WEEKLY REPORT

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CMED DELAYS IMPLEMENTATION OF NEW DRUG PRICING RULES IN BRAZIL

The Drug Market Regulation Chamber (CMED) has postponed the entry into force of Resolution No. 3/2025, which updates the framework for drug pricing in Brazil. The measure, originally set to take effect in April 2026, has been delayed by 30 days following a decision published in the Official Gazette and signed by the Minister of Health. The resolution represents a major overhaul of pricing rules, redefining how entry prices for new medicines are established and aligning the regulatory process more closely with marketing authorization procedures. The postponement signals ongoing adjustments and stakeholder concerns regarding implementation, particularly given the regulation's broad impact on market access, pricing strategies, and regulatory predictability across the pharmaceutical sector. Read more.

BRAZILIAN SENATE TO HOLD PUBLIC HEARING ON GEOGRAPHIC ATROPHY DIAGNOSIS AND ACCESS TO NEW THERAPIES

The Social Affairs Commission of the Federal Senate (CAS) has scheduled a public hearing for May 19 to discuss the current landscape of geographic atrophy (GA), barriers to early diagnosis, and access to new therapies within Brazil's public and private healthcare systems. The initiative, led by Senator Dr. Hiran (PP-RR), aims to address gaps in care for a condition associated with the advanced stage of age-related macular degeneration. Geographic atrophy is a chronic, progressive, and degenerative disease that primarily affects individuals over 60 and is a leading cause of irreversible blindness. More than 300,000 people are estimated to live with the condition in Brazil, with prevalence expected to rise due to population aging. Despite recent international advances, no approved treatments are currently available in the country, prompting discussions on regulatory pathways and incorporation strategies. The hearing will bring together representatives from the Brazilian Council of Ophthalmology, the Brazilian Retina and Vitreous Society, patient advocacy groups, the Ministry of Health, the Brazilian Health Regulatory Agency (Anvisa), and academic experts, including ophthalmologist Mauricio Maia (Federal University of São Paulo – UNIFESP). Read more.

ANVISA HIGHLIGHTS GAINS IN ACCESS, EFFICIENCY, AND INNOVATION IN BRAZIL WITH 2025 MANAGEMENT REPORT

The Brazilian Health Regulatory Agency (Anvisa) has released its 2025 Management Report, consolidating the agency's main results and performance indicators across regulatory activities. The document emphasizes advances in expanding access to regulated products and services, alongside improvements in operational efficiency and digitalization of processes. Key highlights include progress in streamlining regulatory procedures, strengthening risk-based oversight, and expanding initiatives in innovation and research. The report also underscores Anvisa's role in modernizing regulatory frameworks and enhancing transparency, reinforcing its contribution to the Brazilian Unified Health System (SUS) and to a more agile and predictable regulatory environment. Read more.

BRAZIL EXPLORES NEW REGULATORY MODELS TO ACCELERATE ADVANCED THERAPIES

The Brazilian Health Regulatory Agency (Anvisa) is evaluating new regulatory approaches to facilitate the development and approval of advanced therapies, including gene and cell-based treatments. Among the measures under discussion are regulatory advisory models with early

engagement between the agency and developers, as well as conditional or exceptional approvals to accelerate patient access to innovative therapies. These initiatives respond to structural challenges in the field, particularly the limited availability of clinical data at early stages and the high complexity of these therapies. By strengthening collaboration with industry (especially domestic developers) Anvisa aims to support evidence generation throughout the development lifecycle while reducing regulatory uncertainty and timelines. The debate reflects a broader global trend: advanced therapies offer transformative potential for complex and rare diseases but pose significant challenges in terms of cost, evidence requirements, and system sustainability. In Brazil, stakeholders emphasize the need for integrated solutions combining regulation, financing, and access strategies to ensure that innovation translates into real-world patient benefit. Read more.

ANS DEBATES EXPANSION AND REGULATION OF COPAYMENT MODEL IN BRAZIL'S HEALTH PLANS

The National Supplementary Health Agency (ANS) is advancing discussions on the regulation and expansion of copayment mechanisms in private health plans, amid efforts to improve financial sustainability in the sector. The model—already widely used—requires beneficiaries to pay a portion of healthcare costs at the time of service, in addition to monthly premiums. The growing adoption of copayment reflects structural pressures on the system, including rising medical costs and increased utilization. Data indicate that this model has expanded significantly in recent years, as operators seek to balance affordability and cost control while maintaining access. However, the debate remains sensitive, as stakeholders highlight the need to establish clear limits and safeguards to avoid restricting access to care, particularly for high-frequency users and vulnerable populations. Regulatory discussions also focus on defining transparency standards, caps, and consumer protections, aiming to ensure that copayment mechanisms contribute to system sustainability without compromising equity or continuity of care in Brazil's supplementary health sector. Read more.

ANS ADVANCES NEW OVERSIGHT MODEL TO ANTICIPATE RISKS IN HEALTH PLANS

The National Supplementary Health Agency (ANS) is implementing a new hybrid oversight model designed to anticipate risks and improve responsiveness in the supervision of health plan operators, according to Eliane Medeiros, the agency's Director of Supervision. The framework, effective from May 2026, combines traditional complaint analysis with proactive monitoring and risk-based actions. The new approach aims to reduce the historical lag between complaints and regulatory action—previously reaching up to 18 months—by introducing real-time monitoring and selective sampling. It also incorporates artificial intelligence tools, such as the SofIA system, to identify patterns and detect early signs of operational or financial instability among insurers. The model follows a "responsive regulation" logic, prioritizing preventive engagement and guidance with operators before applying sanctions, while maintaining stricter enforcement for repeated non-compliance. Medeiros highlighted that the initiative seeks to improve beneficiary satisfaction and strengthen sector stability, though challenges remain regarding staffing, budget, and the oversight of adjacent markets such as discount health cards. Read more.

BRAZIL'S CONITEC MARKS 15 YEARS WITH LAUNCH OF HEALTH TECHNOLOGY ASSESSMENT SERIES

The National Committee for Health Technology Incorporation (Conitec) marks its 15th anniversary with the launch of a new podcast series highlighting the development of Health Technology Assessment (HTA) within the Brazilian Unified Health System (SUS). The initiative aims to document the institutional trajectory of HTA in Brazil through firsthand accounts from key figures involved in shaping the policy. The series, titled "HTA: a history of SUS," brings together former leaders and experts to discuss the evolution of evidence-based decision-making in technology incorporation, including challenges, milestones, and governance advances. Over the past decade and a half, Conitec has played a central role in evaluating

clinical, economic, and social impacts of new technologies, supporting sustainable and transparent healthcare decisions in Brazil. Read more.

BRAZILIAN PHARMA SECTOR STEPS UP EFFORTS TO COMBAT COUNTERFEIT MEDICINES

Brazilian pharmaceutical industry associations are intensifying coordinated actions to combat the growing circulation of counterfeit medicines, amid rising concerns linked to high-value therapies, supply chain vulnerabilities, and the expansion of digital sales channels. The issue has gained urgency with the rapid growth of GLP-1 drugs and the increasing role of marketplaces, which together are amplifying risks across the production, distribution, and dispensing chain. The challenge is multifactorial and systemic, requiring integrated responses across all stakeholders. Estimates indicate that counterfeit medicines and hospital products generate losses of around R$11.5 billion annually in Brazil, while globally about one in ten medicines in low- and middle-income countries is either falsified or substandard. Online channels alone account for roughly 36% of counterfeit sales, highlighting enforcement gaps and the need for stronger traceability, regulatory oversight, and consumer awareness. Read more.

ILLEGAL "SLIMMING PENS" FROM PARAGUAY RAISE HEALTH RISKS AMONG BRAZILIAN CONSUMERS

Brazilians are increasingly turning to illegal "slimming pens" purchased in Paraguay, driven by high demand for rapid weight-loss treatments and the high cost of approved therapies. The trend has raised significant public health concerns, as many of these products circulate without regulatory approval, medical supervision, or guarantees of authenticity. Experts warn that these products may be falsified or improperly handled, with risks ranging from lack of therapeutic effect to severe adverse reactions. Counterfeit versions may contain incorrect dosages, unknown substances, or contaminants, and are often transported without proper refrigeration—compromising safety and efficacy. Brazilian authorities have intensified enforcement actions amid the expansion of this parallel market, including product seizures and bans on irregular formulations. The National Health Regulatory Agency (Anvisa) has highlighted that unauthorized versions, often marketed online or brought across borders, pose serious health risks and fall outside the country's regulatory safeguards. Read more.

ANVISA LAUNCHES ACTIVE MONITORING PLAN FOR GLP-1 WEIGHT-LOSS PENS IN BRAZIL

The Brazilian Health Regulatory Agency (Anvisa) has launched an active pharmacovigilance plan to monitor the safety of GLP-1 receptor agonists, widely known as weight-loss pens, in real-world conditions of use. The initiative is part of a broader regulatory action plan and focuses on medicines containing semaglutide, tirzepatide, and liraglutide. The strategy introduces a proactive monitoring model based on Real World Data (RWD), with structured case identification and prospective follow-up in healthcare services. To support implementation, Anvisa has engaged around 120 hospitals and care providers to strengthen detection and investigation of adverse events, improving the quality of safety data reported to national systems. The measure responds to the rapid expansion in the use of these drugs in Brazil—originally approved for type 2 diabetes but increasingly used for obesity, including off-label and aesthetic purposes. Authorities also highlighted risks linked to online purchases and counterfeit products, which complicate traceability and safety oversight. Read more.

SEMAGLUTIDE WEIGHT-LOSS PENS SEE PRICES DROP BY UP TO 60% IN BRAZIL

Prices of semaglutide-based weight-loss and diabetes treatments in Brazil are already showing significant reductions, with some offers reaching up to 60% below earlier reference prices, amid increased competition and new access programs. The trend follows the expiration of the molecule's patent in March 2026, which has opened the market to new entrants and pricing strategies. The price movement reflects both industry anticipation of generics and immediate commercial actions by manufacturers, including discounts, bundled offers, and patient access

programs. New initiatives from Brazilian companies and adjusted pricing from originators are bringing monthly treatment costs down substantially, with some programs offering therapies starting below R$300. The broader expectation is that competition from generics and similar products will continue to push prices lower, expanding access to therapies that previously cost over R$1,000 per month. Read more.

BRAZIL FACES PERSISTENT GAPS IN RARE DISEASE DIAGNOSIS AND ACCESS DESPITE POLICY ADVANCES

Patients with rare diseases in Brazil continue to face significant barriers in diagnosis and access to care, despite advances in public policy and growing attention to the topic. The country has an estimated 15 million people living with rare conditions, yet the journey to diagnosis remains lengthy—taking an average of 5.4 years—due to limited specialist availability, fragmented care pathways, and delays in referrals within the healthcare system. Access to treatment also remains uneven. While Brazil has established a national policy for rare diseases since 2014, implementation gaps persist, particularly in the availability of therapies already incorporated into the Brazilian Unified Health System (SUS). Data indicate that only about half of approved technologies are effectively accessible to patients, reflecting bottlenecks between regulatory approval and real-world delivery. Experts point to the need for improved care coordination, faster diagnostic pathways, and updates to evaluation models to better reflect the specificities of rare diseases, including high-cost and advanced therapies. Read more.

BRAZILIAN PHARMA COMPANY EMS SIGNS INTERNATIONAL PARTNERSHIP TARGETING RARE DISEASES

Brazilian pharmaceutical company EMS has entered into a strategic partnership with U.S.-based biotech miRecule to develop next-generation therapies focused initially on rare diseases and conditions with unmet medical needs. The collaboration is led by Rio Biopharmaceuticals, EMS's international arm, and grants access to advanced RNA-based technology platforms aimed at precision medicine. The agreement marks a shift toward co-development of innovative treatments, with EMS participating in molecule design, production, and future clinical studies. The partnership builds on more than R$1.2 billion in recent investments in high-complexity platforms, including peptide manufacturing. The initiative may also enable early-stage clinical trials in Brazil, strengthening the country's role in global pharmaceutical innovation and expanding capabilities in genetic and RNA-targeted therapies. Read more.

ANVISA CONTINUES REVIEW OF ELEVIDYS AND AWAITS COMPANY RESPONSE IN BRAZIL

The Brazilian Health Regulatory Agency (Anvisa) is continuing its technical evaluation of Elevidys, a gene therapy indicated for Duchenne muscular dystrophy, and is currently awaiting additional information from the marketing authorization holder before making a final regulatory decision. Ongoing discussions between the agency and the company involve revisions to clinical protocols, updates to the risk management plan, and refinements to long-term monitoring strategies to ensure the safe and controlled use of the therapy in Brazil. The case follows a precautionary suspension of the product and reflects Anvisa's approach to advanced therapies, emphasizing continuous evidence generation and post-market safety oversight before confirming broader availability in the country. Read more.

BRAZILIAN HEALTH SECTOR SEES RISING DEMAND FOR INNOVATION, SAYS EMBRAPII PRESIDENT

The health sector is emerging as one of the areas with the highest demand for innovation in Brazil, according to Alvaro Toubes Prata, president of the Brazilian Company for Industrial Research and Innovation. The organization has significantly expanded its role as a bridge between academia and industry, with around 500 projects and R$700 million invested in health-related research, development, and innovation across more than 40 units. The institution is increasingly aligned with national industrial and health policies, including efforts to strengthen the Health Economic-Industrial Complex (CEIS). A key shift in strategy is the launch of "high-

impact projects" focused on solving complex societal challenges—such as oncology, active pharmaceutical ingredients, and AI-based diagnostics—moving beyond demand-driven innovation toward mission-oriented initiatives. Embrapii expects to scale its overall portfolio to 1,000 projects and R$1.8 billion in investments by 2026, reinforcing its role in advancing technological capacity and supporting the Brazilian Unified Health System (SUS). Read more.

TOP PHARMACEUTICAL COMPANIES ACCOUNT FOR NEARLY 80% OF BRAZIL'S MARKET REVENUE

The Brazilian pharmaceutical market remains highly concentrated, with the 20 largest companies accounting for 78.3% of total sector revenue over the 12 months ending in March 2026. Together, these firms generated R$163.8 billion out of a total R$209.2 billion recorded by the 50 largest companies operating in the country, according to data from IQVIA. The concentration trend has intensified in recent years, driven in part by strong growth in high-value therapies such as GLP-1 drugs, which have boosted revenues of leading multinational companies. Industry players attribute this dynamic to strategic portfolio management and a shift toward specialty and innovative medicines, reinforcing the dominance of major pharmaceutical groups while opening space for domestic companies in more mature segments. Read more.

BRAZIL PREPARES ALLIANCE OF HIGH-COMPLEXITY ONCOLOGY CENTERS TO STRENGTHEN CANCER POLICY

The Ministry of Health is preparing a new regulatory ordinance to establish an alliance of high-complexity oncology centers aimed at supporting the implementation of Brazil's National Policy for Cancer Prevention and Control. The initiative will initially focus on accelerating the development of Clinical Protocols and Therapeutic Guidelines (PCDTs), many of which remain pending across key tumor types. The alliance is expected to include representatives from High-Complexity Oncology Care Centers (CACONs) across all states, with the possibility of including High-Complexity Units (UNACONs) where needed. These centers will nominate experts to participate in technical working groups responsible for drafting protocols in areas such as prostate, lung, cervical, and ovarian cancers. In addition to protocol development, the initiative may support broader system organization, including strategies such as centralized preparation of high-cost oncology drugs to improve efficiency and scale. The measure reflects a shift toward more coordinated, expertise-driven governance in oncology care within the Brazilian Unified Health System (SUS). Read more.

BREAST CANCER CARE IN BRAZIL MARKED BY REGIONAL DISPARITIES IN ACCESS AND OUTCOMES

Breast cancer remains the most common cancer among women in Brazil, with more than 78,000 new cases annually, but patient outcomes vary significantly across regions due to unequal access to diagnosis and treatment. Structural gaps in screening, specialist availability, and healthcare infrastructure continue to shape different care pathways depending on where patients live. While new therapies and innovations are advancing oncology care, access remains uneven. In some regions, barriers include limited availability of mammography and delayed diagnostic confirmation, while in others the challenges relate to treatment access, quality of imaging, and adherence to clinical protocols. These disparities reflect broader systemic inequalities and highlight the need for region-specific strategies to improve early detection and ensure timely treatment across the Brazilian Unified Health System (SUS). Read more.

AUDITS AND OVERSIGHT OF PARLIAMENTARY AMENDMENTS GAIN PROMINENCE IN BRAZIL'S HEALTH SECTOR

Audits and oversight mechanisms over parliamentary amendments allocated to healthcare are gaining traction in Brazil, amid growing concerns about transparency, efficiency, and alignment with public health planning. The debate has intensified following increased scrutiny from the Supreme Federal Court (STF), which has imposed stricter requirements on traceability, data disclosure, and monitoring of how these resources are used. The volume and relevance of these

funds have expanded significantly in recent years, reaching R$21.4 billion allocated to health in 2026 alone and accounting for a growing share of the Ministry of Health's budget. Experts warn that, despite regulatory advances, challenges persist in ensuring that spending aligns with system-wide priorities, as earmarked funds may bypass technical planning and distort regional healthcare organization. Stakeholders highlight that ongoing audits and control efforts are essential to improve governance, reduce inefficiencies, and ensure that parliamentary-driven allocations effectively contribute to strengthening the Brazilian Unified Health System (SUS), rather than fragmenting resource allocation. Read more.

PAYMENT DELAYS AND DEFAULTS HIT RECORD LEVELS, STRAINING BRAZIL'S HEALTHCARE SUPPLY CHAIN

Payment delays and defaults in Brazil's healthcare sector have reached record levels, putting significant financial pressure on suppliers of medical devices and hospital inputs. Data from industry sources indicate that the total volume of unpaid or delayed resources surpassed R$5.7 billion in 2025, the highest level in the historical series, reflecting a sharp deterioration in financial flows across the system. The problem is driven by a combination of factors, including rising default rates, retention of billing after procedures, and disputed payments, which together are compromising up to 36% of suppliers' revenues. Payment cycles have stretched to an average of around 170 days, forcing approximately 64% of companies to rely on bank financing to sustain operations. The imbalance highlights structural tensions in the healthcare ecosystem, particularly linked to market concentration and the growing bargaining power of large payers. Stakeholders warn that the current dynamics threaten the sustainability of the supply chain and may ultimately impact access to technologies and services if financial conditions continue to deteriorate. Read more.

MORE HIGHLIGHTS

ANS rejects talazoparibe plus enzalutamide for prostate cancer coverage in Brazil

Anvisa, Ministry of Health and Conasems issue guidelines for mobile specialized care units in Brazil

Brazil expands "Agora Tem Especialistas" to include diagnostic imaging services

Anvisa suspends medicines containing clobutinol over safety concerns in Brazil

Anvisa approves new treatment for myasthenia gravis in Brazil

Anvisa doubles fine against Mercado Livre over irregular product sales in Brazil

Conass leadership for 2026–2027 term takes office in Brasília

BRAZIL NEWS

Brazil's Lula suffers heavy defeat as Senate rejects Supreme Court nominee

Brazil Congress overturns Lula veto on bill cutting Bolsonaro coup sentence

Former Brazil President Bolsonaro had shoulder surgery, remains hospitalized

Brazil central bank trims interest rates again, eyeing Iran conflict

Brazil creates more formal jobs than expected in March

Brazil's public debt falls for the first time in 2026