

WEEKLY REPORT



12/13/2025

PHARMACEUTICAL COMPANIES WAIT UP TO SIX YEARS FOR PATENT GRANTS AT INPI, AUDIT FINDS

Pharmaceutical companies in Brazil are facing long delays at the National Institute of Industrial Property (INPI), with some patent applications taking around six years to be examined, according to an audit highlighted in a recent UOL Economia column. The prolonged timelines affect innovators across the sector and have drawn attention to structural challenges within the patent system, including backlog, limited examiner capacity and procedural bottlenecks that hinder timely protection of inventions. Industry sources point out that lengthy patent examinations create uncertainty for research-intensive companies, impacting investment decisions and planning for product launches. The issue is underscored by high-profile cases such as semaglutide patents, where delays of more than a decade have prompted judicial scrutiny and discussions on mechanisms to restore effective protection periods lost during extended review processes. [Read more.](#)

STJ POSTPONES RULING ON SEMAGLUTIDE PATENT DISPUTE

Brazil's Superior Court of Justice (STJ) postponed the judgment that will determine whether the patent for semaglutide, the active ingredient in Ozempic, remains valid in the country. The case is being closely watched by pharmaceutical companies and policymakers, as the court's decision will directly influence when generics and similar products can enter the Brazilian market. The postponement extends uncertainty for manufacturers seeking to launch lower-cost alternatives amid soaring demand for GLP-1-based therapies. The dispute centers on whether the patent received an unlawful extension due to delays at the National Institute of Industrial Property (INPI). A ruling against the extension could open the market to competitors sooner, potentially reducing prices and expanding access. However, with the trial delayed once again, industry stakeholders anticipate continued legal contention and market instability until a final decision is issued. [Read more.](#)

PATENT DELAY OF VONAU FLASH HIGHLIGHTS INNOVATION BOTTLENECK IN BRAZIL

The prolonged review of the patent for the anti-emetic drug Vonau Flash has exposed structural challenges in Brazil's pharmaceutical innovation ecosystem. Researchers and industry experts say the National Institute of Industrial Property (INPI) took 13 years to grant the patent, meaning the product had only about seven years of effective market exclusivity before entering the public domain. This shortened protection undermined years of research and limited returns for the University of São Paulo (USP), which historically relied on royalties from the drug for reinvestment in new projects. Observers argue the case illustrates a broader issue: long patent review times discourage both domestic research and foreign investment, as the costs and risks associated with drug development are high and require predictable intellectual property protection. Experts warn that without more efficient patent processing, innovation incentives for universities and laboratories may continue to weaken, potentially stalling scientific progress and economic returns from homegrown therapies. [Read more.](#)

WAVE OF BIOLOGIC PATENT EXPIRATIONS SET TO RESHAPE BRAZIL'S PHARMACEUTICAL MARKET

A new wave of patent expirations for high-cost biologic medicines is set to significantly alter Brazil's pharmaceutical landscape over the next decade. According to industry specialists, at least 15 major biologics (including treatments for cancer, autoimmune diseases, and rare conditions) will lose exclusivity by 2035, opening space for biosimilars and intensifying competition in the domestic market. The shift is expected to expand patient access, reduce budget pressures on both the public and private health sectors, and stimulate local production capabilities. Experts interviewed by Futuro da Saúde note that Brazil still faces regulatory, technological, and industrial challenges to fully benefit from this transition. Manufacturing complexity, limited biotechnological infrastructure and dependence on imported inputs may constrain the speed at which biosimilars reach the market. [Read more.](#)

NEW SURVEY MAPS BRAZIL'S CLINICAL RESEARCH LANDSCAPE AND HIGHLIGHTS REGIONAL DISPARITIES

A new nationwide survey has mapped the distribution of clinical research activity in Brazil, revealing significant regional disparities and concentration of studies in a limited number of states. Conducted by the Brazilian Clinical Research Alliance (Abracro) in partnership with CT•VI Research, the study shows that São Paulo, Rio de Janeiro, Minas Gerais, and Rio Grande do Sul account for the majority of clinical trials, while vast regions of the country remain underrepresented. The findings underscore structural challenges such as uneven research infrastructure, shortage of qualified personnel and limited institutional support outside major urban centers. The report emphasizes the potential economic and scientific gains of expanding clinical research capacity nationwide, including improved patient access to innovative therapies and strengthened collaboration with global sponsors. Industry representatives argue that regulatory modernization, investment in research networks and incentives for institutional development are essential to reduce inequities and position Brazil as a more competitive hub for clinical trials. [Read more.](#)

ANVISA ACCELERATES REVIEW OF 20 WEIGHT-LOSS INJECTION PENS AT THE MINISTRY OF HEALTH'S REQUEST

Anvisa decided to fast-track the regulatory review of 20 injectable weight-loss products following a formal request from the Ministry of Health. The medicines, based on liraglutide and semaglutide, are under evaluation by companies such as EMS, Megalabs and Momenta. Part of the dossiers is expected to be assessed by the end of 2025, while others are scheduled for analysis in 2026 and 2027. The initiative is aligned with the government's strategy to expand domestic production capacity for GLP-1 therapies amid rising demand and supply constraints. Authorities argue that increasing the number of approved products could reduce dependence on imports and improve market stability. [Read more.](#)

ANVISA UPDATES PRIORITY CATEGORIES FOR DRUG REGISTRATION

Anvisa updated the criteria used to define priority categories for drug registration and post-registration procedures, aiming to improve regulatory efficiency and better align review processes with public health needs. The revision addresses limitations in the previous framework, which stakeholders argued had limited impact on reducing review timelines. The updated rules may influence how innovative therapies, domestically developed products and strategically important medicines are handled within Anvisa's review queue. The agency emphasized that ongoing monitoring will be essential to ensure the new criteria deliver tangible regulatory gains. [Read more.](#)

ANVISA APPROVES REQUIREMENTS FOR ELECTRONIC PRESCRIPTIONS OF CONTROLLED SUBSTANCES

Anvisa approved updated requirements for the issuance and processing of electronic prescriptions for controlled substances, aiming to strengthen traceability, prevent diversion and enhance patient safety. The rules establish standards for digital prescription formats,

authentication mechanisms and secure data exchange across prescribers, pharmacies, and regulatory systems. The measure is part of broader efforts to modernize Brazil's prescription ecosystem and align regulatory practices with digital health initiatives. [Read more.](#)

ANVISA APPROVES 2026–2027 REGULATORY AGENDA WITH 155 STRATEGIC TOPICS

Anvisa approved its Regulatory Agenda for 2026–2027, defining 155 priority topics that will guide rulemaking, regulatory reviews, and strategic initiatives over the next two years. The agenda covers areas such as medicines, health products, clinical research, laboratory oversight, and border control. The agency emphasized that the agenda serves as a strategic roadmap rather than a list of pre-approved regulations. Officials highlighted commitments to regulatory coherence, digital transformation, reliance practices, and risk-based approaches. [Read more.](#)

ANS HIGHLIGHTS REGULATORY AGENDA DEVELOPMENT DURING 120TH CAMSS MEETING

The National Supplementary Health Agency held the 120th meeting of the Supplementary Health Chamber, bringing together representatives from government, industry, and consumer groups. During the meeting, the agency's president stated that the next regulatory agenda is currently under development and will incorporate stakeholder contributions. Discussions addressed structural challenges, transparency initiatives, and mechanisms to strengthen dialogue between regulators and the supplementary health sector. [Read more.](#)

HEALTH INSURERS' PROFITS SURGE 140% IN BRAZIL'S THIRD QUARTER

Brazil's private health insurance sector reported a sharp increase in profits in the third quarter of 2025, with operators posting an operational profit of approximately R\$6.3 billion—an increase of nearly 140% compared with the same period last year, according to data from the National Supplementary Health Agency (ANS). The figure marks the highest quarterly operational result in several years and reflects a combination of robust premium revenues and continued control of claims costs. Industry analysts highlight that strong financial performance was supported by significant investment income amid elevated interest rates, contributing to higher net earnings overall. [Read more.](#)

BRAZIL COULD SEE UP TO 1.2 MILLION LAWSUITS PER YEAR AGAINST HEALTH INSURANCE PLANS

Brasília – Lawsuits filed against private health insurers in Brazil could reach between 900,000 and 1.2 million new cases per year by 2035, according to projections from the Instituto de Estudos de Saúde Suplementar (IESS). The study shows a 112% increase in litigation between 2020 and 2024, driven by regulatory gaps, communication failures between beneficiaries and insurers, and economic incentives that favor legal action. The growth raises concerns about sustainability and regulatory clarity in the supplementary health system. [Read more.](#)

ANS ADDS ROBOTIC PROSTATE CANCER SURGERY TO MANDATORY HEALTH PLAN COVERAGE

The National Supplementary Health Agency (ANS) approved the inclusion of robot-assisted radical prostatectomy for prostate cancer in the Mandatory Coverage List of private health plans. The decision expands access to advanced surgical treatment options and will require health insurers to adapt their coverage policies within the established regulatory timeframe. The procedure is considered one of the most advanced surgical approaches for prostate cancer, offering greater precision, reduced blood loss, and shorter recovery times. The measure is seen as part of broader efforts to modernize Brazil's supplementary health system, although implementation challenges remain due to limited availability of robotic surgery infrastructure. [Read more.](#)

HEALTH SECTOR RECEIVES LARGEST SHARE OF PARLIAMENTARY AMENDMENTS IN BRAZIL'S 2026 BUDGET

The health sector will receive the largest volume of parliamentary amendments in Brazil's 2026 federal budget, according to data released by the Chamber of Deputies. Health-related allocations account for 30.2% of all individual and bench amendments, reflecting lawmakers' sustained focus on directing resources to local healthcare services, infrastructure, and community-based programs. The prominence of health in the amendment distribution reinforces its central role in political negotiations and constituency demands ahead of the implementation of next year's budget. Despite the significant share of resources, specialists warn that the growing dependence of the Unified Health System (SUS) on parliamentary amendments may hinder long-term planning and deepen regional disparities. While these allocations often respond to urgent local needs, they can also divert funding from strategic national programs, limiting the system's ability to execute coordinated policies based on epidemiological priorities. [Read more.](#)

BRAZIL ANNOUNCES R\$18.4 BILLION INVESTMENT TO EXPAND HEALTH INFRASTRUCTURE

The federal government will invest R\$18.4 billion to expand and modernize Brazil's health infrastructure, according to the Ministry of Health. The resources will support the construction, renovation and expansion of Basic Health Units (UBS), Emergency Care Units (UPA), hospitals, and specialized service centers, with the goal of strengthening regional care networks and improving access to essential services across the country. The initiative is part of a broader strategy to reduce structural gaps in the Unified Health System (SUS) and enhance service capacity. The Ministry emphasized that investments will prioritize regions with limited infrastructure and high unmet healthcare needs, aiming to reduce territorial inequalities and improve care continuity. Projects include upgrades to diagnostic capacity, expansion of maternity and neonatal units, and modernization of equipment to support integrated care pathways. According to the government, the funding is expected to accelerate service delivery improvements beginning in 2026. [Read more.](#)

CONITEC HOLDS FIRST MEETINGS WITH DIRECT PARTICIPATION OF CIVIL SOCIETY

Conitec held its first plenary meetings with the formal participation of representatives from civil society, marking a new phase in the committee's governance and decision-making process. The initiative follows recent changes to Conitec's internal rules and reflects the Ministry of Health's efforts to expand transparency and social participation in health technology assessment within the Unified Health System (SUS). According to the committee, the presence of civil society representatives aims to strengthen dialogue, incorporate patient and societal perspectives into evaluations, and increase the legitimacy of recommendations on the incorporation, exclusion, or alteration of health technologies. The move is part of a broader institutional agenda to modernize Conitec's procedures and reinforce participatory mechanisms in public health policy. [Read more.](#)

CONITEC'S ROTATING CHAIR MODEL DRAWS CRITICISM OVER GOVERNANCE AND CONTINUITY

Specialists and former members of Conitec have raised concerns about the committee's rotating chair model, arguing that the monthly alternation of presidency among representatives undermines continuity, governance, and accountability in decisions on health technology incorporation. According to the report, frequent leadership changes hinder long-term planning, disrupt the technical flow of evaluations, and may weaken the committee's ability to maintain consistent criteria when assessing drugs, procedures, and devices for the Unified Health System (SUS). Experts note that the model, established after changes to the committee's structure, has generated operational challenges and increased the complexity of coordination among participating institutions. Critics argue that Conitec's mandate—central to ensuring evidence-based incorporation—is incompatible with fragmented leadership, and that a more stable

governance framework would strengthen transparency, predictability and the quality of decisions that shape national access to health technologies. [Read more.](#)

MEDICAL SOCIETIES IN BRAZIL ISSUE NEW WARNING AGAINST TESTOSTERONE USE IN WOMEN

Brazilian medical societies issued a new joint warning condemning the use of testosterone therapy and so-called “beauty chips” in women. Specialists highlighted the lack of scientific evidence supporting these treatments and warned of adverse effects such as cardiovascular risks, metabolic disturbances and virilization. The organizations called for stricter oversight, improved professional guidance and clearer public communication to prevent inappropriate use of hormone therapies. [Read more.](#)

EXPANSION OF MAMMOGRAPHY ACCESS IN THE SUS FACES GEOGRAPHIC CHALLENGES

Efforts to expand access to mammography within Brazil’s Unified Health System (SUS) continue to face significant barriers related to geographic distribution, infrastructure limitations, and unequal availability of diagnostic services. Although the Ministry of Health has announced initiatives to broaden screening capacity, specialists note that many regions still lack sufficient equipment, trained personnel, and referral networks, particularly in rural and remote areas where travel distances and waiting times reduce adherence to breast cancer screening. [Read more.](#)

BRAZIL STRENGTHENS NATIONAL CARDIOVASCULAR CARE POLICY

The Ministry of Health announced measures to reinforce the National Policy for Cardiovascular Care, aiming to reduce the burden of heart disease through expanded prevention, early diagnosis, and integrated care across all levels of the Unified Health System (SUS). The initiative includes updated clinical protocols, increased training for health professionals and strengthened coordination between primary care, specialized services, and emergency response networks. [Read more.](#)

BRAZILIAN CAR-T THERAPY ACHIEVES COMPLETE REMISSION IN 72% OF PATIENTS

A Brazilian-developed CAR-T cell therapy produced and administered domestically demonstrated complete remission in 72% of patients with advanced B-cell blood cancers, according to initial results from a study led by Einstein Hospital in partnership with the Ministry of Health. In the trial, 81% of participants showed a positive response to the immunotherapy, marking a significant milestone for locally manufactured advanced cancer treatments and indicating potential for expanded access and reduced reliance on imported therapies. [Read more.](#)

BRAZIL LAUNCHES ORION PUBLIC HEALTH RESEARCH COMPLEX

The Orion project is an unprecedented public health initiative in Brazil that will build a cutting-edge laboratory complex for advanced research on infectious agents in Campinas, São Paulo. With a public investment of approximately R\$1.6 billion, the facility will include the first Biosafety Level 4 (NB4) laboratory in Latin America connected to the Sirius particle accelerator, enabling high-precision studies of high-risk pathogens and accelerating the development of diagnostics, vaccines, and treatments. Designed to boost national scientific capacity and health system resilience, the Orion complex will support advanced pathogen imaging and analysis, contribute to epidemiological surveillance strategies, and serve as a platform for pre-clinical research that can underpin public health policy and industrial innovation in Brazil. [Read more.](#)

EXPANSION OF MEDICAL SCHOOLS THROUGH COURT INJUNCTIONS ADVANCES IN CITIES LACKING INFRASTRUCTURE

The expansion of medical school programs in Brazil continues through court injunctions that allow new courses to open in municipalities without adequate teaching hospitals or healthcare infrastructure. The trend has intensified despite a freeze on new authorizations by the Ministry of Education. Experts warn that injunction-driven expansion undermines quality standards and may worsen imbalances between the number of medical graduates and available residency positions, affecting professional training and healthcare delivery. [Read more.](#)

STAGNATION OF MEDICAL RESIDENCY PROGRAMS FUELS GROWTH OF NON-ACCREDITED SPECIALIZATIONS

The lack of expansion in accredited medical residency positions in Brazil is driving growth in specialization courses that operate without evaluation by the Ministry of Education. With residency slots failing to keep pace with the growing number of medical graduates, many physicians are turning to alternative programs offering certificates but lacking formal recognition. Specialists warn that the trend risks fragmenting postgraduate medical education and weakening training standards, reinforcing the need to expand residency capacity and strengthen accreditation mechanisms. [Read more.](#)

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