

WEEKLY REPORT



10/18/2025

DELAY IN ANVISA'S REVIEW OF FEZOLINETANT SPARKS DEBATE ON BRAZIL'S NATIONAL MENOPAUSE POLICY

The House Health Committee held a public hearing on Thursday (16) to discuss Brazil's National Policy for Comprehensive Care for Women in Menopause, amid growing criticism over delays by Anvisa in reviewing Fezolinetant — a non-hormonal drug already approved in other countries for the treatment of menopausal symptoms. Representative Romero Rodrigues (Pode-PB), who proposed the debate, emphasized that menopause remains an overlooked public health issue in the Unified Health System (SUS). He noted that millions of Brazilian women lack adequate care, as most cannot afford private treatment. Rodrigues presented two related initiatives: Bill 2812/2025, which integrates menstrual health into the SUS, and a motion urging the Ministry of Health to prioritize and fund menopause-focused programs. Participants stressed the urgent need for a structured national policy. Adriana Ferreira, president of the Instituto Menopausa Feliz, said 45 million Brazilian women are in the climacteric or menopausal phase and called the condition “a matter of public health and social justice.” She urged for a permanent, interministerial policy supported by budgetary targets, professional training, and equitable access to hormonal and non-hormonal therapies, citing international models from the UK, Spain, Australia, and Canada. Gynecologists André Malavasi, André Vinícius Florentino, and Juliana Risso (UERJ) described severe care gaps in the SUS, outdated therapies, and lack of training among physicians. They highlighted the need for modern treatments — including bioidentical hormones and non-hormonal options like Fezolinetant — as well as comprehensive support from multidisciplinary teams. The hearing also included representatives from the Federal Council of Medicine (CFM) and the Ministry of Health. CFM delegate Dr. Raphael Câmara supported the creation of a national menopause policy, recommending the establishment of a dedicated coordination unit within the Ministry. The ministry's Women's Health coordinator, Mariana Seabra Souza Pereira, reaffirmed the government's commitment, noting ongoing training programs, updated clinical manuals, and plans to improve access to specialists and therapies available through the SUS. The session concluded with consensus on the need to treat menopause as a long-term public health priority, ensuring access, equity, and dignity for Brazilian women. [Read more.](#)

BRAZILIAN CONGRESS CAN DEBATE CREATION OF NATIONAL DAY FOR CLIMACTERIC AND MENOPAUSE AWARENESS

Representative Ana Paula Lima (PT-SC) has submitted a request to the Chamber of Deputies' Health Committee for a public hearing to discuss the creation of the National Day for Climacteric and Menopause Awareness. The proposal, outlined in Request No. 277/2025, is scheduled for a vote during the committee's deliberative session on Wednesday (15). The initiative supports the discussion of Bill 875/2025, also authored by Lima, which seeks to institutionalize the commemorative date to promote awareness and improve healthcare for women during the climacteric phase. According to the representative, the Unified Health System (SUS) still lacks comprehensive clinical protocols and adequate access to both hormonal and non-hormonal therapies. This gap, she noted, affects women's quality of life, productivity, and overall well-being, with indirect economic consequences. [Read more.](#)

BRAZIL CREATES PERMANENT COMMITTEE TO ADDRESS HEALTH JUDICIALIZATION

The Ministry of Health establishes the Permanent Committee for the Rationalization of Judicialization (CPRJ) through Ordinance GM/MS No. 8,420, published in the Official Gazette on October 17. The new body, with deliberative authority, aims to advise the Health Minister on optimizing the use of public resources, improving compliance with court decisions, and promoting the de-judicialization of the public health system. The CPRJ will prepare annual work plans, monitor compliance with judicial rulings, and coordinate institutional dialogue to reduce litigation in the Unified Health System (SUS). The committee brings together representatives from 15 internal units, including the Executive Secretariat (which will chair the body), the Department of Health Judicialization Management, and the Secretariats of Specialized Care, Science and Technology, and Digital Health. The group will meet monthly and may approve its own resolutions, to be published in the Official Gazette. By fostering inter-agency coordination, the initiative seeks to strengthen legal and administrative governance and mitigate the financial impact of court-ordered treatments on the SUS. [Read more.](#)

HOUSE HEALTH COMMITTEE PASSES BILL CREATING MANAGED ACCESS AGREEMENTS IN THE SUS

The Health Committee of Brazil's House of Representatives passed, on Wednesday (15), the substitute text presented by Representative Rafael Simões (UNIÃO-MG) to Bill 667/2021, establishing Managed Access Agreements (Acordos de Acesso Gerenciado – AAGs) as instruments for the acquisition and incorporation of health technologies in the Unified Health System (SUS). Sponsored by Representative Eduardo da Fonte (PP-PE), the original proposal introduced the concept of Risk-Sharing Agreements (Acordos de Compartilhamento de Risco – ACRs), allowing the Ministry of Health to partner with pharmaceutical companies to incorporate innovative medicines and treatments even amid uncertainties about cost-effectiveness and budget impact. The substitute text maintains the bill's main purpose but updates its framework to align with international best practices in health technology management. The AAG model authorizes the Executive Branch to sign contracts with companies holding Anvisa registrations, linking payment to demonstrated clinical and economic outcomes. Among the main adjustments, the rapporteur removed a clause that tied public procurement prices to Conitec's evaluations to avoid overlap with the Drug Market Regulation Chamber (CMED). He also clarified that private health plan operators may adopt similar mechanisms under private-law agreements. [Read more.](#)

BRAZIL CREATES WORKING GROUP TO IMPLEMENT NATIONAL SYSTEM OF ETHICS IN HUMAN RESEARCH

The Ministry of Health has established a temporary working group to support the implementation of the National System of Ethics in Human Research (SINEP) and the National Instance of Ethics in Research (INAEP). The measure, formalized through Ordinance SECTICS/MS No. 85 of October 14, 2025, was published in the Official Gazette on Wednesday (15). The initiative follows Decree No. 12,651 of October 7, 2025, which regulates Law No. 14,874 of May 28, 2024 — the legal framework that restructured Brazil's human research ethics system. The group will guide the transition from the National Research Ethics Commission (CONEP) to the newly created INAEP, review existing resolutions, and propose complementary rules to operationalize the new system. The working group will include representatives from the Secretariat for Science, Technology and Innovation and the Health Economic-Industrial Complex (SECTICS), the National Health Council (CNS), the CONEP Executive Secretariat, and the Department of Information and Informatics of the SUS (SEIDIGI/MS). Experts may also be invited to participate in advisory roles. The group's initial mandate will last three months, extendable for another three, and it must deliver a final report with recommendations and draft regulatory acts for the system's full implementation. Participation will be considered a public service activity without remuneration. [Read more.](#)

BRAZILIAN SENATOR CHALLENGES NEW REGULATION ON HUMAN RESEARCH ETHICS

Senator Jorge Seif (PL-SC) has presented a proposal to suspend the federal government's new regulation on human research ethics, arguing that it exceeds the executive's authority and weakens participant protections. The measure, introduced through Legislative Decree No. 830/2025, seeks to overturn the recently enacted decree that governs the National System of Ethics in Research with Human Subjects. According to Seif, the regulation alters essential provisions established by Law No. 14,874/2024, approved after nearly a decade of congressional debate to define clear ethical and legal standards for clinical research in Brazil. He claims that the government's decree undermines those safeguards by excluding funding agencies from liability, extending deadlines for ethical review, and allowing simplified evaluations for low-risk studies in the human and social sciences. The senator emphasized that such changes contradict the intent of Congress to maintain strict ethical oversight of research involving human participants. He warned that the new rules may reduce the accountability of sponsors and weaken guarantees of safety, dignity, and informed consent for study volunteers. The proposed decree (PDL 830/2025) specifically targets Decree No. 12,651, of October 7, 2025, which regulates Law No. 14,874, of May 28, 2024. Seif argues that by modifying key definitions and deadlines, the executive branch has overstepped its constitutional authority. [Read more.](#)

BRAZIL'S CLINICAL RESEARCH LAW EXPECTED TO BOOST INVESTMENT IN NATIONAL PHARMA SECTOR

The Grupo FarmaBrasil, which brings together twelve major national pharmaceutical companies, expects a significant increase in investment following the implementation of Brazil's new Clinical Research Law. The legislation, recently regulated by the federal government, establishes a clearer framework for conducting clinical studies and is viewed by the industry as a turning point for innovation in the country. According to FarmaBrasil, the law will attract both domestic and international investment, potentially doubling the number of clinical trials conducted in Brazil and positioning the country among the world's top ten in research volume. The measure modernizes ethical and procedural standards, strengthens partnerships between academia and the private sector, and leverages Brazil's strong research base and genetic diversity to attract new studies. Industry representatives emphasize that the law will generate long-term economic and scientific benefits by accelerating access to innovative therapies, reducing costs and delays, and integrating Brazil more effectively into the global research ecosystem. [Read more.](#)

BRAZILIAN INDUSTRY LAUNCHES "BUSINESS MOVEMENT FOR HEALTH" TO STRENGTHEN ROLE IN NATIONAL HEALTH POLICY

The National Confederation of Industry (CNI) and the Social Service of Industry (SESI) have launched the Business Movement for Health (Movimento Empresarial pela Saúde – MES), an initiative designed to mobilize the industrial sector in shaping Brazil's health policy agenda. The program seeks to foster collaboration between companies, the government, and health institutions to address systemic challenges in both public and private healthcare. The MES will prioritize three central themes for 2026–2027: data intelligence and interoperability, mental health, and cost control in private health plans. According to organizers, around 70% of Brazil's 53 million private health plan beneficiaries are covered through employer-sponsored collective schemes, positioning the industrial sector as a key player in discussions on sustainability, access, and innovation in healthcare. The initiative is expected to enhance dialogue between industry and policymakers, promote public-private partnerships, and stimulate investment in health technologies, prevention programs, and workforce well-being. [Read more.](#)

BRAZIL LAUNCHES R\$20 BILLION INVESTMENT FUND TO EXPAND HEALTH INFRASTRUCTURE

The federal government has announced the creation of the Social Infrastructure Investment Fund (Fundo de Investimento em Infraestrutura Social – FIIS), with an initial allocation of R\$20 billion to strengthen Brazil's healthcare and education systems. The fund aims to finance the construction, renovation, and modernization of health units, as well as the purchase of medical

equipment and vehicles, prioritizing underserved regions. The initiative will be operated by the National Bank for Economic and Social Development (Banco Nacional de Desenvolvimento Econômico e Social – BNDES), with R\$10 billion disbursed in 2025 and another R\$10 billion in 2026. The credit line will offer preferential financing terms to municipalities participating in programs such as Agora Tem Especialistas, which seeks to expand access to medical specialists in the public system. According to the government, the measure is part of a broader effort to stimulate investment, improve infrastructure, and enhance the quality of public services across Brazil's health network. [Read more.](#)

BRAZIL SEES 68 LAWSUITS BY FOREIGN LABS SEEKING PATENT EXTENSIONS

Foreign pharmaceutical companies operating in Brazil have filed 68 lawsuits to extend the validity of medicine patents, representing an increase of around 25% over the past two years, according to a survey by Grupo FarmaBrasil. The lawsuits seek to bypass a 2021 ruling by the Supreme Federal Court (STF), which prohibited the extension of patent terms for pharmaceuticals in cases where the review by the National Institute of Industrial Property (INPI) exceeded the standard 20-year period. The decision was a milestone in limiting prolonged monopolies in the Brazilian pharmaceutical market. Of the actions filed so far, courts have already issued 36 rulings denying the requests for patent extensions. The disputes are mainly promoted by multinational laboratories seeking to preserve exclusive rights over high-value medicines, delaying the entry of cheaper generic versions into the market. The judicial trend reinforces tensions between innovation incentives and the need to ensure timely access to medicines, especially in the context of the Unified Health System (SUS), where delays in generic competition can increase government spending and reduce access to treatment. [Read more.](#)

BRAZILIAN REGULATOR PROPOSES HEALTH-PLANS MODEL BASED ON PREVENTIVE CARE PATHWAYS

The director-president of the National Supplementary Health Agency (Agência Nacional de Saúde Suplementar – ANS), Wadih Damous, announced plans to introduce a new model of health plans centred on preventive care pathways ("linhas de cuidado preventiva"). Speaking at the National Congress of Private Hospitals on October 15 2025, Damous said the proposal is a priority and aims to engage private health-plan operators in offering structured care models that emphasise early intervention, chronic-disease management and cost containment. Under the concept, health-plan providers would shift from the traditional reactive model toward coordinated care that encourages prevention, reduces hospitalizations and lowers long-term costs. Damous noted that the ANS would work with specialists and stakeholders to design the regulatory framework and emphasized that the model could result in more affordable premiums if successfully scaled. [Read more.](#)

BRAZIL TO FUND CANCER DRUGS UNDER THREE FINANCING MODALITIES

The federal government will finance oncology medicines through three distinct mechanisms, according to a new ordinance from the Ministry of Health. The measure establishes a clearer framework for the procurement and distribution of cancer drugs within the Unified Health System (SUS), aiming to improve access, coordination, and financial predictability. The three modalities include: direct acquisition by the Ministry of Health, shared procurement between federal, state, and municipal levels, and targeted funding through partnerships with authorized institutions. The model seeks to streamline the supply of high-cost oncology treatments, reduce regional disparities, and ensure continuity of care for cancer patients. According to the Ministry, the reform also aligns with the National Policy for Pharmaceutical Assistance, creating more transparent governance for cancer drug financing and reducing reliance on judicial decisions for patient access. [Read more.](#)

BRAZILIAN HEALTH INSURERS REPORT 63% RISE IN CANCER DRUG SPENDING

Spending by private health insurers on oncology medicines increased by 63% between 2021 and 2024, according to data from the National Federation of Supplementary Health

(FenaSaúde). The surge is driven mainly by the rapid incorporation of new oral cancer treatments into mandatory health plan coverage. In 2024, expenditures on cancer drugs reached approximately R\$4.2 billion, accounting for 70% of all new technologies added to the supplementary health coverage list since 2022. Despite the sharp growth, oncology treatments still represent less than 20% of total medicine spending by private plans, estimated at R\$22.6 billion last year. The figures highlight the growing financial pressure on the private health sector amid expanding access to high-cost therapies. Insurers are calling for new reimbursement and risk-sharing models to balance access to innovation with long-term system sustainability. [Read more.](#)

CANCER-SPECIALIZED HOSPITALS LOSE INVESTMENT APPEAL IN BRAZIL

Hospitals dedicated exclusively to oncology care are losing attractiveness for investors in Brazil, according to Valor Econômico. Rising operating costs, shifts in treatment models, and changes in patient profiles have led to a preference for integrated hospital networks and outpatient cancer centers instead of large, standalone oncology units. Industry experts note that the expansion of advanced outpatient therapies and home-based treatments has reduced the demand for inpatient cancer facilities. At the same time, the high cost of specialized infrastructure and uncertain reimbursement conditions have discouraged new projects in the sector. Major hospital groups are now prioritizing diversified networks combining oncology services with other specialties, a trend that could reshape Brazil's healthcare landscape. The move also reflects a global shift toward more decentralized, patient-centered cancer care models, with growing emphasis on early diagnosis and minimally invasive therapies. [Read more.](#)

BRAZIL RECORDS 284% RISE IN CANCER CASES AMONG ADULTS UP TO AGE 50 IN THE PUBLIC HEALTH SYSTEM

The number of cancer cases diagnosed in Brazilians aged up to 50 years increased by 284% between 2013 and 2024, according to data from the Unified Health System (SUS). The total rose from around 45,500 to 174,900 cases, reflecting a growing incidence of early-onset cancers across the country. The sharpest increases were seen in breast cancer, up 45% among women under 50, and colorectal cancer, which rose 160% in the same age group. Specialists attribute the trend to lifestyle and environmental factors such as poor diet, obesity, sedentary behavior, and limited access to early screening and diagnosis. The findings highlight an urgent need to strengthen prevention strategies, expand cancer screening programs for younger populations, and address modifiable risk factors to contain the growing public health burden. [Read more.](#)

BRAZIL'S CANCER CASE RISE REFLECTS DATA-CAPTURE IMPROVEMENTS, NOT NECESSARILY REAL INCREASE, SAYS INCA

The Instituto Nacional de Câncer (INCA) has attributed the recent uptick in recorded cancer cases in Brazil to enhanced data-capture and registry coverage rather than a true rise in disease incidence. INCA officials clarified that the expansion of population-based cancer registries and improved reporting mechanisms—particularly in historically under-covered regions—have contributed to higher case numbers being logged. They stressed that while awareness of increasing burden is essential, the figures do not automatically translate into worsened epidemiological trends. [Read more.](#)

BRAZIL SURPASSES PRE-PANDEMIC LEVELS OF PROSTATE CANCER SURGERIES UNDER THE SUS

The Unified Health System (SUS) performed 37,917 prostate cancer surgeries in 2024, surpassing pre-pandemic levels and marking a 30% increase compared to 2019, according to data from the Institute of Urology, Oncology and Robotic Surgery (IUCR). The figures indicate a consistent recovery of surgical activity following the Covid-19 disruption. After a sharp decline to 20,186 procedures in 2020, the number of surgeries gradually increased: 21,762 in 2021, 30,189 in 2022, and 34,176 in 2023. The 2024 total reflects both the reduction of waiting lists

and the expansion of urological care capacity in the public network. The study also highlights a shift in regional distribution. While the Southeast region accounted for 52.6% of procedures in 2019, its share dropped to 46.5% in 2024. Meanwhile, the Northeast and North regions increased participation to 26.6% and 6.3%, respectively, reflecting broader national access to specialized oncology surgeries. [Read more.](#)

URINARY INCONTINENCE AFTER PROSTATE CANCER TREATMENT REMAINS UNTREATED IN BRAZIL'S PUBLIC SYSTEM

Urinary incontinence following prostate cancer treatment continues to affect thousands of Brazilian men without access to adequate rehabilitation or surgical solutions in the Unified Health System (SUS). Specialists note that although most patients recover continence within a year, between 5% and 10% experience persistent, severe symptoms. Experts highlight that advanced therapies — such as artificial urinary sphincters and specialized implants — are not covered by the SUS, leaving patients dependent on private care. The absence of structured rehabilitation programs and access to innovative treatments significantly impacts quality of life, mental health, and social reintegration for survivors. The situation underscores the need for public policies focused on post-cancer rehabilitation, expansion of urological care, and greater equity in access to recovery treatments across Brazil. [Read more.](#)

BRAZILIAN DOCTORS FAIL TO COMPLY WITH NEW CFM RULE ON CONFLICT-OF-INTEREST DISCLOSURE

Seven months after the Federal Council of Medicine (CFM) established a rule requiring physicians to disclose relationships with the pharmaceutical and medical device industries, only 30 professionals have filed declarations nationwide, according to UOL. The measure, introduced through Resolution 2.386/2024, aims to bring more transparency to financial ties between doctors and private companies. The low compliance rate — equivalent to just 0.005% of Brazil's more than 600,000 registered physicians — exposes the challenges in implementing the regulation. The CFM has not yet published the submitted declarations nor launched a monitoring mechanism to ensure adherence. The rule covers sponsorships, research funding, consulting fees, and any form of payment or partnership involving doctors and healthcare companies. Experts say the lack of enforcement risks perpetuating opaque practices and weakens public trust in medical independence, especially in prescription and procurement decisions within the public health system. [Read more.](#)

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