

WEEKLY REPORT



10/04/2025

BRAZIL SENATE APPROVES NEW FRAMEWORK FOR TAX EXEMPTION ON MEDICINES

The Federal Senate approved the Complementary Bill (PLP) 108/2024, part of the tax reform regulation, incorporating an amendment that changes the rules for granting tax exemptions on medicines. According to rapporteur Senator Eduardo Braga (MDB-AM), proposals authored by Senators Dr. Hiran (PP-RR) and Mara Gabrilli (PSD-SP) aim to expand access to essential treatments by broadening the scope of exemptions for high-cost and continuous-use medicines. The new framework establishes that exemptions will apply by lines of care, rather than by specific drug names. With the approved text, the rates of IBS and CBS are reduced to zero on medicines registered by Anvisa, provided they are indicated, according to their sanitary registration, for: I – rare diseases; II – neglected diseases; III – oncology; IV – diabetes; V – HIV/AIDS and other sexually transmitted infections (STIs); VI – cardiovascular diseases; VII – the “Farmácia Popular do Brasil” program or equivalent. The bill now returns to the House of Representatives for further consideration of the Senate’s changes. [Read more.](#)

EXPERTS CALL FOR MORE AGILITY IN BRAZIL’S DRUG PRICING PROCESS

Specialists at the 4th Brazilian Health Innovation Summit call for a more agile and transparent process in the pricing of innovative medicines, arguing that delays in regulatory decisions postpone patients’ access to new therapies. According to Julia Paranhos, coordinator of the Innovation Economics Group at UFRJ, the slow definition of prices directly impacts the time it takes for drugs to reach the market. Daniela Marreco, director at Anvisa, also defended greater flexibility in pricing rules but stressed the need for constant monitoring of market dynamics to ensure sustainability. [Read more.](#)

CLINICAL TRIALS LAW REACHES STF AS REGULATION AWAITS

The Brazilian Clinical Trials Law, passed in 2024, has now been challenged before the Supreme Federal Court (STF) by the Brazilian Society of Bioethics (SBB), which requests annulment on constitutional grounds. The dispute centers on provisions that shift the obligation of post-study treatment to the SUS and modify the structure of ethical oversight. Under the new law, pharmaceutical sponsors were obliged to supply investigational treatments to study participants for up to five years after commercial availability or public system adoption. The SBB argues this imposes an undue financial burden on the health system. The law also creates a new National Ethics in Research Instance (Inaep), weakening the authority of Conep, the existing national ethics committee within the National Health Council. The Ministry of Health confirms that regulation of the law is in the final stages, currently under evaluation at the Brazilian government and is expected to be published imminently. Until a ruling is issued by the STF, the legal challenge is not expected to alter the regulation timeline. Backers of the law, including Interfarma and ABRACRO, contend it offers needed legal clarity and incentives to boost Brazil’s clinical trials environment. They project potential economic benefits including growth in research investment, job creation, and improved patient access to innovative therapies. [Read more.](#)

BRAZILIAN FORUM HIGHLIGHTS INNOVATION AS A PILLAR FOR HEALTH SOVEREIGNTY

The 16th National Forum on Technological Innovation in Health, organized by the Instituto Ação Responsável, brought together government officials, parliamentarians, industry leaders, and

researchers to discuss the challenges and opportunities for strengthening innovation in Brazil's health sector. The discussions centered on how technology can drive industrial development, access to care, and the sustainability of the Unified Health System (SUS). The Ministry of Health emphasized three strategic fronts: regulation, including the implementation of the new Clinical Trials Law and the modernization of the drug pricing policy; investment in strategic research areas such as genomics and cancer; and the use of public procurement to stimulate national production. Anvisa reaffirmed its commitment to innovation, citing efforts to modernize processes, support startups, and expand the use of artificial intelligence, while the Ministry of Development, Industry and Commerce (MDIC) highlighted the Nova Indústria Brasil (NIB) program and the "Mais Produção" plan, which will make R\$ 23 billion in credit available to the health sector. [Read more.](#)

DELAY IN SUS DRUG DELIVERY REACHES 11 YEARS, SAYS REPORT

Some medicines already incorporated into Brazil's public health system (SUS) take up to 11 years to reach patients, according to a report by O Estado de S. Paulo. Experts warn that such delays can represent "the difference between cure and death," particularly for those with cancer or rare diseases. The study, based on data from Interfarma and the Oncoguia Institute, highlights that the problem lies not in the approval process itself but in the implementation and distribution of treatments. While Conitec recommends the incorporation of new drugs, the actual delivery often faces regulatory bottlenecks, budget constraints, and logistical failures across states and municipalities. The report also points to weaknesses in supply chain planning and monitoring, resulting in long waits for patients even after government approval. The situation underscores the persistent gap between policy decisions and access to innovative therapies within the SUS. [Read more.](#)

CONITEC CONSIDERS NEW CRITERIA FOR RARE DISEASE TREATMENTS

The National Commission for the Incorporation of Technologies in the SUS (Conitec) is evaluating the creation of a budget impact threshold and a special assessment process for rare and ultra-rare diseases, aiming to improve transparency and sustainability in the adoption of high-cost therapies. The proposal was discussed during a workshop organized by the Brazilian Network for Health Technology Assessment (Rebrats) and Fundacor, which brought together experts to analyze international models for incorporating treatments for rare diseases. The discussion focused on how Brazil could adapt these experiences to its public health context. Among the ideas under review are: - Establishing a maximum cost threshold for new technologies incorporated into the SUS; - Developing specific criteria for evaluating rare disease medicines, considering limited clinical evidence and high treatment costs; and - Implementing mitigation strategies, such as gradual introduction, price negotiations, and access restrictions for specific patient groups. [Read more.](#)

BRAZIL'S NEW ANS PRESIDENT PLEDGES BALANCE AND CONSUMER RIGHTS IN HEALTH PLANS

Wadih Damous, the newly appointed head of Brazil's National Agency of Supplementary Health (ANS), emphasized his commitment to safeguarding consumer rights while maintaining financial viability for health plan operators. Drawing on his experience as former director of Senacon (National Consumer Secretariat), he said his approach will prioritize preventive action over reactive measures. He stressed that consumers — often the weaker party in health plan contracts — must receive timely and appropriate care. Damous stated that he intends to integrate the private health insurance sector more closely with the SUS, and support the "Agora Tem Especialistas" program by facilitating debt swaps: operators providing services to SUS users might exchange debt burdens for service provision. On updating the mandatory benefits list, he reaffirmed ANS's role in incorporations grounded in evidence, and noted that the process is structured to ensure timelines (180 days for most updates, shorter for oncology) and stakeholder participation. He acknowledged challenges posed by an aging population and rising costs, emphasizing that no consumer can be denied entry into an active health plan due to age or preexisting conditions — a protection rooted in the law of health plans. [Read more.](#)

BRAZIL DEBATES INNOVATION AND PATENT TERM EXTENSIONS AT ABIFINA SEMINAR

The Brazilian Association of Fine Chemical, Biotechnology and Specialties Industries (Abifina) held the 16th International Seminar on Patents, Innovation and Development (SIPID), gathering experts from government, industry, and academia to discuss innovation policies, legal certainty, and national production. Participants warned about the risks of judicial patent term extensions (Patent Term Adjustment, PTA), not provided under Brazilian law, and their potential impact on SUS costs. The government reaffirmed its commitment to reduce patent examination times to two years by 2026 through the use of artificial intelligence. [Read more.](#)

NOVO NORDISK CHANGES LEADERSHIP IN BRAZIL AMID PATENT DISPUTE

Danish pharmaceutical company Novo Nordisk announced a leadership change in its Brazilian operations amid an ongoing legal dispute over the liraglutide patent, the active ingredient in drugs such as Ozempic. Isabella Wanderley, who had led the company in Brazil since 2021, recently stepped down. According to Novo Nordisk, the move is part of a broader leadership transition process. Until a new head is appointed, operations in the country will be overseen by Allan Finkel, vice president for Latin America. The change comes at a sensitive time for the company in Brazil. The validity of the liraglutide patent is being challenged in court after rulings allowed competitors to market similar products. The shift also reflects growing market pressures, including competition from Eli Lilly, and concerns over the upcoming loss of exclusivity for key molecules by 2026. [Read more.](#)

EUROFARMA AND NOVO NORDISK FORGE PARTNERSHIP FOR DISTRIBUTION OF NEW INJECTABLE PENS

Brazilian pharmaceutical company Eurofarma and Danish multinational Novo Nordisk have established a strategic partnership to expand the distribution of semaglutide-based injectable products in Brazil. Under the agreement, Eurofarma will be responsible for the distribution and promotion of two new brands: Poviztra, indicated for the treatment of obesity and overweight with associated comorbidities, and Extensior, aimed at patients with type 2 diabetes. The collaboration seeks to broaden access to innovative therapies and strengthen supply across Brazil, reaching regions and healthcare providers not currently covered by Novo Nordisk. According to Allan Finkel, vice president for Latin America and Brazil, the initiative reflects the company's goal of expanding access to advanced treatments while maintaining high standards of quality and safety. Renata Campos, president of Eurofarma in Brazil, emphasized that the company's strong commercial presence and distribution capacity will help ensure that more patients benefit from these therapies, reinforcing Eurofarma's commitment to innovation and public health. [Read more.](#)

MEN AND WOMEN UNAWARE OF RISK FACTORS FOR BREAST AND PROSTATE CANCER, BRAZILIAN SURVEY SHOWS

A survey conducted by Ipsos-Ipec, commissioned by Pfizer, reveals that a large share of men and women do not recognize key risk factors for breast cancer and prostate cancer. For breast cancer, many women missed awareness of lifestyle-related risks: 64% did not identify alcohol consumption, 63% were unaware of excess weight, and 84% did not recognize nulliparity (not having children) as risk factors. About 63% ignored the protective role of breastfeeding. Regarding prostate cancer, the study found that 71% of men did not associate advanced age, 85% did not see ethnicity (especially Black race) as a factor, and 60% overlooked obesity. Family history, often perceived as dominant, is overemphasized: in opinions of 34% of respondents, genetic inheritance is the main driver, although age remains the most significant risk factor. [Read more.](#)

SUS TO OFFER ROBOT-ASSISTED PROSTATE CANCER SURGERY

The Ministry of Health has incorporated radical prostatectomy assisted by robotic surgery into the SUS for patients with clinically advanced prostate cancer. Under the regulation, health

agencies have up to 180 days to implement the procedure, which will be based on Conitec's final recommendation for inclusion of the technology. [Read more.](#)

BRAZIL ESTIMATES 73,600 NEW BREAST CANCER CASES IN 2025

The National Cancer Institute (Inca) releases new data estimating 73,610 new breast cancer cases in Brazil this year, as part of the October Pink awareness campaign. The findings are presented in the publication Control of Breast Cancer in Brazil: Data and Numbers 2025, which compiles statistics on incidence, mortality, risk factors, prevention, access to exams, and treatment to support health professionals and policymakers. According to Inca, breast cancer remains the leading cause of cancer deaths among women in Brazil, with over 20,000 deaths recorded in 2023. Between 2020 and 2023, mortality decreased among women aged 40 to 49. The Southeast region shows the highest incidence, while Santa Catarina leads among individual states. In mortality rates, the South, Southeast, and Northeast regions rank highest, with Roraima, Rio de Janeiro, and Rio Grande do Sul showing the greatest figures. [Read more.](#)

BRAZILIAN STUDY HIGHLIGHTS GAPS IN CARE FOR HUNTINGTON'S DISEASE PATIENTS

The Brazilian Huntington's Association (ABH), with support from Teva Brasil, launched a national survey titled Mapping Huntington's Disease in Brazil: Profile of People with HD, Caregivers, and At-Risk Family Members. The study provides an unprecedented overview of the social, economic, and health impacts of the disease in the country. According to the results, nearly 30% of patients rely exclusively on public or family support, while only 20% receive disability benefits and 26% have access to any social assistance. [Read more.](#)

MINISTRIES APPROVE NEW MEDICAL CURRICULUM GUIDELINES

The Ministries of Health and Education have officially approved new National Curriculum Guidelines (DCNs) for Medicine in Brazil, updating the framework for medical education to better align with the country's health priorities and the needs of the Unified Health System (SUS). The updated guidelines emphasize primary care, interprofessional training, and integration with SUS services, requiring that at least 30% of medical internship hours take place in public health facilities. They also introduce digital health tools and new assessment mechanisms, including a national exam for medical students every two years, which could become a prerequisite for medical residency programs. According to the ministries, the reform seeks to train physicians with a stronger focus on comprehensive care and health equity, strengthening collaboration between universities and the public system. The implementation of the new guidelines will be gradual, allowing institutions to adapt their curricula and teaching structures. [Read more.](#)

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[Legislative Assembly in Minas Gerais passes bills to expand public policies for people with rare diseases](#)

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