WEEKLY REPORT

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BRAZIL REVISES PRICING RULES FOR NEW MEDICINES AND EXPANDS NEGOTIATION MECHANISMS FOR INNOVATIVE THERAPIES

The Drug Market Regulation Chamber (CMED) published a new resolution revising the criteria used to define prices for newly launched medicines in Brazil, expanding negotiation mechanisms for products classified as innovative while tightening rules for incremental innovation claims. Under the updated framework, companies seeking differentiated pricing will need to provide stronger evidence of therapeutic benefits, economic advantages or healthcare system impact. The measure is part of a broader effort to modernize Brazil's pharmaceutical pricing model amid growing debates over access, innovation and regulatory transparency. The new rules also establish stricter international reference pricing criteria, preventing launch prices in Brazil from exceeding the lowest price observed in countries used as CMED benchmarks. Read more.

INTERFARMA CALLS FOR REVISIONS TO BRAZIL'S NEW DRUG PRICING RULES AND WARNS OF REGULATORY UNCERTAINTY

The Pharmaceutical Industry Research Association (Interfarma) publicly defended revisions to Resolution No. 3/2025 of the Drug Market Regulation Chamber (CMED), arguing that important aspects of Brazil's new pharmaceutical pricing framework still require greater clarity, predictability and legal certainty. While supporting the modernization of the country's drug pricing system, the association stated that the effectiveness of the reform depends on a stable and transparent regulatory environment capable of encouraging innovation and investment. Interfarma welcomed the government's decision to postpone the resolution's implementation by 30 days, describing the delay as an opportunity to improve technical aspects of the regulation. According to the association, concerns include the criteria used for price definition, the use of off-label comparators in pricing evaluations, the operationalization of provisional pricing mechanisms and the predictability of rule enforcement. Interfarma also criticized requirements related to the submission of the Drug Price Information Dossier (DIP) without what it considers a clear legal basis and warned that provisions linked to manufacturing origin or production location could create competitive distortions. The entity argues that regulatory uncertainty may delay product launches, reduce incentives for introducing innovative medicines in Brazil and ultimately affect patient access to new therapies. Read more.

BRAZIL STUDY QUESTIONS DRUG PRICE CAP SYSTEM AND HIGHLIGHTS GAPS IN CMED REGULATION

A study cited by journalist Miriam Leitão has raised new concerns about Brazil's pharmaceutical price regulation system, identifying cases in which the maximum price authorized by the government exceeded actual public procurement prices by as much as 2,686%. The research, conducted by the Brazilian Institute for Consumer Protection (Idec) alongside healthcare specialists, examines the methodology used by the Drug Market Regulation Chamber – CMED to establish medicine price ceilings in the country. According to the study, the gap between regulated ceiling prices and real market prices may create room for significant price increases, particularly in scenarios involving supply shortages or limited competition. Consumer advocates argue that the current model reduces the effectiveness of price regulation and may negatively affect access to medicines, while industry representatives maintain that pricing flexibility is necessary to ensure supply security, innovation and market sustainability. The findings add

momentum to ongoing discussions about potential reforms to Brazil's drug pricing framework and greater transparency in CMED's regulatory criteria. Read more.

BRAZIL SUPREME COURT JUSTICE PROMOTES CONFIDENTIAL PRICING AND RISK-SHARING AGREEMENTS FOR HIGH-COST MEDICINES

Supreme Federal Court Justice Gilmar Mendes has intensified discussions on new financing models for high-cost medicines in Brazil, defending both confidential pricing mechanisms and risk-sharing agreements as tools to expand access to innovative therapies while reducing pressure on public healthcare budgets. Speaking at recent events involving government officials, regulators, pharmaceutical companies and legal experts, Mendes argued that confidential discounts for medicines purchased by Brazil's Unified Health System (SUS) could allow the government to negotiate lower prices without affecting international reference prices, while risk-sharing arrangements could distribute the financial uncertainties associated with expensive treatments among manufacturers and healthcare payers. The debate comes amid growing concerns over judicialization, rare disease treatments and the sustainability of healthcare financing. Risk-sharing agreements have attracted increasing attention as authorities evaluate alternatives for funding advanced therapies, including gene therapies and other treatments that can cost millions of reais per patient. Participants in the discussions highlighted international experiences with outcome-based payment models and confidential procurement arrangements, which are designed to link reimbursement to real-world treatment performance and budget impact. According to stakeholders involved in the discussions, both mechanisms could become increasingly relevant as Brazil seeks to balance patient access, innovation and fiscal sustainability in the public and private healthcare systems.

ANVISA REPORTS 11% INCREASE IN CLINICAL TRIAL APPLICATIONS IN 2025

The Brazilian Health Regulatory Agency (Anvisa) reported an 11% increase in clinical trial applications submitted in Brazil in 2025, according to the agency's annual clinical research report. Anvisa received 352 clinical trial dossiers last year, compared with 315 in 2024, reflecting continued growth in research activity involving new medicines and biological products. The agency noted, however, that the increase does not yet reflect the practical effects of Brazil's new Clinical Research Law, as the regulation was only fully implemented in late 2025. The report also showed that Phase 3 studies remained dominant, accounting for 64% of all submissions, while Phase 1 trials represented only 4% of studies over the last five years, highlighting Brazil's continued role as a destination for late-stage multinational research rather than early-stage innovation. Anvisa further reported that 93% of clinical trials submitted during the period originated from foreign sponsors. The agency stated that future data may better demonstrate the impact of Law 14.874/2024 and new regulations designed to accelerate approvals, improve regulatory efficiency and strengthen Brazil's position as a clinical research hub. Read more.

ANVISA INCREASES TRANSPARENCY IN BIOLOGICAL AND RADIOPHARMACEUTICAL REVIEW QUEUES

The Brazilian Health Regulatory Agency (Anvisa) announced changes to the public disclosure of review queues for biological products and radiopharmaceuticals, aiming to improve transparency and regulatory predictability. The agency will simplify the current structure by consolidating priority review requests into a single priority queue, replacing the existing model that separates cases under different prioritization regulations, including RDC 205/2017 and RDC 1.001/2025. The new system will also include applications that were initially submitted through the ordinary pathway but later received priority status after regulatory approval. According to Anvisa, the measure will provide a more complete view of pending priority reviews and facilitate monitoring by companies, healthcare stakeholders and the public. The initiative is part of broader efforts to reduce regulatory backlogs, modernize review processes and strengthen communication with the regulated sector, particularly in strategic areas such as biological medicines and radiopharmaceuticals. The agency has recently implemented

additional measures focused on queue reduction, optimized reviews and increased efficiency in the assessment of innovative health technologies. Read more.

ANVISA EXPANDS APPROVALS FOR MIGRAINE, DIABETES AND PARKINSON'S DISEASE TREATMENTS

The Brazilian Health Regulatory Agency (Anvisa) approved a series of new therapies and registrations aimed at expanding treatment options for patients with chronic and neurological diseases in Brazil. Among the decisions, the agency authorized a new medicine for migraine prevention, approved a treatment for Parkinson's disease and granted registration for a generic medicine used in the treatment of type 2 diabetes. The approvals are part of Anvisa's ongoing efforts to increase access to innovative and lower-cost therapies while strengthening competition in the pharmaceutical market. According to the agency, the new migraine treatment offers an additional option for patients with recurrent and disabling headaches, while the Parkinson's therapy expands the range of available treatments for managing motor symptoms associated with the disease. In parallel, the approval of a generic medicine for type 2 diabetes is expected to increase market competition and improve affordability for patients requiring long-term glycemic control.

ANVISA EXPANDS INDICATION OF LUNG CANCER IMMUNOTHERAPY

The Brazilian Health Regulatory Agency (Anvisa) approved an expanded indication for Tevimbra® (tislelizumab), allowing its use in adult patients with resectable non-small cell lung cancer (NSCLC) who face a high risk of disease recurrence. Under the new authorization, the immunotherapy may be administered in combination with platinum-based chemotherapy before surgery and later used as adjuvant treatment following tumor removal. The decision broadens the therapeutic role of tislelizumab in earlier stages of lung cancer management and reflects growing regulatory support for perioperative immunotherapy strategies in oncology. According to Anvisa, the expanded indication is intended for patients whose tumors can be completely removed through surgery, but who remain at elevated risk of recurrence after treatment. The approval follows evidence showing benefits from combining immunotherapy with chemotherapy before surgical intervention and continuing treatment afterward to reduce the likelihood of disease progression. The decision adds to a series of recent regulatory approvals involving new oncology indications and advanced cancer therapies in Brazil. Read more.

BRAZILIAN COURTS CHALLENGE ANVISA RESTRICTIONS ON IMPORTS OF PARAGUAYAN WEIGHT-LOSS DRUGS

The growing importation of GLP-1 and GIP-based weight-loss medicines from Paraguay has sparked a legal and regulatory dispute between patients and the Brazilian Health Regulatory Agency – Anvisa. The controversy centers on restrictions imposed by the agency on the personal importation of medicines such as semaglutide and tirzepatide, amid concerns over product quality, traceability, storage conditions and patient safety. As demand for obesity treatments continues to rise, consumers and some legal experts have argued that personal imports should remain permitted under specific circumstances, particularly when substantial price differences exist between Brazil and neighboring countries. The debate has intensified following a series of court decisions authorizing patients to import Paraguayan versions of tirzepatide for personal use despite Anvisa's restrictions. Judges have granted injunctions when patients present valid medical prescriptions, demonstrate therapeutic necessity and show no commercial intent, arguing that treatment interruptions may pose significant health risks. Anvisa maintains that the products lack Brazilian regulatory approval and may present safety concerns, while patient advocates contend that access should be preserved when supported by medical supervision. Legal specialists note that the cases could establish important precedents regarding the limits of Anvisa's authority, cross-border access to medicines and the balance between individual rights and public health protections. Read more.

ANVISA HALTS IRREGULAR PRODUCTION OF COMPOUNDED WEIGHT-LOSS INJECTIONS

The Brazilian Health Regulatory Agency (Anvisa) suspended the production and commercialization of compounded weight-loss injections manufactured irregularly by a compounding pharmacy after identifying violations involving the handling and preparation of injectable products. According to the agency, the company was producing formulations marketed as alternatives to GLP-1-based obesity treatments without complying with regulatory requirements applicable to sterile injectable medicines, raising concerns about product quality, safety and traceability. The enforcement action comes amid rapidly growing demand for weight-loss therapies such as semaglutide and tirzepatide in Brazil, which has fueled the emergence of compounded and non-industrialized alternatives. Anvisa stated that injectable products require strict manufacturing controls to prevent contamination and ensure product stability, efficacy and patient safety. The case reinforces broader regulatory concerns over unauthorized obesity treatments and the expansion of parallel markets seeking to meet increasing demand for anti-obesity medicines. Read more.

BRAZILIAN PHARMACEUTICAL INDUSTRY SUPPORTS BAN ON COMPOUNDED WEIGHT-LOSS INJECTIONS AMID SAFETY CONCERNS

Pharmaceutical industry representatives are defending stricter regulatory measures against compounded injectable weight-loss treatments, arguing that products prepared by compounding pharmacies should not be used as substitutes for industrially manufactured GLP-1 medicines such as semaglutide and tirzepatide. The debate intensified after the Brazilian Health Regulatory Agency (Anvisa) suspended the production of irregular compounded obesity injections and increased oversight of the sector. Industry associations contend that injectable medicines require rigorous manufacturing controls, quality validation and sterility standards that differ substantially from traditional compounding activities. According to stakeholders interviewed by Valor Econômico, the growing demand for obesity treatments has encouraged the expansion of compounded alternatives amid shortages and high prices of branded GLP-1 therapies. Pharmaceutical companies argue that the use of compounded injectables may create risks related to contamination, dosage inconsistencies and lack of clinical validation. Representatives of the compounding sector, however, maintain that pharmacies operate under existing regulations and help meet patient demand when commercial products face supply constraints. The discussion comes as Brazil experiences rapid growth in the obesity treatment market and increasing regulatory scrutiny over alternative formulations of high-demand medicines. Read more.

BRAZILIAN HEALTH REGULATORY AGENCY APPROVES FIRST NATIONAL SEMAGLUTIDE PEN FOLLOWING OZEMPIC PATENT EXPIRATION

The Brazilian Health Regulatory Agency (Anvisa) approved the registration of Ozivy, the first nationally developed semaglutide pen authorized in Brazil following the expiration of Novo Nordisk's patent for Ozempic in March 2026. Manufactured by Brazilian pharmaceutical company EMS, the product contains synthetic semaglutide, the same active ingredient used in Ozempic, and was approved for the treatment of adults with type 2 diabetes as an adjunct to diet and exercise. The approval marks the first regulatory authorization for a semaglutide-based competitor since the patent expired, opening the market to new entrants and increasing competition in one of the fastest-growing pharmaceutical segments. According to Anvisa, Ozivy underwent the agency's technical review process for efficacy, safety and quality and will be marketed as a once-weekly injectable pen. The approval is expected to intensify competition in Brazil's GLP-1 market, which has experienced strong demand driven by diabetes treatment and growing interest in obesity therapies. EMS has indicated that it also plans to seek authorization for weight-loss indications in the future. Industry analysts expect the arrival of national competitors to increase access and place downward pressure on prices as additional semaglutide products enter the Brazilian market. Read more.

BRAZIL TO DEFINE MAXIMUM PRICE FOR FIRST NATIONAL SEMAGLUTIDE PEN WITHIN WEEKS, SAYS HEALTH MINISTER

Health Minister Alexandre Padilha said Brazil's pharmaceutical pricing authorities are expected to define the maximum price for Ozivy, the first nationally developed semaglutide pen approved by the Brazilian Health Regulatory Agency (Anvisa), within two to three weeks. The product, developed by Brazilian pharmaceutical company EMS, was recently authorized following the expiration of Novo Nordisk's patent protection for Ozempic in Brazil and is expected to become one of the first local competitors in the country's rapidly expanding GLP-1 market. According to EMS executives, the company expects the product to be launched at a price approximately 30% lower than Ozempic, although final commercialization depends on pricing approval by the Drug Market Regulation Chamber – CMED. The decision is being closely monitored by industry stakeholders, healthcare providers and patients, as increased competition in the semaglutide market could expand access to diabetes treatments and place downward pressure on prices. The case also highlights broader discussions regarding pharmaceutical competition, patent expirations and affordability of GLP-1 therapies in Brazil. Read more.

BRAZIL PATENT TERM EXTENSION PROPOSAL FACES GROWING OPPOSITION FROM HEALTH AND INNOVATION GROUPS

A growing coalition of healthcare, academic, consumer protection and domestic pharmaceutical industry organizations is opposing Bill of Complementary Law (PLP) 32/2026, which would create a patent term adjustment mechanism in Brazil for cases involving administrative delays by the National Institute of Industrial Property – INPI. The proposal would allow patent holders to receive up to five additional years of protection when delays in patent examination are not attributable to applicants. Supporters argue that the measure would strengthen legal certainty, protect innovation and align Brazil with international intellectual property practices. Opponents include the Brazilian Institute for Consumer Protection (Idec), the Brazilian Society of Bioethics (SBB), the Brazilian Association of Fine Chemicals, Biotechnology and Specialties (ABIFINA), PróGenéricos, Grupo FarmaBrasil (GFB), the Brazilian Association of Collective Health (Abrasco), the Brazilian Academy of Sciences (ABC) and the Forum of Innovation and Technology Transfer Managers (Fortec). These organizations argue that the proposal could reintroduce mechanisms similar to those struck down by the Supreme Federal Court (STF) in 2021, delaying the entry of generic and biosimilar medicines, increasing healthcare expenditures and creating barriers to access within Brazil's Unified Health System (SUS). The Pharmaceutical Research and Manufacturers Association (Interfarma), meanwhile, has supported the bill, arguing that compensation for administrative delays would promote innovation and improve Brazil's competitiveness in attracting research and development investments. Read more.

ANS SETS 5.11% CAP FOR INDIVIDUAL AND FAMILY HEALTH PLAN PREMIUMS

The National Supplementary Health Agency (ANS) approved a maximum annual adjustment of 5.11% for individual and family health insurance plans in Brazil, the lowest positive increase established by the regulator since the current methodology was introduced, excluding the exceptional negative adjustment applied during the Covid-19 pandemic in 2021. The new ceiling will apply between May 2026 and April 2027 and affects approximately 7.7 million beneficiaries, representing about 14.5% of the country's private health insurance market. According to ANS, the adjustment calculation considers medical and hospital cost inflation, healthcare utilization rates and efficiency gains within the sector. The measure applies only to individual and family plans regulated by the agency, while collective plans (which account for the majority of Brazil's supplementary healthcare market) remain subject to direct negotiations between operators and contracting entities. Consumer groups continue to advocate for stronger oversight of collective plan increases, while industry representatives argue that rising healthcare costs, technological incorporation and demographic changes continue to pressure operators' financial sustainability. Read more.

BRAZILIAN HEALTH INSURERS TARGET HIGH-INCOME CLIENTS WITH CONCIERGE SERVICES AND EXCLUSIVE CARE MODELS

Health insurance companies in Brazil are increasingly competing for high-income customers by expanding premium healthcare offerings that include concierge services, exclusive care units, personalized medical coordination and differentiated hospital access. Major operators have been investing in luxury-oriented healthcare models as demand grows among affluent consumers seeking faster access, greater convenience and more personalized healthcare experiences. According to industry executives, the segment has shown strong growth despite broader cost pressures affecting the supplementary healthcare market. The strategy reflects a broader movement toward segmentation within Brazil's private healthcare sector, where insurers are creating differentiated products aimed at retaining higher-value customers and reducing migration to competing plans. Premium offerings often include dedicated care teams, preventive health programs, executive health check-ups and access to exclusive facilities. The trend also highlights ongoing challenges involving healthcare affordability and inequalities in access, as operators seek to balance service differentiation with rising medical costs and increasing regulatory scrutiny over healthcare quality and sustainability. Read more.

ANS AND ABBVIE SIGN AGREEMENT TO EXPAND DISCOUNTS FOR HIGH-COST MEDICINES IN PRIVATE HEALTHCARE

The National Supplementary Health Agency (ANS) and pharmaceutical company AbbVie signed a technical cooperation agreement aimed at expanding the use of discount and managed-entry mechanisms for high-cost medicines in Brazil's supplementary healthcare sector. The initiative is designed to support discussions on alternative access models that may help reduce the financial impact of innovative therapies on private health insurers while expanding patient access to treatment. The agreement is considered one of the first formal collaborations involving the regulator and a pharmaceutical company focused on value-based healthcare arrangements in the private market. According to stakeholders involved in the discussions, the partnership may contribute to the development of outcome-based agreements, discount models and other risk-sharing mechanisms linked to the performance of medicines in real-world settings. The initiative comes amid growing pressure from the incorporation of expensive therapies, particularly in areas such as oncology, immunology and rare diseases. Industry experts view the agreement as part of a broader movement to explore new healthcare financing models capable of balancing innovation, sustainability and patient access within Brazil's supplementary healthcare system. Read more.

BRAZIL REVISES ONCOLOGY PHARMACEUTICAL CARE ORDINANCE AND KEEPS JUNE IMPLEMENTATION TIMELINE

The Ministry of Health revised the ordinance that established the Oncology Pharmaceutical Care Component (AF-Onco) and detailed the next regulatory steps needed to implement the policy within Brazil's Unified Health System (SUS). During a meeting of the Tripartite Intermanagers Commission (CIT), the ministry reaffirmed its plan to finalize pending regulatory measures in June, including rules for oncology-specific High Complexity Outpatient Procedure Authorizations (APACs), prior authorization criteria, dilution center operations and priority technology definitions. The revised ordinance introduces technical and operational adjustments, including changes to the prior authorization model, which will now be conducted by a multidisciplinary technical team rather than a SUS audit physician. The government also expanded responsibilities for states, municipalities and oncology centers in mapping dilution facilities and organizing drug distribution flows. According to Executive Secretary Adriano Massuda, the AF-Onco framework may also serve as a model for organizing access to high-cost therapies in other areas, including rare diseases. The ministry plans to conclude regulatory agreements by late June, launch a pilot project in July and implement the new pharmaceutical care system in September. Read more.

BRAZIL FACES GAPS IN STATE ONCOLOGY PLANS AS CANCER POLICY OVERHAUL ADVANCES

Fifteen Brazilian states have not updated their oncology plans to reflect the guidelines established under the National Policy for Cancer Prevention and Control, raising concerns about the ability of local healthcare systems to implement new cancer care strategies and coordinate access to treatment. According to discussions held during the first 2026 meeting of the National Cancer Institute's Consultative Council (Consinca), outdated plans may compromise regional planning, service organization and monitoring efforts at a time when the Ministry of Health is advancing reforms such as the Oncology Pharmaceutical Care Component (AF-Onco). The Ministry of Health stated that it intends to support states in updating their oncology plans and integrating new monitoring mechanisms, including 86 indicators currently under development to assess cancer policy implementation across the country. Specialists warn that the lack of updated planning may hinder efforts to identify care gaps, organize oncology networks and expand access to services such as radiotherapy and innovative cancer treatments. The issue has gained additional relevance as the federal government works to operationalize AF-Onco and strengthen coordination between federal, state and municipal healthcare authorities. Read more.

BRAZIL LAUNCHES NATIONAL CENTER FOR DOMESTIC PRODUCTION OF ADVANCED CAR-T CANCER THERAPIES

The federal government launched the CAR-T Therapy Development and Production Center at the Oswaldo Cruz Foundation – Fiocruz, marking a major step toward the domestic production of one of the world's most advanced cancer treatments. Backed by BRL 330 million in public investment, the initiative aims to establish fully national manufacturing capacity for CAR-T cell therapies, which currently cost up to USD 400,000 per patient abroad and are expected to become available through Brazil's Unified Health System (SUS). The center will use a trispecific duoCAR-T platform transferred from U.S.-based organization Caring Cross, designed to recognize and attack three cancer targets simultaneously. According to the Ministry of Health, the technology is expected to benefit patients with leukemia, lymphoma and multiple myeloma, while also strengthening Brazil's strategic autonomy in advanced therapies. CAR-T treatment involves collecting a patient's immune cells, genetically modifying them to recognize cancer cells and reinfusing them into the body. Government officials stated that the project is part of a broader strategy to expand access to innovative oncology treatments, strengthen local biopharmaceutical production and position Brazil as a regional leader in advanced healthcare technologies. Read more.

BRAZIL PLANS TWICE-YEARLY MEDICAL LICENSING EXAM STARTING IN 2027

The Ministry of Education (MEC) plans to apply the National Medical Evaluation Exam (Enamed) twice a year starting in 2027, expanding the frequency of the assessment as part of broader efforts to strengthen quality control in medical education. According to government officials, the proposal is being discussed internally and would allow more frequent evaluations of medical graduates while increasing flexibility for candidates entering residency programs and the healthcare workforce. The initiative comes amid growing concerns over the rapid expansion of medical schools in Brazil and debates regarding professional qualification standards. The Enamed was created to assess the competencies of graduating medical students and generate indicators on the quality of medical education programs across the country. Expanding the exam to two annual editions could also facilitate regulatory monitoring and provide more frequent performance data for educational institutions and policymakers. Read more.

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