased while prices have surged. The kit Sestamibi, used in myocardial perfusion scans, nearly doubled in price — from R\$ 795 to R\$ 1,565 over this period. Regulatory and logistical challenges further compound the problem. Observers noted that Anvisa's approval criteria and restrictive rules have discouraged private sector competition and constrained production, particularly for regional markets. Meanwhile, production is concentrated in aging facilities at IPEN, and transport logistics pose serious hurdles, with airlines often refusing to carry radiopharmaceuticals due to liability concerns. If supply fails, diagnostic and therapeutic procedures in nuclear medicine (spanning oncology, cardiology, neurology, and thyroid disorders) could be severely impacted. [Read more.](#)

### **BRAZIL SENATE APPROVES PROVISIONAL MEASURE FOR "AGORA TEM ESPECIALISTAS" PROGRAM**

The National Congress approved Provisional Measure 1,301/2025, creating the Agora Tem Especialistas program, which aims to accelerate access to specialist consultations, diagnostics, and elective surgeries in partnerships with private providers under the SUS. The MP allows private hospitals and clinics (for- or non-profit) to voluntarily register with the program. In exchange, they may receive tax credits and other fiscal incentives for services provided to SUS users. In one key innovation, the MP enables debt swaps: private hospitals and health insurers could offset federal tax liabilities by offering services to SUS patients. The measure is valid until December 31, 2030. Though services may begin this year, tax deductions and credits become effective starting 2026. [Read more.](#)

### **BRAZIL SEEKS TO REDUCE ORGAN DONATION REFUSALS AND PRIORITIZE PEDIATRIC TRANSPLANTS**

The Ministry of Health launched a new National Policy for Donation and Transplants to reduce the country's high refusal rate for organ donation, currently around 45%, and to give priority

in transplant queues to children and adolescents. The plan includes awareness campaigns, financial incentives for hospital teams, and the creation of the PRODOT program to improve logistics and monitoring. The government will allocate R\$ 20 million annually to support the initiative. [Read more.](#)

## **HEALTH COMMITTEE RAPPORTEUR ENDORSES BILL REMOVING REQUIREMENT FOR ORIGIN-COUNTRY APPROVAL OF MEDICINES**

Congressman Júnior Mano (PSB-CE) presented a favorable report in the Health Committee on Bill 2142/2025, which amends Brazil's Pharmaceutical Surveillance Law to eliminate the requirement that imported medicines be registered in their country of origin before obtaining approval in Brazil. The proposal maintains as a prerequisite only certification in Good Manufacturing Practices (GMP), whether national or foreign. Authored by former senator Ana Amélia, the bill modifies Article 18 of Law No. 6,360/1976, conditioning drug registration on proof of GMP certification in line with Anvisa's regulations. It also repeals paragraphs 1 and 2 of the article, which currently require the Certificate of Pharmaceutical Product (CPP) from the country of origin. In his report, the congressman emphasized that the original rule, created in the 1970s to compensate for weak domestic oversight, has become outdated following the strengthening of Brazil's regulatory framework and the establishment of Anvisa in 1999. He argued that the requirement now acts as a regulatory barrier, delaying the entry of innovative medicines and preventing Brazil from being an early market for new products. [Read more.](#)

## **SEARCHES ON INTERNET FOR TYLENOL AND PARACETAMOL IN BRAZIL SURGE UP TO 270% IN ONE WEEK**

On Google, Brazil registered a surge in searches for Tylenol and paracetamol over the past week, with growth reaching as high as 270% compared to the prior period. The spike is likely tied to recent public discourse, including controversial statements linking paracetamol use in pregnancy to autism. Although no causal connection is supported by scientific evidence, the debate appears to have driven the sudden interest. Analysts caution that such search trends can reflect public concern or confusion, underscoring the importance of timely regulatory communication and health education to reassure the population. [Read more.](#)

### **MORE HIGHLIGHTS**

[Brazil updates on Elevidys® suspension and ongoing safety review](#)

[Ordinance published that changes the composition of Conitec committees](#)

[Cancer Subcommittee discusses the regulation of research and development of vaccines, medicines, and therapies against the disease](#)

[Congressman proposes creation of Special Committee to Combat Cancer, Stroke and Heart Disease](#)

[Bill creating the national symbol for rare diseases approved](#)

[Bill to create the National Rare Disease Monitoring System is approved by the Health Committee](#)

[In a public hearing on Chronic Thromboembolic Pulmonary Hypertension, experts advocate the creation of an awareness day and the development of a PCDT](#)

[Representative presents favorable opinion on the bill that creates the Support Program for Donation Campaigns for the Acquisition of High-Cost Medicines](#)

**BRAZIL NEWS**

[Trump's change of heart on Lula may be thanks to Brazilian beef tycoon](#)

[Lula tells UN that attacks on Brazil's institutions are unacceptable](#)

[US hits Brazilian judge's wife with sanctions as Trump showdown deepens](#)

[Bolsonaro's legal team asks for his release from house arrest](#)

[Brazil lawmaker Eduardo Bolsonaro charged with coercion](#)

[Brazilians protest efforts to shield Bolsonaro and lawmakers from courts](#)

[Brazil's Lula, Ukraine's Zelenskiy discuss Russia conflict on UN sidelines](#)

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[Abra pulls plug on Gol-Azul deal, ending talks on major Brazil airline merger](#)