

WEEKLY REPORT



12/20/2025

BRAZIL'S NATIONAL CONGRESS FINALIZES TAX REFORM VOTE WITH DRUG EXEMPTIONS BY LINE OF CARE

Brazil's House of Representatives concluded on December 16 the vote on amendments to Complementary Bill (PLP) 108/2024, which regulates the consumption tax reform, restoring the Senate's decision to apply zero rates of the Goods and Services Tax (IBS) and the Contribution on Goods and Services (CBS) to medicines based on specific lines of care. With the approval of the remaining highlights, the bill now moves to presidential sanction. Under the final text, tax exemptions will apply to medicines used in the treatment of rare or neglected diseases, cancer, diabetes, HIV/AIDS and other sexually transmitted infections, cardiovascular diseases, as well as medicines included in the Farmácia Popular program. The law establishes that the IBS Management Committee and the Ministry of Finance, in consultation with the Ministry of Health, must publish and update the list of exempt medicines every 120 days, ensuring alignment with therapeutic priorities and public health policies. Lawmakers also approved the removal of the proposed 2% cap on the Selective Tax applied to sugary beverages, a change introduced by rapporteur Deputy Mauro Benevides (PDT-CE). The amendment passed by 242 votes to 221, leaving the Selective Tax rate to be defined through subsequent regulation. The Selective Tax will apply to goods and services considered harmful to health or the environment. Brazil's consumption tax reform establishes three new taxes: the Goods and Services Tax (IBS), administered by states and municipalities; the Contribution on Goods and Services (CBS); and the Selective Tax, both under federal jurisdiction. The first regulatory bill for the new tax framework was approved and sanctioned in 2024, and the current bill completes the legislative framework required for implementation. The bill now awaits presidential sanction, the final step before the new rules enter into force. [Read more.](#)

BRAZIL STJ BLOCKS EXTENSION OF OZEMPIC PATENT AMID INDUSTRY CONCERNS OVER LEGAL CERTAINTY

Brazil's Superior Court of Justice (STJ) unanimously rejected a request by Novo Nordisk to extend the patent term for semaglutide, the active ingredient in Ozempic and Rybelsus. The ruling reinforces the interpretation that pharmaceutical patents in Brazil are limited to 20 years from the filing date and cannot be extended to compensate for administrative delays at the National Institute of Industrial Property (INPI), consolidating a restrictive view on patent term adjustments. Industry representatives acknowledge that the decision clarifies jurisprudence but warn that it may deepen concerns over legal certainty and innovation incentives in Brazil. Associations representing research-based companies have repeatedly argued that prolonged patent examination timelines at INPI (often exceeding a decade) undermine predictability and discourage long-term investment in R&D-intensive products. According to the innovative pharmaceutical sector, the inability to offset such delays places Brazil at a competitive disadvantage compared to other jurisdictions that offer compensatory mechanisms. With the semaglutide patent set to expire in March 2026, the ruling accelerates expectations of market entry by generics and similar products, pending approval by Anvisa. While industry groups support competition after the lawful exclusivity period, they caution that abrupt shifts in patent protection without parallel reforms to examination timelines may disproportionately affect high-cost, biologically complex medicines. The debate is likely to intensify in Congress and within the Executive Branch around structural reforms to INPI and broader intellectual property policy. [Read more.](#)

BRAZIL NOVO NORDISK CRITICIZES STJ DECISION, CALLS FOR MODERNIZATION OF PATENT SYSTEM

Following the Superior Court of Justice's (STJ) unanimous denial of its request to extend the semaglutide patent term in Brazil, Danish pharmaceutical company Novo Nordisk issued a formal statement expressing strong concern over the decision and its implications for innovation and investment in the country. The ruling maintains the current patent expiry of March 2026 for the active ingredient in Ozempic and Rybelsus, aligning with the statutory 20-year protection period despite administrative delays at the National Institute of Industrial Property (INPI). In its communication, Novo Nordisk stated that it "regrets" the STJ's ruling and underscored the structural challenges posed by extended patent examination timelines, which it argued reduce effective exclusivity and deter research and development. The company highlighted the absence of legal mechanisms (such as a Patent Term Adjustment (PTA)) to compensate for protracted INPI review periods, framing this gap as a barrier to legal certainty and a deterrent to bringing new health technologies to Brazil. According to Novo Nordisk, unpredictability in patent protection affects the entire innovation ecosystem, from scientific research to patient access to advanced therapies. [Read more.](#)

PATENT RULING COULD BROADEN ACCESS TO MEDICINES, SAYS ABIFINA

The decision by Brazil's Superior Court of Justice (STJ) to reject extensions of patent terms has been welcomed by the Brazilian Association of Fine Chemicals, Biotechnology and Specialty Industries (ABIFINA), which says the ruling can help expand access to medicines nationwide. The association argues that the clarification of patent duration creates greater legal certainty and supports planning by both government and private sector players to increase the offer and competition of pharmaceutical products. According to ABIFINA's president, Andrey Freitas, the STJ's interpretation that patents end after their established period — without automatic extensions due to administrative delays (removes ambiguity that previously complicated strategic decisions for producers, regulators, and policymakers. He described the outcome as a "significant victory" that could lead to broader availability of quality medicines at more accessible prices by enabling earlier entry of generics and similar products into the market. [Read more.](#)

BRAZIL BACKLOG IN PATENT GRANTS ERODES EXCLUSIVITY AND WEAKENS INNOVATION INCENTIVES

Delays in patent examination at the National Institute of Industrial Property (INPI) are significantly shortening the effective exclusivity period for inventors in Brazil, reducing predictability for investors, and weakening incentives for research and development in sectors like biotechnology and pharmaceuticals. Under current law, patents are valid for 20 years from the filing date; however, extended examination periods mean that much of this time elapses before protection is even granted, shrinking the period during which the patent holder can commercially exploit the invention. Data from INPI show a growing gap between filings and grants, with nearly four times as many patent applications filed as concessions issued in the first months of 2025, highlighting a structural backlog in the system. Extended wait times, often exceeding a decade in technical sectors, are well above averages seen in the United States, European Union, and Japan, where applications typically conclude within three to five years. Industry advocates and innovation stakeholders argue that this backlog erodes legal certainty and diminishes Brazil's attractiveness for long-term, research-intensive projects. As a result, the National Congress is debating legislative proposals — including PL 2.210/2022 with Amendment 4 and PL 5.810/2025 — that would introduce mechanisms like Patent Term Adjustment (PTA) to compensate patent holders for delays attributable to the examination process. Proponents contend that, without such compensation, inventors cannot fully benefit from their legally granted rights, undermining broader innovation ecosystems. [Read more.](#)

BRAZIL STUDY HIGHLIGHTS ANTICOMPETITIVE PRACTICES BY PHARMACEUTICAL INDUSTRY

A newly released study compiled in the book *Anticompetitive Conduct in the Pharmaceutical Sector*, published by the Brazilian Center for Strategic Studies, documents 129 cases of anticompetitive conduct by pharmaceutical companies worldwide. The research raises concerns over strategies that restrict competition, inflate prices and limit access to essential medicines, including unjustified price increases, abuse of patent rights, coordinated delays to generic entry and cartel-like behavior. The study cites international and domestic examples. In the United Kingdom, regulatory maneuvers reportedly led to price increases of up to 2,600% for an epilepsy medicine. In South Africa, high prices are described as having prevented access to a breast cancer therapy for thousands of patients. In Brazil, the book references an antitrust investigation involving scopolamine, in which the Administrative Council for Economic Defense (CADE) identified indications of coordinated production restrictions and pricing practices over extended periods. Industry associations responded by contesting the study's conclusions. Interfarma, which represents research-based pharmaceutical companies, stated that the sector operates under robust ethical and regulatory standards and emphasized the need to contextualize international cases within Brazil's current legal framework. FarmaBrasil highlighted the role of lengthy patent examination timelines at the National Institute of Industrial Property (INPI) in generating legal uncertainty and noted multiple judicial actions seeking patent extensions beyond statutory terms. [Read more.](#)

BRAZIL SENATE LAUNCHES PARLIAMENTARY FRONT FOR PHARMACEUTICAL INDUSTRY

The Federal Senate has formally installed the Parliamentary Front of the Pharmaceutical Industry, a bicameral group aiming to strengthen dialogue between lawmakers, the health sector and industry stakeholders on public policy, regulation, and competitiveness. The launch ceremony took place on December 16, 2025, with senators and industry representatives highlighting the role of the pharmaceutical sector in innovation, economic development, and national health security. The group's agenda includes advancing legislative and regulatory initiatives to modernize intellectual property frameworks, reduce barriers to clinical research and accelerate access to advanced therapies. Legislators stressed the importance of evidence-based policy and stable legal conditions as essential to attract investment and support domestic production of high-complexity medicines and biotechnological products. Senators participating in the front also underscored priorities such as improving regulatory efficiency in partnership with Anvisa, addressing backlog in patent examination at the National Institute of Industrial Property (INPI), and fostering conditions for integration into global pharmaceutical innovation chains. The initiative is expected to facilitate structured engagement between Congress, industry associations, and federal agencies, including the Ministry of Health, in shaping the sector's strategic direction. [Read more.](#)

ANVISA LAUNCHES PUBLIC CONSULTATION TO REVIEW CLINICAL TRIALS REGULATIONS

Brazil's health regulator ANVISA has launched a public consultation to review and update its regulatory framework for clinical trials, following the enactment of Law No. 14.874/2024, which modernizes rules governing research involving humans. The initiative was approved during the 21st meeting of Anvisa's Collegiate Board on December 17 and seeks to align existing norms with the new legal framework while preserving regulatory rigor and participant safety. The consultation focuses on proposed changes to RDC No. 945/2024, including adjustments to documentation requirements such as the Investigational Product Dossier (DPI) and the Clinical Development Dossier (DDCM). According to Anvisa, some information currently required from sponsors may no longer be necessary under the updated law, and the review aims to reduce redundancies, streamline submissions and improve regulatory efficiency. The agency expects the revised framework to strengthen Brazil's attractiveness for clinical trials and support innovation in health research. [Read more.](#)

BRAZIL ANVISA TECHNICAL STAFF WARN PRIORITIZING OZEMPIC RIVALS COULD SLOW PRIORITY MEDICINES

Technical staff within Anvisa have expressed concerns that the agency's plan to accelerate the review of marketing authorizations for competitors to Ozempic and similar GLP-1 products could delay the approval of other therapies considered high priority for public health. According to internal notes shared with stakeholders, analysts warn that directing limited evaluation capacity toward weight-management and diabetes drugs may divert resources from applications for medicines targeting serious or rare conditions. The critique comes amid ANVISA's adoption of a priority review mechanism for GLP-1 receptor agonists — including semaglutide and liraglutide-based products — which was introduced as part of a broader tactical plan to reduce regulatory backlogs and address public health concerns such as demand growth and illicit trade. Technical teams argue that, given the agency's finite workforce and high volume of pending applications, prioritizing one class of compounds could inadvertently postpone evaluation of submissions for treatments of cancer, neurological disorders, rare diseases, and other urgent therapeutic areas. [Read more.](#)

ANVISA INNOVATION COMMITTEE SETS STRATEGIC PRIORITIES

The National Health Surveillance Agency (Anvisa) has launched its Regulatory Monitoring Committee for Health Innovation, holding its inaugural meeting and defining core priorities for monitoring and supporting innovative health technologies in Brazil. The committee was formalized by Ordinance No. 1,385/2025 on November 10 and held its first session on December 19, marking a new step in the agency's efforts to align regulatory processes with scientific and technological developments. The committee's initial agenda includes four strategic technology areas: polilaminin (research targeting spinal cord injury treatment), a vaccine against chikungunya, endoprotheses, and the Wolbachia method for blocking *Aedes aegypti* transmission. Its mandate is to monitor and support regulatory evaluation, act as an internal articulation body between Anvisa directorates and technical units, propose regulatory adjustments where needed, and foster partnerships with external research institutions and international regulators. [Read more.](#)

BRAZIL ANVISA PRESIDENT ADVOCATES AGENCY ROLE IN PROMOTING NATIONAL HEALTH INNOVATION

The president of Brazil's National Health Surveillance Agency, Leandro Safatle, has articulated a strategic vision for Anvisa that emphasizes the agency's role not only as a regulator but also as a catalyst for national innovation in health. Safatle stated that regulatory processes should be aligned to support research and development of Brazilian-made medicines and technologies, highlighting the need for regulatory frameworks that facilitate local innovation and competitiveness. According to statements reproduced in media coverage, ANVISA is expected to pursue a balance between safeguarding public health and fostering an environment conducive to innovation, including engagement with research institutions, industry stakeholders, and international partners. Safatle's comments reflect ongoing efforts to modernize regulatory culture, reduce unnecessary barriers to product development, and strengthen Brazil's position in the global health technology landscape. [Read more.](#)

BRAZIL CMED SET TO PUBLISH REVISED DRUG PRICING POLICY AND SETS OUT REGULATORY AGENDA FOR 2026

Brazil's Chamber for Drug Market Regulation (CMED) is expected to publish an updated drug pricing policy by the end of 2025, concluding a long-running review of the framework in force since 2004. The reform aims to modernize price-setting criteria, introduce clearer rules for biosimilars and incremental innovation, and adjust mechanisms used to establish ceiling prices in the Brazilian market. According to CMED's Executive Secretariat, the revised policy will differentiate biosimilars from generics, applying a discount rate lower than the standard 35% required for generics, in an effort to better reflect development costs and market dynamics. Incremental innovation products are expected to be classified into subcategories, allowing more calibrated pricing based on therapeutic contribution and competition, responding to long-standing demands from industry and other stakeholders. In parallel, CMED sets out an ambitious regulatory agenda for 2026. Planned initiatives include new rules for pricing

medicines supplied through court orders, extraordinary price review mechanisms outside the annual adjustment cycle, expanded market monitoring requirements, revisions to price adequacy coefficients, and the development of specific criteria for advanced therapies, an area still insufficiently covered by current regulation. [Read more.](#)

BRAZIL CONITEC UPDATES NORMATIVE FRAMEWORK TO ENHANCE TECHNOLOGY ASSESSMENT

The National Committee for Health Technology Incorporation (Conitec) has published a comprehensive Regulatory Innovation Guide detailing recent regulatory changes introduced by Decree No. 12,716/2025 and GM/MS Ordinance No. 8,817/2025, which reformulate the decision-making process for health technology assessment and incorporation into Brazil's Unified Health System (SUS). According to the official document, the updates aim to strengthen transparency, stakeholder participation, and technical rigor across Conitec's procedures, helping interested parties better understand how clinical evidence, cost-effectiveness, and budgetary impact are weighed during assessments. The guide is intended for health system managers, healthcare professionals, researchers, Health Technology Assessment Units (HTA Units), manufacturers, and civil society organizations, with the goal of fostering more informed and qualified participation in Conitec's evaluation and incorporation processes. [Read more.](#)

CONITEC INCORPORATES NEW MEDICINES FOR LEUKEMIA AND CHRONIC HEPATITIS C INTO SUS

The National Commission for the Incorporation of Technologies in the Unified Health System (Conitec) has recommended the incorporation of new medicines into Brazil's Unified Health System (SUS) following deliberations held in December 2025. Among the key decisions are the inclusion of asciminib for the treatment of chronic myeloid leukemia and a sofosbuvir/velpatasvir oral regimen (200 mg/50 mg) for chronic hepatitis C in children aged 3 to 11 years, expanding therapeutic options for these patient groups. In addition to oncology and virology therapies, Conitec also approved other technologies for incorporation into the SUS, including dimethicone 92% for tungiasis, emicizumab for prophylactic treatment of severe hemophilia A in young children without inhibitors, and multiple pneumococcal conjugate vaccines for pediatric use, including high-risk populations. The decisions also involve updates to clinical protocols and therapeutic guidelines. [Read more.](#)

BRAZIL ANS UPDATES MANDATORY COVERAGE LIST TO INCLUDE CANCER AND OSTEOPOROSIS THERAPIES

The National Supplementary Health Agency (ANS) approved an update to the List of Health Procedures and Events, expanding mandatory coverage for beneficiaries of private health insurance plans. The update, approved by the ANS Collegiate Board on December 19, 2025, revises the Utilization Guidelines (DUTs) to include two key technologies with expanded indications, effective January 2, 2026. The revised list now includes abemaciclib, an oral therapy for the adjuvant treatment of early breast cancer in adult patients at high risk of recurrence (hormone receptor-positive, HER2-negative, node-positive disease), with an adjustment to the DUT for the therapeutic category Oral Antineoplastic Therapy. In addition, romosozumab will become subject to mandatory coverage under the expanded DUT for osteoporosis in postmenopausal women with severe disease and prior treatment failure, as defined by specific clinical criteria, including multiple fractures during previous therapy or significant loss of bone mineral density. [Read more.](#)

BRAZIL ANS APPROVES NEW SUPERVISION MODEL FOR SUPPLEMENTARY HEALTH SECTOR

The National Supplementary Health Agency (ANS) has approved a new supervision model for Brazil's private health insurance sector, aiming to modernize regulatory oversight, accelerate responses to beneficiary complaints, and strengthen incentives for compliance among health plan operators. The rule was approved by the ANS Collegiate Board and will enter into force on May 1, 2026, applying exclusively to infractions committed after that date. Under the new

framework, the ANS introduces sampling-based analysis of individual demands, enabling faster and more effective responses without undermining the handling of beneficiary complaints. The model also redesigns planned and strategic inspection actions, categorizing them according to severity levels and operator performance metrics, and adopts a responsive regulation approach that combines preventive, inductive, and sanctioning instruments. The update reflects a shift from a traditionally reactive and punitive oversight model toward a system designed to anticipate and prevent conflicts, promote best practices among operators, and intensify adherence to regulatory standards. The regime also introduces adjustments to infraction typologies and penalty structures, including progressively escalating fines, signaling a stricter stance against non-compliance. [Read more.](#)

BRAZIL ANS OPENS PUBLIC CONSULTATION TO BUILD REGULATORY AGENDA FOR 2026–2028

The National Supplementary Health Agency (ANS) has launched a Public Call for Contributions to gather input from society for the development of its Regulatory Agenda 2026–2028, the strategic regulatory roadmap that will guide the agency's priorities and actions over the next three years. The initiative invites submissions from citizens, industry stakeholders, consumer protection bodies, and health sector representatives through an electronic form available on the ANS portal until January 31, 2026. The public consultation mechanism aims to collect technical inputs, proposals, and evidence to strengthen the regulatory planning process and ensure that the agenda reflects the diversity of perspectives within the supplementary health sector. ANS President Wadih Damous emphasized the importance of a participatory and transparent process, noting that collaboration with civil society, health plan operators, consumer defense entities, and service providers will be key to identifying the main regulatory challenges and priorities for the upcoming cycle. [Read more.](#)

BRAZIL PRIVATE HEALTH SECTOR TO PILOT SHARED PATIENT DATA SYSTEM TO IMPROVE CARE COORDINATION

A consortium of private hospitals, pharmacies and clinical laboratories has announced plans to pilot an interoperable patient data sharing platform aimed at improving care coordination, reducing redundant exams, and enhancing clinical decision-making across institutions. The initiative, led by InovaHC, the innovation arm of Hospital das Clínicas of the University of São Paulo, seeks to adopt a model inspired by open finance, enabling patients to authorize the secure exchange of their health information among participating providers. Under the proposed model — often referred to as OpenCare Interop — patient consent determines which data are shared and for what purpose, empowering individuals to control access while facilitating continuity of care across medical settings. Participating players are expected to include major private clinical networks, diagnostic groups, and retail pharmacy chains, with implementation anticipated over the next six to eight months, pending technical integration and regulatory alignment. [Read more.](#)

BRAZIL COMPLAINTS BY CANCER PATIENTS AGAINST HEALTH PLANS TRIPLE IN FIVE YEARS

Complaints filed by cancer patients against private health insurance plans in Brazil have nearly tripled over the past five years, according to recent reporting based on data from the National Supplementary Health Agency (ANS) and analyzed by Folha de S.Paulo. Between 2020 and 2025, the number of complaints related to cancer care issues increased from approximately 3,391 to 9,693, illustrating a sharp rise in disputes between beneficiaries and operators over coverage, contract terminations, and denials of services during critical treatment periods. [Read more.](#)

BRAZIL STJ RULES HEALTH PLAN NOT OBLIGED TO COVER HOME USE SOMATROPIN

The Superior Court of Justice (STJ) has upheld a lower court decision confirming that private health plans are not required to cover the cost of somatropin for home administration, in a dispute involving SulAmérica Saúde. The case centered on a beneficiary's claim to compel the

operator to provide somatropin, a hormone therapy indicated for growth hormone deficiency but prescribed for domiciliary use. The STJ found that, under the Law No. 9.656/1998 and prevailing jurisprudence, plans are not obliged to fund drugs administered outside formal health units unless they fall into specific categories: oral antineoplastics and related therapies, medicines administered in home care regimes, or those explicitly listed in the ANS mandatory coverage list for that purpose. [Read more.](#)

BRAZIL EXPERTS VOICE CONCERN OVER SURGE IN HEALTH TREATMENT LAWSUITS

A sharp rise in judicial actions seeking access to health treatments in Brazil was the focus of a public hearing held on December 16 by the Health Committee of the Chamber of Deputies. Specialists, legislators, and legal representatives highlighted the complexities and consequences of patients increasingly turning to the courts to secure medications, procedures and care not readily provided by either the Unified Health System (SUS) or private health plans. The debate reflected underlying systemic challenges, including high rates of treatment denials, prolonged waiting lists for consultations and surgeries, and failures to implement public health policies in a timely manner. [Read more.](#)

BRAZIL 45% OF POPULATION RATE GOVERNMENT PERFORMANCE IN HEALTH AS NEGATIVE, IPSOS-IPEC SHOWS

A new Ipsos-Ipec opinion survey reveals that 45% of Brazilians evaluate the federal government's performance in health as "poor" or "terrible", reflecting persistent public dissatisfaction with the administration's handling of health policy and services. The poll was conducted among 2,000 respondents in 131 municipalities between December 4 and 8, 2025, with a margin of error of two percentage points and a 95% confidence level. The negative assessment combines responses classified as "poor" (14%) and "terrible" (31%), while 27% of participants rated the performance as "good" (8%) or "excellent" (19%), and another 27% described it as "fair." The share of those who did not respond was around 2%. Historical data from the Ipsos-Ipec series indicate that perceptions of the government's health performance have remained predominantly unfavorable throughout 2024–2025, peaking at 48% negative in June 2025 and recurring near similar levels in recent months, suggesting a sustained challenge in public perception of health governance. [Read more.](#)

BRAZIL AND OXFORD UNIVERSITY SIGN STRATEGIC PACT TO ACCELERATE CANCER VACCINE DEVELOPMENT

The Ministry of Health and the University of Oxford (UK) formalized a Letter of Intent to accelerate research and development of vaccines for cancer prevention, marking a significant step in international cooperation on cutting-edge health technologies. The agreement was signed on December 19 and brings together Brazilian scientific institutions, including the National Center for Research in Energy and Materials (CNPEM), Fiocruz, and leading hospitals, with the University of Oxford's Centre for Immuno-Oncology to jointly explore immunological therapies and vaccine platforms. The cooperation focuses on three strategic axes: collaborative discovery in immunology and oncology, the use of artificial intelligence for cancer vaccine design, and the establishment of a binational clinical trial accelerator. A bilateral steering committee and technical missions to Brazilian laboratories and hospitals are planned as next steps to structure research priorities and implementation pathways. [Read more.](#)

BRAZIL EXPANDS SUS ACCESS TO MAMMOGRAPHY FOR WOMEN FROM AGE 40

President Luiz Inácio Lula da Silva has sanctioned Law No. 15.284/2025, broadening access to the mammography exam through the Unified Health System (SUS) for all women aged 40 years and older, regardless of symptoms. The norm, published in the Official Gazette on December 19, alters provisions in Law No. 11.664/2008, which governs cancer prevention, detection, treatment, and follow-up services within the public health system. Under the new framework, mammograms will be guaranteed to women starting at age 40 in accordance with Ministry of Health guidelines, which may extend screening recommendations to additional age groups over time. The law aims to enhance early detection of breast cancer, a leading cause of cancer morbidity and mortality among Brazilian women; those aged 40–49 account for an estimated 23 % of new cases, and early diagnosis is associated with better clinical outcomes and survival. [Read more.](#)

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