

WEEKLY REPORT



09/06/2025

NOVO NORDISK SECURES PATENT EXTENSION IN BRAZIL FOR LIRAGLUTIDA-BASED WEIGHT-LOSS PENS

A federal judge in Brasília granted a preliminary injunction extending by eight years the patent for liraglutide, the active ingredient in Novo Nordisk's weight-loss pens Victoza and Saxenda. The decision came after the court ruled that the prolonged delay of over 13 years by the National Industrial Property Institute (INPI) violated principles of efficiency and reasonable procedural duration. The ruling mandates that the INPI publish the decision in the Industrial Property Review and update the procedural status, under penalty of a daily fine of R\$ 1,000. Novo Nordisk also announced its intention to seek similar relief for the semaglutide patent, used in drugs like Ozempic and Wegovy. [Read more.](#)

BRAZIL'S CLINICAL TRIALS LAW COULD INCLUDE 286,000 NEW BRAZILIAN PARTICIPANTS, STUDY FINDS

A new study by Interfarma, in partnership with IQVIA, estimates that Brazil's recently approved clinical trials law could enable the inclusion of 286,000 new Brazilian participants in drug trials. According to the analysis, this regulatory milestone has the potential to elevate Brazil into the top 10 global hubs for clinical trials. The projections suggest that the annual number of trials initiated may rise from 254 to 635, with an estimated additional investment of R\$ 2.1 billion per year. The findings also anticipate a significant economic impact (potentially generating R\$ 6.3 billion annually) and creating 56,000 new skilled jobs. Interfarma Executive Director Renato Porto emphasized Brazil's favorable attributes, including a large urbanized, ethnically diverse population and strong scientific infrastructure, which could further boost the country's appeal for clinical trials. [Read more.](#)

NEW ANVISA LEADERSHIP DEFINES BOARD COMPOSITION

The new director-president of the National Health Surveillance Agency (Anvisa), Leandro Pinheiro Safatle, began his mandate on Friday (29/8), after signing the appointment document with Health Minister Alexandre Padilha. On the same day, he also swore in new directors Daniela Marreco Cerqueira and Thiago Lopes Cardoso Campos. The agency published Resolution Anvisa 993/2025 in the Official Gazette, defining the composition of Anvisa's Collegiate Board as follows: Leandro Pinheiro Safatle — Director-President; Daniel Meirelles Fernandes Pereira — Second Directorate; Daniela Marreco Cerqueira — Third Directorate; Rômison Rodrigues Mota — Fourth Directorate; and Thiago Lopes Cardoso Campos — Fifth Directorate. The resolution revoked RDCs 953/2025 and 980/2025 and took effect on the date of publication. Read more: <https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2025>

ANVISA PLANS REGULATORY ADVICE MODEL TO SUPPORT DRUG DEVELOPMENT

João Batista Júnior, Anvisa's manager for Blood, Cells, Tissues, Organs, and Advanced Therapy Products, announced that the agency is working on a regulatory advice model to assist companies throughout the drug development process. The initiative will be incorporated into the update of Collegiate Board Resolution (RDC) 506, which regulates clinical research. The goal is for Anvisa to provide closer monitoring after research authorization, guiding subsequent steps such as pricing and incorporation. Batista Júnior explained that the update to RDC 506 responds to challenges brought by Law 14.874/2024, which requires Anvisa to respond to research requests within 90 days. If no decision is made, studies may begin by default. "We

are very concerned about this aspect, but we cannot avoid it — we must comply with the law,” he said during a debate on advanced technologies this week. [Read more.](#)

ANVISA UPDATES INVESTIGATION ON GENE THERAPY DRUG ELEVIDYS

Anvisa has issued new details on the ongoing investigation into the gene therapy drug Elevidys® (delandistrogeno moxeparvovexq), while maintaining its temporary suspension. The measure, enacted via Resolution-RE 2,813/2025 on July 25, remains in force following reports of three deaths from acute liver failure in U.S. clinical trials involving the same viral vector technology (AAVrh74). Elevidys® was approved in Brazil in December 2024 for ambulatory pediatric patients (ages 4 to 7) with Duchenne muscular dystrophy. Only around ten patients have received the treatment so far, with no cases of severe liver toxicity reported locally. Anvisa reaffirmed that all decisions are grounded in scientific evidence and regulatory rigor, with patient safety as its top priority. [Read more.](#)

NEW MEMBERS OF BRAZIL’S ANS BOARD ARE OFFICIALLY SWORN IN BY THE HEALTH MINISTER

Health Minister Alexandre Padilha officially inducted the new leadership of the National Supplementary Health Agency (ANS) on Tuesday (2/9). In a ceremony at the agency’s headquarters in Rio de Janeiro, he swore in Wadih Damous as director-president and Lenise Secchin as director for Product Regulation (DIPRO). The event included senior officials from government, judiciary, Fiocruz, and health plan operators. In his speech, Damous emphasized ANS’s crucial role as a sector regulator: “We must fulfill our mission to society, addressing key challenges faced by beneficiaries. We will work closely with the Health Ministry and contribute actively to initiatives like the Agora Tem Especialistas program.” Lenise Secchin acknowledged her long-standing career at ANS and stressed a commitment to collaborative policymaking and constructive dialogue with all stakeholders. [Read more.](#)

HEALTH INSURANCE SECTOR POSTS RECORD PROFIT OF R\$ 12.9 BN IN FIRST HALF OF 2025

Brazil's health insurance sector achieved a historic profit of R\$ 12.9 billion in the first half of 2025, marking an increase of approximately 132% compared to the same period in 2024, according to data released by the National Supplementary Health Agency (ANS). This result represents about 6.8% of the sector’s total revenue, which totaled around R\$ 190 billion during the semester. The strong performance was driven by both operational and financial gains. The operating result—revenues minus direct healthcare costs—reached R\$ 6.3 billion, a 157% rise year-on-year and the largest figure since 2021. Financial revenues, buoyed by high interest rates, added R\$ 6.8 billion to the bottom line, a 55% increase. Large health plan operators led the gains, but smaller and medium-sized providers also posted significant growth. Meanwhile, the sector continued to see a reduction in sinistrality (claims-to-revenue ratio), falling to 81.1%, the lowest level ever recorded in a first-half period excluding 2020. [Read more.](#)

BRAZIL’S HOSPITALS INVEST IN THEIR OWN HEALTH INSURANCE PLANS

Facing growing verticalization in private health plans for higher-income clients, hurdles in securing accreditation with operators, and shrinking coverage in recent years, several hospitals across Brazil are developing their own health insurance plans. The Kora hospital group launched its own operator in April to serve Vitória (ES), where its main unit is located. In Porto Alegre, Hospital Moinhos de Vento created an insurance plan initially aimed at employees, with potential to expand to the broader market depending on future sector dynamics. In Rio de Janeiro, Rede Casa already has 130,000 users under its Klini health plan, founded in 2020. Also in 2020, Hospital Sagrada Família in São Paulo’s eastern zone introduced its own plan, which grew from 5,500 to 21,000 clients in the past 12 months, according to ANS data. These initiatives are seen as protection strategies for mid- and high-tier hospitals, should operators prioritize their own verticalized networks. While verticalization has so far been more common in lower-priced products, the trend is expanding. [Read more.](#)

BRAZIL SEEKS INDEPENDENT STRUCTURE TO CONFRONT FUTURE EPIDEMICS, EXPERTS URGE

Researchers and public health experts argued that Brazil needs to create an independent structure dedicated to epidemic preparedness, highlighting vulnerabilities exposed during the Covid-19 pandemic. During a public debate, specialists emphasized that while Brazil has strong scientific institutions and a universal health system, coordination and governance failures undermined responses to health crises. They advocated for a permanent body — autonomous from political cycles — to oversee epidemic prevention, response, and innovation. [Read more.](#)

MINISTRY OF HEALTH SUPPORTS AI BILL, CONSIDERS TEXT BALANCED

The Ministry of Health hosted on Tuesday (2) a seminar to debate Bill 2.338/2023, which proposes the regulation of artificial intelligence in Brazil. The discussion focused on the bill's scope, legislative process, and potential impacts on the health sector. Already approved by the Senate, the proposal is now under review in the Chamber of Deputies. The legislation establishes national guidelines for the use of AI, defining responsibilities and ensuring rights for the population. AI systems applied in health — such as those assisting in diagnostics or medical procedures — would be classified as high-risk when significant risks to physical or mental integrity exist. This classification requires stricter criteria, including human supervision, testing protocols, and measures to mitigate discriminatory bias. Ana Estela Haddad, Secretary of Information and Digital Health, praised the Senate's version as "very good," noting its provisions on risk minimization, human oversight, and accountability. She emphasized that the government's role has been to align the bill with other federal initiatives supporting sovereign infrastructure. [Read more.](#)

BRAZIL TO INAUGURATE FIRST PUBLIC SMART HOSPITAL WITH AI, 5G AMBULANCES, AND TELEHEALTH

The Ministry of Health has announced the launch of ITMI-Brazil, the country's first public smart hospital. Located within the Hospital das Clínicas complex of the University of São Paulo's Medical School, the institute will open in late 2027 with 800 beds dedicated to adult and pediatric emergencies in neurology, neurosurgery, cardiology, intensive care, and other urgent care. This high-tech medical facility will integrate artificial intelligence, 5G-connected ambulances, and telehealth services, aiming to drastically reduce emergency response times—from 17 hours to just 2 hours. ITMI-Brazil is envisioned not only as a hospital but as a center for digital health innovation and training, covering domains like AI, cybersecurity, engineering, and clinical telemetry. The 150,000 m² facility will meet international protocols for sustainability and safety while promoting humane patient care. The project also includes building a national network of smart ICUs in 10 state capitals—such as Brasília, Belém, Fortaleza, and Porto Alegre—interlinked with ITMI-Brazil. These units will enable real-time AI-assisted bed regulation and clinical support. The initiative is funded by US\$ 320 million from the New Development Bank (NDB-BRICS) and aligns with federal priorities to modernize the SUS through innovation and autonomy. [Read more.](#)

BRAZIL'S GOVERNMENT AUTHORIZES HIRING OF 300 TEMPORARY STAFF FOR MINISTRY OF HEALTH AND UP TO 191 FOR ANS

The Ministry of Health (MS) has been authorized to hire 300 temporary professionals to strengthen activities related to oversight, analysis, and reimbursement of public funds, in compliance with determinations from the Federal Court of Accounts (TCU). The contracts will last up to four years and may be extended based on technical justification. The new hires will work in procedures such as project accreditation, accountability, refunding of resources, initiation of Special Account Audits (TCE), administrative investigations, debt registration, and judicial enforcement. Recruitment will be prioritized through the candidate list from the first edition of the National Unified Exam (CNU). If the list is exhausted, the ministry may conduct a simplified selection process in accordance with reservation policies established by law. The National Supplementary Health Agency (ANS) has also been authorized to hire up to 191 temporary professionals. According to the joint ordinance published on Thursday (4) by the

Ministry of Management and Innovation in Public Services (MGI) and the Ministry of Health, ANS may also use the CNU list or, if necessary, conduct a simplified process, provided all legal requirements for inclusion policies are met. [Read more.](#)

HEALTH MINISTRY CITES HIGH COSTS TO JUSTIFY NON-INCORPORATION OF HEREDITARY AMYLOIDOSIS TREATMENTS INTO SUS

Patients, families, and healthcare professionals pushed during a public hearing of the Senate's Science and Technology Committee (CCT) for the inclusion of new treatments for hereditary amyloidosis in Brazil's public health system (SUS). The Ministry of Health, however, cited budget constraints as a major barrier. Hereditary amyloidosis is a rare progressive disease caused by liver protein deposits in various organs, such as the heart, nerves, and kidneys. Symptoms include hand and foot weakness, fatigue, shortness of breath, and cardiac arrhythmias. While a cure remains elusive, treatments are available to slow disease progression. Luciana Costa Xavier, General Coordinator of Health Technology Assessment at the Health Ministry, acknowledged that discounts offered by manufacturers were still insufficient. She proposed stronger industry engagement and budget expansion to allow access. [Read more.](#)

BRAZIL'S SENATE COMMITTEE PASSES BILL ON TAX EXEMPTION FOR DONATED MEDICINES

The Senate's Economic Affairs Committee (CAE) approved a bill (PL 4.719/2020) that exempts donated medicines from federal taxes. The proposal mandates that donations must have at least six months of remaining shelf life and be directed to the Union, states, federal district, municipalities, Santa Casas, the Brazilian Red Cross, or certified charitable entities. The exemptions cover PIS/Pasep, Cofins, and the Industrialized Products Tax (IPI), and recipients must distribute the medicines on a non-profit basis — resale is prohibited. The bill now moves to the Senate Plenary. [Read more.](#)

MORE HIGHLIGHTS

[Public hearing urges free access to nusinersen for type 3 spinal muscular atrophy patients in Brazil](#)

[Anvisa bans glucose-measuring rings for lack of efficacy and registration](#)

[Anvisa approves mirvetuximab soravtansina for platinum-resistant ovarian cancer in Brazil](#)

[Brazil's Mercado Livre moves into the drugstore sector, unsettling pharmacy stocks](#)

[Bill establishing the National Policy for Women's Health Care during Climacteric and Menopause is received by the Health Committee](#)

BRAZIL NEWS

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[The Brazilian judge defying Trump is testing peers' patience](#)

[Bolsonaro rights to defense in Brazil coup trial were restricted, lawyer says](#)

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