WEEKLY REPORT

01/31/2026

BRAZIL'S PHARMA LOBBY BATTLE INTENSIFIES AS OZEMPIC PATENT NEARS EXPIRY

The approaching expiration of the patent for semaglutide-based medicines such as Ozempic in Brazil has triggered a lobbying battle within the National Congress of Brazil as industry groups seek to shape legislation that could affect market competition and generic entry. The patent, held by the Danish company Novo Nordisk, is set to expire in March 2026, opening the door for manufacturers to produce lower-cost alternatives. However, Novo Nordisk and allied lawmakers are backing Bill 5810/2025, which would allow extensions of patent terms by up to five years in cases where administrative delays at the National Institute of Industrial Property are deemed responsible for lost effective protection time, arguing this would ensure predictability for innovation investment. Proponents of the extension, including some leaders in the Liberal Party (PL) and Progressive Party (PP), say the measure would harmonize Brazil's intellectual property framework with practices in other markets and support research and development. Opposing voices, including national manufacturers organized under Grupo FarmaBrasil, argue that extending exclusivity would delay the entry of generics and biosimilars, reduce competition, and hurt access to more affordable treatments for both patients and public health systems such as the Unified Health System. The dispute reflects broader tensions between protecting pharmaceutical innovation and expanding access, with the potential impacts of any legislative change closely watched by both industry and health policy stakeholders. Read more.

BRAZIL'S WEIGHT-LOSS DRUG MARKET COULD REACH R$1 TRILLION AMID GLP-1 BOOM

The Brazilian market for weight-loss medications, especially GLP-1 agonists such as semaglutide and tirzepatide, is experiencing rapid expansion and could eventually generate up to R$ 1 trillion in economic activity across the broader health and retail ecosystem, according to a detailed market analysis published by Panorama Farmacêutico. Although current sales remain far smaller, the category's growth has been driven by strong demand for injectable therapies originally developed for type 2 diabetes that also promote significant weight loss, reshaping pharmacy revenue streams, and consumer behavior. Many of these products, including Ozempic, Wegovy and Mounjaro, now command a significant share of pharmacy sales despite logistical and security challenges in storage and distribution. The analysis highlights that the potential R$1 trillion market reflects not only direct sales of weight-loss drugs themselves but also downstream impacts on related segments such as nutritional supplements, dermocosmetics and broader wellness services, as patients adopt holistic approaches to health. However, there are notable access barriers: only a minority of Brazilian pharmacies are currently equipped to handle cold-chain logistics, and distribution remains concentrated among larger pharmacy networks, limiting availability in smaller and remote markets. Wider adoption of generics and biosimilars could expand access and volume, while also reshaping pricing and profitability dynamics for pharmacies and manufacturers alike. Read more.

BRAZILIAN PHARMA INDUSTRY BODY WARNS NEW DRUG PRICING RULES COULD BACKFIRE

The Sindusfarma has issued a strong critique of new drug pricing regulations introduced at the end of 2025, arguing that the policy changes embedded in Resolution No. 3/2025 of the Medicines Market Regulation Chamber (CMED) risk increasing bureaucracy, legal uncertainty, and instability across Brazil's pharmaceutical market. The association's president-executive, Nelson Mussolini, articulated these concerns in an opinion piece, asserting that several elements of the new framework diverge from international best practices and could inadvertently hamper innovation and patient access to medicines. According to Sindusfarma, a key worry is the requirement that manufacturers submit pricing requests before obtaining sanitary approval from the National Health Surveillance Agency (Anvisa), a step that in many mature regulatory jurisdictions, such as the United States or European Union, comes later in the development process. The association also flagged provisions allowing CMED to determine prices if companies fail to meet submission deadlines, along with expanded use of provisional pricing and a larger "reference basket" of foreign markets, which it claims introduces complexity and unpredictability into Brazil's regulatory environment. Sindusfarma warns that such uncertainty may increase litigation, contract instability, and operational risk for both public and private purchasers, ultimately undercutting sustainable access to medicines. Read more.

BRAZILIAN COURT ORDERS EMS TO COMPENSATE THE NATIONAL GOVERNMENT AFTER TECHNOLOGY TRANSFER FAILURE

A federal court in Rio de Janeiro has ruled that EMS and Instituto Vital Brazil must reimburse the Federal Government of Brazil for contractual failures in a Productive Development Partnership (PDP) agreement with the Ministry of Health of Brazil. The PDP, set up in 2012, aimed to localize production of the cancer medicine mesylate of imatinib used in the public health system by transferring the full production technology to the public partner. According to the judgment delivered by Judge Vivian Machado Siqueira of the 29th Federal Court of Rio, the technology transfer obligation was not fulfilled despite regular delivery of the medicine to patients, undermining the core purpose of the contract. The court determined partial nullity of the agreement and that the value paid beyond market prices for the unfulfilled transfer must be repaid, though the exact amount will be calculated in subsequent proceedings. The ruling holds EMS responsible for 90 % of the reimbursement owed to the Union, with transportation of the remaining liability to the Instituto Vital Brazil. The government's position highlights that payments above market levels were justified only by the expectation of full technology absorption, which did not materialize, constituting an "unjust enrichment" under Brazilian civil law. EMS has contested the decision and filed appeals, asserting that the transfer was completed and underpinning its argument with the existing regulatory approval that enables the Instituto Vital Brazil to produce the medicine. Read more.

BRAZIL AND CHINA DISCUSS STRENGTHENING COOPERATION ON DRUG AND VACCINE PRODUCTION

Representatives from the Ministry of Health's Secretariat for Science, Technology and Health Innovation (SCTIE) met with a high-level delegation from Sinopharm's state-linked pharmaceutical group, including executives from its CNBG unit and affiliated entities like the Beijing Institute of Biological Products (BIBP) and East Biotech, to explore strategic cooperation opportunities to bolster production of medicines, vaccines and blood-derived products. The meeting, held in Brasília on 22 January, focused on identifying avenues for collaboration that can help develop technological capabilities and enhance scientific and production sovereignty in health technologies for both countries. Officials highlighted Brazil's interest in leveraging its Productive Development Partnerships (PDP) and Development and Local Innovation (PDIL) programs as instruments to facilitate partnerships with Chinese industry and research institutions, with the goal of expanding access to strategic health products for the Unified Health System (SUS). The discussion builds on prior ministerial engagement, including missions by the Brazilian Minister of Health to China in 2025, with an emphasis on combining technological platforms, innovation, and cost-effective production to benefit public health. Read more.

BRAZIL MERCOSUL–EU TRADE DEAL BRINGS OPPORTUNITIES AND RISKS FOR PHARMACEUTICALS

The recently signed Mercosul–European Union** Partnership Agreement**, a historic free-trade pact concluded after more than two decades of negotiations and formalized in January 2026, is set to create one of the world's largest preferential trade areas, covering tariffs on goods including pharmaceuticals, machinery, and agricultural products. If ratified by the Parliament of the European Union and the Brazilian National Congress, the agreement will gradually reduce import duties on a wide range of products traded between the blocs—potentially lowering prices for medicines and active pharmaceutical ingredients imported into Brazil and expanding export opportunities for Brazilian producers. The deal extends tariff cuts over phased schedules lasting up to about a decade, supporting deeper commercial integration across global supply chains. However, industry analysts and domestic stakeholders also highlight potential challenges for Brazil's pharmaceutical sector. While tariff reductions could make some imported drugs and components cheaper, increased competitive pressure from European producers might affect local manufacturing, especially in sectors with weaker technological capacity. Critics have also expressed concern about how regulatory convergence and stronger intellectual property standards embedded in broader trade frameworks might influence access to generics and biosimilars, although explicit "TRIPS-plus" measures were not included in the final treaty text after sustained civil society pressure during negotiations. Balancing expanded market access with protections for domestic industry and health sovereignty will be a central theme as lawmakers and industry groups analyze the pact ahead of final approvals. Read more.

BRAZIL ROCHE PROJECTS GROWTH RECOVERY IN BRAZIL IN 2026 AFTER PORTFOLIO CHANGE

Roche is projecting a recovery in its growth trajectory in Brazil in 2026, reflecting strategic adjustments to its product portfolio and renewed momentum after recent market challenges. According to reporting based on Valor Econômico, the Swiss drugmaker expects its business in Brazil to benefit from a mix of innovative therapies and portfolio optimization, positioning the country as a key growth market amid broader company efforts to offset global macroeconomic and currency headwinds. Locally, Roche has been adapting its offerings to align with demand in areas such as oncology, immunology, and specialized medicines, while navigating dynamics such as pricing pressures and competition from biosimilars. Roche's broader global outlook also signals mid single-digit sales growth and high single-digit core earnings per share growth in 2026, supported by continued uptake of key medicines and an expanding pipeline—a context that could reinforce Brazil's contribution to the group's performance. The strategic shift includes prioritizing products with strong clinical demand and adjusting to a dynamic environment where digital health channels, pricing policies and local regulatory factors shape market access. As such, executives see Brazil not only as a significant operational region but also as a growth platform that can help sustain Roche's performance amid evolving global pharmaceutical trends. Read more.

BRAZIL MINISTRY OF HEALTH EXPANDS FUNDING TO ATTRACT PARTICIPATION IN AGORA TEM ESPECIALISTAS

The Ministry of Health has increased the financial remittances offered to encourage hospitals and medical providers to join the federal program Agora Tem Especialistas, a scheme designed to reduce waiting times for specialist consultations, procedures, and surgeries within the Unified Health System (SUS). Under the revised terms, the amount reimbursable for surgical procedures contracted through the program could be up to four times the SUS reference rates, compared with the previous level of up to 1.5 times, signaling a more generous incentive structure to attract participation from private and philanthropic hospitals. This adjustment reflects a broader federal effort to integrate unused capacity from the private sector into public health delivery and to address longstanding backlogs in specialist care across cardiology, orthopedics, oncology, and other priority areas. Proponents argue that higher reimbursement rates and clearer contractual conditions may help accelerate institutional adhesion to the program, which seeks to mobilize private infrastructure and trained specialist teams to expand access for SUS patients in underserved regions. The enhanced incentives also align with

elevated federal budget allocations for Agora Tem Especialistas in recent years and complement other strategies to streamline specialist medical care and surgical throughput. Analysts and health policy observers note that financial inducements will need to be paired with improvements in coordination, workforce distribution, and referral networks to realize significant reductions in waiting lists over the medium term. Read more.

BRAZIL ANVISA AUTHORISES MEDICINAL CANNABIS CULTIVATION AND EXPANDS THERAPEUTIC USE

National Health Surveillance Agency (ANVISA) has approved a new regulatory framework that authorizes, under strict conditions, the cultivation of cannabis for medicinal purposes in Brazil, marking a significant shift in the country's approach to plant-based therapies. The resolution allows legal entities to grow cannabis with a tetrahydrocannabinol (THC) content of up to 0.3 %, strictly for the production of medicines and other health products under sanitary control, in line with a Superior Court of Justice (STJ) determination to regulate cultivation by 31 March 2026. Meanwhile, patient associations and research institutions may also engage in authorized cultivation activities under controlled programs. In addition to cultivation, ANVISA's decision broadens permitted uses of cannabis-derived medicines, authorizing the sale of cannabidiol in compounding pharmacies and expanding routes of administration to buccal, sublingual, and dermatological formulations beyond the previously allowed oral and inhaled forms. The regulation also facilitates importation of raw plant material or extracts for pharmaceutical manufacturing and expands access to therapies for patients with chronic and debilitating conditions, subject to medical prescription. This development aims to enhance regulatory certainty, reduce dependence on imports and support domestic research, production, and patient access to cannabis-based treatments in the Brazilian health system. Read more.

BRAZIL ANVISA DECISION THAT EXPANDED MEDICINAL CANNABIS ACCESS IS EXPECTED TO REDUCE LEGAL DISPUTES

A recent regulatory decision by the National Health Surveillance Agency (ANVISA) that broadens access to medicinal cannabis products and allows new participants such as compounding pharmacies to produce cannabidiol therapeutics is expected to mitigate the high volume of litigation seen in the sector. Under the updated rules, pharmacies of manipulation can extract active cannabis ingredients for local production rather than relying exclusively on imported ready-to-use inputs, a change that specialists say will help correct market imbalances and reduce legal claims brought by pharmacies and patients seeking judicial authorizations for access. By providing clearer regulatory pathways and integrating more healthcare actors into the regulated market, the decision aims to reduce uncertainty that had driven extensive legal action. Experts quoted in the reporting also see increased competition and pricing dynamics as a possible outcome of the regulatory shift, with expanded participation in cannabis therapeutics potentially lowering costs and encouraging sector-wide compliance with safety standards. The new framework, which authorizes cultivation of Cannabis sativa with a THC limit of up to 0.3 % for medicinal and research purposes and includes provisions for phased implementation, responds in part to sustained judicial pressure that previously filled regulatory gaps in access to cannabis-based medicines. Read more.

ANVISA APPROVAL DOES NOT MEAN IMMEDIATE ACCESS TO NEW MEDICINES

Even after the National Health Surveillance Agency (ANVISA) grants marketing authorization to a new pharmaceutical product in Brazil, patients do not automatically gain immediate access to that medicine. According to reporting from Folha de S. Paulo, the regulatory approval is just one step in a broader process: after ANVISA's decision, companies must still demonstrate that the medicine can be manufactured at scale with consistent quality, undergo price approval where applicable, and complete distribution arrangements before the product reaches pharmacies and health systems. In addition, public and private coverage pathways are separate: inclusion in the National Supplementary Health Agency (ANS) mandatory list or evaluation by the National Commission for Health Technology Incorporation (CONITEC) for the Unified Health System (SUS) are additional processes that influence whether and how patients

can receive the treatment. The reporting highlights that each of these steps (production readiness, price regulation, and technology incorporation) has its own timeline and criteria, meaning that even after regulatory clearance there can be months or longer before broad access is realized. In the private market, private insurers must update their coverage lists based on ANS rules before including newly authorized medicines, while in SUS the CONITEC assessment and Ministry of Health decision precede procurement and dispensing. These layers of regulatory, pricing, and coverage decisions help ensure safety, cost-effectiveness, and health system sustainability but also explain why ANVISA's approval alone does not equal immediate availability for patients across Brazil. Read more.

BRAZIL ANS WILL FORM WORKING GROUP TO REGULATE DISCOUNT HEALTH CARDS

The National Supplementary Health Agency (ANS) announced plans to establish a working group by February 2026 to begin structuring the regulatory framework for discount health cards, a product that has proliferated in Brazil as an alternative to traditional private health insurance. ANS President Wadih Damous said in an interview with JOTA that the initiative responds to growing judicial and market pressure for regulatory clarity on the cards' operation, distinguishing them from conventional health plans, and improving consumer protection. The move follows a Superior Tribunal of Justice (STJ) decision affirming ANS's competence to oversee discount cards, based on their function in connecting users with medical services, even if they do not provide traditional coverage of financial risk. The working group is expected to map the market, discuss definitions and operational norms, and propose regulatory contours for the segment—helping ensure transparency, clear differentiation from health plans and stronger consumer rights in a space that has grown without formal oversight. Read more.

BRAZIL ADDS NEW CANCER MEDICINE TO MANDATORY PRIVATE HEALTH COVERAGE LIST

The National Supplementary Health Agency (ANS) has approved the incorporation of a new oncology medicine into Brazil's Mandatory Health Procedures and Events List, expanding the treatments that must be covered by private health insurance plans nationwide. The decision follows a technical assessment and public consultation process and applies to adult patients diagnosed with intermediate- and high-risk primary myelofibrosis, as well as post-polycythemia vera and post-essential thrombocythemia myelofibrosis—rare hematologic cancers that affect bone marrow function and blood cell production. According to the regulator, the inclusion aims to broaden therapeutic options and improve clinical outcomes for patients with limited treatment alternatives. Once the decision comes into force, health insurers will be required to provide coverage for the medicine under the conditions defined by ANS, reinforcing the agency's role in periodically updating the coverage list in line with scientific evidence and cost-effectiveness criteria. The measure is part of ANS's broader regulatory mandate to ensure access to effective and safe treatments within Brazil's supplementary health system. Read more.

BRAZIL PRIVATE HEALTH PLANS SEE FASTER GROWTH IN SPENDING ON MEDICINES THAN ON MEDICAL SERVICES

Spending by private health insurance plans in Brazil on medications and pharmacy-dispensed products grew at a significantly faster pace than expenditures on medical and hospital services in recent years, according to a sector analysis published by Medicina S/A. Data show that while total costs for medical and hospital care expanded moderately, outlays on medicines rose sharply, reflecting broader trends in drug utilization, higher prices for innovative therapies and greater patient reliance on outpatient pharmacological treatment. This shift has implications for how insurers manage benefit designs, premium levels, and cost-containment strategies, particularly in light of pressures on private plan sustainability and consumer affordability. Sector analysts note that the acceleration in medicine-related costs is linked to multiple factors: rising incidence of chronic diseases requiring long-term drug regimens, increased uptake of high-cost specialty medicines, and the expansion of digital pharmacy channels that facilitate medication access. Insurers are responding with diverse strategies such as formularies, negotiation with

drug manufacturers, utilization management tools and preventive health initiatives aimed at slowing cost growth and balancing comprehensive coverage with financial sustainability. These developments are reshaping the economics of supplementary health in Brazil, where pharmaceutical expenditure now represents a growing share of total plan costs and a central focus for regulatory and industry discussion. Read more.

BRAZIL DIGITAL HEALTH IN SUS ADVANCES WITH EXPANDED TELEHEALTH AND RNDS RECORDS

Brazil's Ministry of Health has reported significant progress in **digital health initiatives within the Unified Health System (SUS), driven by the expansion of telehealth services and the increasing use of the National Health Data Network (RNDS) as a central digital platform. In 2025, the public system added 36 new telehealth centres (with over one-third based in municipal health secretariats), while telehealth services were provided across 52 % of Brazilian municipalities, totaling 5.7 million remote consultations. At the same time, RNDS aggregated 4.3 billion health records, representing a nearly fivefold increase over three years as part of the broader digital strategy for the health sector. These developments reflect a push to leverage digital tools to improve access to care, speed up diagnoses, and strengthen continuity of services across geographically diverse regions. The RNDS now includes vast datasets—from laboratory results and immunizations to high-complexity procedure authorizations and medication prescriptions—and its formal recognition as SUS's official interoperability platform has opened the door to integrations with private sector data such as through the National Supplementary Health Agency (ANS), which contributed an additional 1 billion records from supplementary health in 2025. By enhancing connectivity, data sharing and telehealth coverage, digital health strategies aim to reduce inequities, support clinical decision-making, and modernize public healthcare delivery, although stakeholders continue to work on infrastructure, privacy and capacity challenges as the agenda unfolds. Read more.

BRAZIL HIGHLIGHTS DIGITAL PATIENT TRENDS FOR HEALTHCARE IN 2026

A recent online event and study release titled "Digital Patient Profile: new data set to impact medical practices in 2026" showcased new insights into how Brazilian patients are engaging with healthcare through digital technologies. Organized by the global health platform Doctoralia, the Doctoralia Connect session on January 27, 2026, presented data showing that over 88 million medical consultations in Brazil were scheduled digitally in 2025, reflecting a structural shift in patient behavior toward mobile and online interaction. The study also found that the majority of users access health services via smartphones and that women account for about 72 % of digital engagements, often arranging care not only for themselves but also for family members. The event underscored that digital engagement is not just about technology: patients increasingly expect seamless booking, transparent information, and personalized interactions across digital channels, and these expectations are reshaping how healthcare professionals organize care delivery. Insights shared in the session highlighted trends such as the rise in telemedicine utilization, reputation management through online reviews, and a broader cultural change toward patient empowerment in decision-making. These developments point to a digital health landscape in Brazil where digital touchpoints become integral to patient journeys and clinical practice in 2026. Read more.

BRAZIL ONLINE SALES OF MEDICINES CONSOLIDATE AS MAJOR RETAIL CHANNEL

Sales of medicines through online channels in Brazil have become a structural and rapidly growing component of the pharmaceutical market, with digital purchases increasingly accepted by consumers and retailers alike. Data compiled from the main digital pharmacies and brick-and-mortar networks shows that, between December 2024 and November 2025, online pharmacy sales exceeded R$ 20 billion, a record figure that reflects both rising demand and deeper consumer confidence in e-commerce mechanisms for acquiring medications and health-related products. During this period, digital channels accounted for approximately 18 % of total pharmacy sales, compared with just 3 % in 2020, signaling a pronounced shift toward digital retailing in pharmaceutical commerce. Industry groups attribute this expansion to broader

digital adoption and improvements in logistics, mobile accessibility, and platform reliability, which are making e-commerce a mainstream channel for medicine procurement rather than a niche alternative. The number of customers shopping for medicines online surpassed 150 million over the 12-month period, with an average of 12.6 million customers per month, reinforcing how online platforms now play a strategic role in how Brazilians manage their health needs. Analysts and sector representatives expect the trend to continue as digital penetration deepens and regulatory clarity around online pharmaceutical sales evolves, potentially reshaping distribution models and competitive dynamics in Brazil's healthcare retail sector. Read more.

MORE HIGHLIGHTS

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