WEEKLY REPORT

CONSULTORES
Relações Governamentais

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CMED SETS 2026 DRUG PRICE ADJUSTMENT CAP AT 3.81%

Brazil's drug pricing regulator, the Drug Market Regulation Chamber (CMED), authorizes a maximum price adjustment of up to 3.81% for medicines sold in pharmacies starting April 1, 2026. The annual adjustment follows a regulated formula based on inflation and productivity gains, with three tiers depending on market competition: 3.81% for highly competitive drugs, 2.47% for mid-level competition, and 1.13% for low-competition products. Despite the authorized ceiling, authorities emphasize that price increases are not automatic, as manufacturers and retailers may apply lower adjustments or maintain current prices depending on market dynamics. The average permitted increase of 2.47% is the lowest in nearly two decades and remains below recent inflation levels, reflecting efforts to balance consumer protection with industry sustainability. Read more.

ANAHP SUGGESTS LOW-COVERAGE HEALTH PLANS TO EXPAND PRIVATE INSURANCE ACCESS

The executive director of the National Association of Private Hospitals (Anahp), Antonio Britto, calls for a structured debate on the creation of lower-coverage health insurance plans as a strategy to expand Brazil's supplementary health sector. The proposal targets middle- and lower-middle-income populations, where affordability remains a key barrier and where current offerings fail to meet demand. The idea faces resistance from consumer protection groups, which argue that limited-coverage plans could shift more complex and costly care to the Unified Health System (SUS). Still, proponents contend that introducing more accessible products could increase early diagnosis and bring new users into the system, potentially benefiting both private providers and overall healthcare utilization. Read more.

EXPERTS HIGHLIGHT DRUG PRICE NEGOTIATION AS PATHWAY TO EXPAND ACCESS

Specialists and industry representatives highlight that stronger negotiation mechanisms with the pharmaceutical industry could improve access to high-cost medicines in Brazil, particularly within the supplementary health sector. During a recent event, stakeholders point to pricing flexibility, such as confidential discount, as a key tool to address affordability challenges driven by increasingly expensive therapies. Experts note that Brazil's high level of price transparency may limit its ability to secure deeper discounts, as domestic prices often serve as international benchmarks. While regulators and the Ministry of Health are exploring alternative models, including confidential agreements and structured discount proposals, the debate remains centered on how to balance access, sustainability, and incentives for innovation in both public and private systems. Read more.

BRAZIL FACES REGULATORY CHALLENGES WITH GLP-1 ANALOGUES AMID PATENT EXPIRY

The National Health Surveillance Agency (Anvisa) is preparing for a surge in market applications for GLP-1 analogue drugs following the patent expiry of semaglutide, triggering a series of regulatory discussions on how to assess these therapies. The agency is currently reviewing around 20 registration requests and has launched technical seminars to anticipate regulatory pathways and align with international standards. Key challenges include how to properly classify these product (whether as biological or synthetic drug) along with concerns over long-term safety, monitoring requirements, and the expansion of indications beyond approved uses.

Regulators also highlight the need to balance innovation and access with the sustainability of the Unified Health System (SUS), while ensuring rational use amid rising demand for these therapies in obesity and diabetes treatment. Read more.

BRAZIL EYES ORAL WEIGHT-LOSS DRUG LAUNCH AS NOVO NORDISK NEGOTIATES WITH SUS

Novo Nordisk is advancing plans to introduce an oral version of its GLP-1 therapy for weight loss in Brazil, as part of a broader strategy to expand access beyond injectable treatments such as Ozempic. In an interview, a senior executive highlights expectations that the new formulation could improve adherence and convenience for patients, while also aligning with growing demand for obesity treatments in the country. The company is also in ongoing discussions with the Ministry of Health regarding potential incorporation into the Unified Health System (SUS), although challenges remain around cost, large-scale access, and budget impact. The expected patent expiry of semaglutide in Brazil is likely to reshape the competitive landscape, potentially enabling price reductions and broader availability of GLP-1-based therapies in the coming years. Read more.

BRAZIL OPENS CALL TO SELECT EXPERTS IN RESEARCH ETHICS INVOLVING HUMAN SUBJECTS

Brazil's Ministry of Health launches a public call to select specialists in ethics in research involving human subjects, aiming to strengthen the National Research Ethics framework. The selection will support the composition of the national ethics body responsible for evaluating and guiding ethical standards in clinical and scientific studies across the country. Candidates will be evaluated based on academic background, technical-scientific qualifications, and professional experience in human research, including prior participation in Research Ethics Committees (RECs). The application process is fully electronic and open for 30 days, reinforcing transparency and merit-based selection criteria in the governance of research ethics in Brazil. Read more.

BRAZIL ISSUES GUIDANCE TO EXPAND CIVIL SOCIETY PARTICIPATION IN HEALTH TECHNOLOGY DECISIONS

The Executive Secretariat of the National Committee for Health Technology Incorporation (Conitec) publishes a new Q&A document to guide the participation of civil society organizations (OSCs) in the evaluation and incorporation of technologies within Brazil's Unified Health System (SUS). The material outlines eligibility criteria, application procedures, and the role of OSC representatives in Conitec's deliberative process. The document also explains how OSCs engage through a rotating seat with voting rights, detailing their contributions across different stages of health technology assessment, including meetings and public consultations. It further emphasizes the importance of conflict-of-interest disclosures to ensure transparency and credibility in decision-making, reinforcing efforts to institutionalize qualified social participation in Brazil's health governance. Read more.

BRAZIL JOINS CONSORTIUM TO ACCELERATE DEVELOPMENT OF CANCER VACCINES

Brazil is strengthening its role in advanced oncology research with the creation of a consortium aimed at accelerating the development of cancer vaccines. The initiative brings together hospitals, research centers, and public institutions, with international collaboration including the University of Oxford, to enable clinical trials in the country and expand access to cutting-edge immunotherapies. The consortium will focus on both therapeutic vaccines (designed to stimulate the immune system in patients already diagnose) and preventive vaccines targeting high-risk populations. Researchers highlight the use of artificial intelligence and genomic data to identify optimal targets, potentially shortening development timelines and reducing costs. The effort also seeks to position Brazil as a key hub for clinical research and future local production of these technologies, addressing rising cancer incidence and treatment costs. Read more.

BRAZIL APPROVES NEW LUNG CANCER TREATMENT TO EXPAND THERAPEUTIC OPTIONS

The National Health Surveillance Agency (Anvisa) approves the monoclonal antibody serplulimab (Olizu®) for the first-line treatment of adult patients with extensive-stage small cell lung cancer. The therapy is indicated for use in combination with carboplatin and etoposide and has demonstrated improved overall survival in clinical studies. Small cell lung cancer is an aggressive form of the disease, characterized by rapid progression and high metastatic potential. The approval adds a new immunotherapy option to Brazil's oncology arsenal, particularly for advanced-stage patients, and reflects ongoing efforts to expand access to innovative cancer treatments in the country. Read more.

BRAZIL SIGNS DEAL TO EXPAND ACCESS TO CANCER IMMUNOTHERAPY IN SUS

Brazil's Ministry of Health signs a partnership agreement with the Instituto Butantan and MSD to enable local production of the immunotherapy pembrolizumab under a Productive Development Partnership (PDP). The initiative aims to expand access to advanced cancer treatments within the Unified Health System (SUS), moving beyond traditional chemotherapy options. The agreement is expected to benefit more than 13,000 patients annually across five major cancer indications, including cervical, lung, breast (triple-negative), esophageal cancer, and melanoma. The PDP establishes gradual technology transfer over up to ten years, strengthening domestic manufacturing capacity and supporting broader access to innovative therapies in the public system. Read more.

BRAZIL TO TEST LUNG CANCER SCREENING PROGRAM IN PUBLIC HEALTH SYSTEM

The National Cancer Institute (INCA) announces a pilot study to evaluate the feasibility of implementing a lung cancer screening program within the Unified Health System (SUS). Conducted in partnership with the Rio de Janeiro municipal health authority and supported by AstraZeneca, the initiative aims to generate evidence for a future national guideline focused on early detection and mortality reduction. The two-year study will initially include at least 397 high-risk participants (primarily smokers or former smokers) and will use low-dose computed tomography (LDCT), a method associated with a 20% reduction in lung cancer mortality, rising to 38% when combined with smoking cessation. Currently, lung cancer screening is not part of national guidelines, despite evidence showing it can significantly reduce late-stage diagnoses. Read more.

ANVISA LAUNCHES DASHBOARD TO TRACK 2026–2027 REGULATORY AGENDA

The National Health Surveillance Agency (Anvisa) publishes a new monitoring dashboard for its 2026–2027 Regulatory Agenda, providing real-time visibility into the progress of priority regulatory initiatives. The tool centralizes information on timelines, stages of regulatory processes, and upcoming opportunities for public participation, enhancing transparency and stakeholder engagement. The dashboard supports the implementation of the agency's 2026–2027 agenda, which includes 161 priority topics across areas such as medicines, food, medical devices, and cross-cutting issues. By consolidating planning and execution data in a single interface, the initiative aims to improve regulatory predictability and facilitate monitoring of ongoing and future rulemaking activities. Read more.

AGENCY EXPANDS LIST OF RADIOPHARMACEUTICALS TO FOSTER INNOVATION AND ACCESS

The National Health Surveillance Agency (Anvisa) approves an update to its regulatory framework expanding the list of radiopharmaceuticals eligible for simplified registration pathways, increasing the number of products from 33 to 57. The measure allows companies to demonstrate safety and efficacy using published clinical data, provided the studies match the intended therapeutic or diagnostic indications. The decision, approved unanimously by Anvisa's board, aims to reflect recent market expansion and stimulate new product registrations, improving patient access to nuclear medicine technologies. The agency highlights that the

update aligns with existing regulations, including RDC 738/2022, and is expected to strengthen innovation and regulatory predictability in the sector. Read more.

ANVISA TO HOLD MARKETPLACES ACCOUNTABLE FOR IRREGULAR HEALTH PRODUCT SALES

The National Health Surveillance Agency (Anvisa) is preparing new regulations to govern the online sale of medicines and health products, with a strong focus on digital platforms such as marketplaces and delivery apps. According to director Daniel Pereira, platforms that allow the commercialization of irregular products will also be held accountable, not just the suppliers. The upcoming regulatory update aims to modernize existing rules—currently based on RDC 44/2009—by addressing issues such as prescription validation, pharmacist oversight in digital environments, and operational standards for online sales. The agency also plans to intensify inspections in digital channels, reflecting rapid growth in the sector, where online pharmacy sales have expanded significantly. Read more.

BRAZIL INAUGURATES RARE DISEASE INNOVATION CENTER TO ADVANCE RESEARCH AND CARE

A new innovation center focused on rare diseases is inaugurated in São Paulo, led by the Hospital Israelita Albert Einstein, with support from a private family donation. The initiative targets glycogenosis, a rare metabolic disorder, and aims to integrate research, innovation, and patient care in a single model, combining scientific development with structured clinical pathways. The center is expected to establish international partnerships, develop new therapies and digital tools, and implement a replicable care model across Latin America. Read more.

MORE HIGHLIGHTS

Brazil updates obesity guidelines with new recommendation for weight-loss injectables

Brazil strengthens primary care focus to tackle chronic diseases burden

Brazil faces gaps in HPV vaccination among adolescents, study warns

BRAZIL NEWS

Stronger polls buy Flavio Bolsonaro time on economic team

Brazil's Lula announces Alckmin as running mate for 2026 election

Petrobras allows distributors to pay for 55% jet fuel hike in installments

Brazil central bank needs time to assess impact of oil price shock, Galipolo says

Brazil's central bank boosts gold holdings to second-largest reserve asset in 2025

Brazil creates fewer formal jobs than expected in February

Brazil enlists bank managers to combat deforestation

TikTok seeks Brazil fintech license to offer credit

Renewable energy producers downsize operations in Brazil due to operational restrictions

WTO talks end in deadlock after Brazil blocks deal on e-commerce duties