WEEKLY REPORT

12/27/2025

BRAZIL'S CMED PUBLISHES UPDATED PRICING RULES FOR MEDICINES

Brazil's Drug Market Regulation Chamber (CMED) published, on Wednesday, December 24, a new resolution revising the national framework for medicine pricing, updating the criteria used to define maximum prices at market entry and during post-approval adjustments. The measure represents one of the most significant revisions to Brazil's drug pricing rules in recent years and reflects an effort to modernize regulatory tools while increasing transparency and methodological clarity. The new framework expands the basket of reference countries used for international price benchmarking, refines the classification parameters for medicines, and updates the methodology applied to calculate factory prices and consumer price ceilings. According to CMED, the changes aim to align Brazilian pricing practices more closely with international standards while addressing distortions identified under the previous model. Another relevant element is the introduction of clearer procedural stages and analytical criteria for price-setting and review requests. By detailing documentation requirements and timelines, the resolution seeks to reduce uncertainty for pharmaceutical companies during product launches and lifecycle price adjustments, a long-standing concern among market participants operating in Brazil's tightly regulated pharmaceutical environment. The resolution also formally replaces Resolution CMED No. 2/2004, which had governed drug pricing for more than two decades. The previous framework relied heavily on static international price comparisons and offered limited differentiation between types of medicines, with fewer procedural safeguards and less emphasis on technological or therapeutic innovation. Under the new Resolution CMED No. 3/2025, pricing rules are substantially restructured, introducing a detailed taxonomy of medicine categories and clearly distinguishing between innovative products, incremental innovations, biological medicines, and new pharmaceutical presentations. In addition, the regulation establishes the Price Information Dossier (DIP) as a mandatory and standardized submission, requiring companies to provide structured technical, clinical and economic evidence to justify proposed prices. The change signals a shift toward a more evidence-based and value-oriented pricing regime, which may increase preparation requirements for market entry but is expected to improve predictability and regulatory consistency over time. Read more.

ANVISA APPOINTS SUBSTITUTE DIRECTOR TO FOURTH DIRECTORATE

Brazil's National Health Surveillance Agency (ANVISA) appointed, on December 26, Marcelo Mario Matos Moreira as Substitute Director of the Fourth Directorate, following the expiration of the term of Director Rômison Rodrigues Mota on December 19. The decision was taken during an extraordinary meeting of the Collegiate Board and formally disclosed by the agency. Moreira has been a career civil servant at ANVISA since 2005 and currently serves as head of the General Management of Biological Products, Radiopharmaceuticals, Blood, Tissues, Cells, Organs, and Advanced Therapies. According to the agency, his appointment ensures continuity in the Fourth Directorate's activities while the formal process for a permanent appointment is not concluded. With the change, the Collegiate Board is now composed of Leandro Pinheiro Safatle as Director-President, Daniel Meirelles Fernandes Pereira in the Second Directorate, Daniela Marreco Cerqueira in the Third Directorate, Marcelo Mario Matos Moreira as Substitute Director in the Fourth Directorate, and Thiago Lopes Cardoso Campos in the Fifth Directorate. Read more.

BRAZIL'S ANVISA PUBLISHES Q&A DOCUMENT ON RDC 945/2024

Brazil's National Health Surveillance Agency (ANVISA) published, on December 26, a Questions and Answers (Q&A) document addressing the application and interpretation of Resolution of the Collegiate Board (RDC) No. 945/2024, which establishes rules and procedures for the conduct of clinical trials in Brazil. The material is intended to clarify recurring questions raised by the regulated sector following the entry into force of the new regulation. According to ANVISA, the Q&A covers aspects related to the scope of RDC 945/2024, including types of clinical trials subject to the rule, documentation requirements, and the roles and responsibilities of sponsors and other stakeholders involved in clinical research activities conducted in the country. The document also addresses provisions of Normative Instruction (IN) No. 338/2024, which complements RDC 945/2024 by detailing criteria and procedures for optimized regulatory analysis of clinical trial submissions. The Q&A consolidates guidance on how the two normative acts should be applied in practice. The questions and answers were compiled based on inquiries received by the agency and are available on ANVISA's website as a support tool for stakeholders involved in clinical research under the new regulatory framework. Read more.

NEW REGULATORY FRAMEWORK MAY BOOST BRAZIL'S HERBAL MEDICINES SECTOR

A new regulatory framework for herbal medicines approved earlier this month by Brazil's National Health Surveillance Agency (ANVISA) is expected to unlock growth opportunities for the herbal products sector, according to an analysis published by Valor Econômico on December 26. Industry representatives argue that the revised rules could help transform a traditionally fragmented segment into a more competitive and innovation-driven market. The updated framework is seen as a turning point for companies that rely on plant-based active ingredients, as it introduces regulatory pathways better aligned with the specific characteristics of herbal medicines. By differentiating regulatory requirements according to levels of scientific evidence and traditional use, the new model may reduce entry barriers that previously limited product development and formal registration. Executives and sector specialists interviewed by Valor highlight that Brazil, despite its vast biodiversity, has historically underperformed in the commercialization of herbal medicines compared with European markets. The new rules are expected to encourage greater private investment, stimulate partnerships with research institutions, and promote the sustainable use of native plant species, potentially expanding both domestic supply and export capacity. From a market perspective, the framework may also improve regulatory predictability, a key factor for long-term investment decisions. While companies still face challenges related to scaling production and ensuring consistent quality standards, stakeholders view the regulatory shift as a necessary condition for positioning herbal medicines as a more relevant segment within Brazil's broader pharmaceutical and health products market. Read more.

ANVISA WARNS OF HEALTH RISKS FROM MANIPULATED SLIMMING PENS

Brazil's National Health Surveillance Agency (ANVISA) issued a public health alert, on December 20, warning consumers about the risks associated with purchasing and using manipulated or falsified "slimming pens", such as products marketed under names like Mounjaro and Ozempic. The agency highlighted that the sale and use of unauthorized medications in this category pose serious health dangers and constitute a heinous crime under Brazilian law. The warning comes amid increasing demand for these injectable treatments, popularized by influencers and celebrities, often sought without medical supervision or appropriate clinical criteria. ANVISA emphasized that products manipulated outside the regulated supply chain may lack proper active ingredients, contain contaminants, or fail to meet quality and safety standards. The agency reminded the public that these injectable medications are only lawfully dispensed upon presentation and retention of a medical prescription, and that unauthorized versions should be reported to the regulator. Individuals experiencing adverse symptoms after using such products are advised to discontinue use and seek medical evaluation. Read more.

ANVISA BANS SALE AND ADVERTISING OF NEEDS AND BWELL MEDICINES

Brazil's National Health Surveillance Agency (ANVISA) determined on December 23 the prohibition of sale, distribution and advertising of all medicines marketed under the Needs and Bwell brands, which are associated with the RD Saúde group and offered by Raia Drogasil stores, after finding that the company does not hold authorization to operate as a manufacturer of pharmaceuticals. Under the agency's decision, the ban applies to all lots of the affected medicines, regardless of where they are offered, including physical stores, online platforms, and third-party vendors. ANVISA clarified that the prohibition also extends to any person or entity that markets or disseminates advertisements for the products subject to the ban. RD Saúde responded by stating that it is not a pharmaceutical manufacturer and that the medicines in question are produced by licensed and authorized pharmaceutical industries and duly registered with ANVISA, with the company indicating its intention to file an administrative appeal. Read more.

MAJORITY OF LAWSUITS AGAINST HEALTH PLANS SEEK MEDICINES AND TREATMENTS, CNJ DATA SHOW

According to a study by the National Council of Justice (CNJ), the majority of lawsuits filed against private health plans in Brazil relate to access to medicines and medical treatments, with data covering the period from August 2024 to July 2025. The study shows that courts received more than 123,000 new cases in first instance and 108,000 in second instance related to supplementary health during that timeframe. The CNJ analysis indicates that medicines and treatments account for 69% of actions filed against health plans, with half of those cases involving technologies not included in the National Regulatory Agency for Private Health Insurance and Plans (ANS) mandatory coverage list. Other categories of claims include claims for indemnification (18.7%), demands related to autism spectrum disorder (ASD) (10%) and cancer or oncology therapies (16.5%), with percentages summing above 100% due to multiple claims per lawsuit. Read more.

BRAZIL'S ANS OPENS CALL FOR TEMPORARY HIRING OF 191 PROFESSIONALS

Brazil's National Supplementary Health Agency (ANS) published, on December 23, 2025, a public call for recruitment and appointment to hire 191 professionals on a temporary basis under the Unified National Public Contest (CPNU1) waitlist. The contracts are expected to last one year, with the possibility of extension, to strengthen the agency's workforce under rules of exceptional public interest. The recruitment is exclusively for candidates approved and listed on the CPNU1 waiting list, covering thematic blocks and specified specialties. Of the 191 positions, 155 are for professionals with general higher education, 12 for Administration or Accounting Sciences, 14 for Law, and 10 for the Health area. The agency will publish the list of candidates called for contract signature in the Official Gazette of the Union and on relevant platforms, and the deadline for document submission is scheduled between January 5 and January 13, 2026. Read more.

BRAZIL'S PRESIDENT ENACTS INTO LAW MEASURE UNLOCKING SOCIAL FUND RESOURCES FOR EDUCATION AND HEALTH

Brazil's President enacted into law, on December 22, legislation approved by the Federal Senate that unlocks the use of resources from the Social Fund (Fundo Social) for investments in education and health, formally putting the measure into force and allowing the allocation of funds to social policies. The law expands the authorized uses of the fund, which had previously been subject to legal restrictions. The Social Fund is financed mainly by revenues linked to Brazil's oil and gas sector and other federal financial sources. Under the new law, resources may be directed to healthcare actions and services, including investments in the Unified Health System (SUS), as well as to education policies, increasing budgetary flexibility in priority areas. During the legislative process, lawmakers argued that the change responds to persistent financing constraints in health and education. Read more.

IARC DIRECTOR WARNS NO COUNTRY CAN ABSORB LOOMING CANCER TSUNAMI WITHOUT PREVENTION

On December 26, the director of the International Agency for Research on Cancer (IARC), an arm of the World Health Organization (WHO), warned that without effective prevention strategies, no country will be able to cope with the anticipated surge in cancer cases in the coming decades, according to reporting by Folha de S.Paulo. The statement was made during an international seminar on cancer control hosted by the Oswaldo Cruz Foundation (Fiocruz) in Rio de Janeiro. Elisabete Weiderpass, epidemiologist and head of IARC, emphasized that prevention remains the weakest link in global cancer control policy, despite its potential to avert up to half of all cancer cases worldwide. She attributed the slow progress in prevention to a lack of political will, insufficient public awareness and commercial opposition from industries profiting from harmful products. Weiderpass highlighted that countries with middle-income economies, such as Brazil, are particularly at risk of experiencing a "tsunami" of new cancer cases, driven by aging populations and rising exposure to risk factors. The projected global increase in cancer incidence and mortality, she noted, will strain health systems that are largely structured around treatment rather than primordial and primary prevention. Read more.

TUBERCULOSIS TREATMENT ADVANCES SCIENTIFICALLY BUT STALLS ON SOCIAL INEQUALITY

Although scientific advances in tuberculosis (TB) treatment have improved therapeutic options, progress in reducing TB burden in Brazil is hindered by social inequalities that limit access to care and adherence to treatment. The article from Folha de S.Paulo underscores the persistent challenge of translating biomedical innovation into equitable public health outcomes. The report notes that new TB drugs and shorter treatment regimens have shown promise in clinical studies, with several therapeutic options recommended to improve patient outcomes and reduce transmission. However, Brazil continues to face high TB incidence in vulnerable populations, driven by factors such as poverty, overcrowded living conditions, limited health service access, and barriers to sustained treatment adherence. Public health experts cited in the report emphasize that social determinants of health, including income inequality, unstable housing and food insecurity, are central to the ongoing TB epidemic. Read more.

MORE HIGHLIGHTS

Over 6 million Brazilians need bariatric surgery amid public system backlog

Brazil's MEC allows in-person nursing courses at former EAD poles

Brazil's ANVISA prohibits alulose-based products

BRAZIL NEWS

Jair Bolsonaro backs son's Brazil presidential bid, undergoes hernia surgery

Brazil's top court orders detention of ex-head of highway police after escape attempt

Apple to allow third-party app stores in Brazil to settle iOS case with regulator

Rocket crashes in Brazil's first commercial launch; Innospace shares tumble

Aegea takes steps towards an IPO that could be Brazil's first in over 4 years

Brazil's ComBio expects revenue to hit $430 mln as corn ethanol clients increase output