WEEKLY REPORT

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CMED PREPARES PHARMACEUTICAL INDUSTRY FOR BRAZIL'S TAX REFORM

Brazil's Drug Market Regulation Chamber (CMED) held a meeting with pharmaceutical industry representatives to discuss the implementation of the country's tax reform and its implications for regulated medicine prices. During the meeting, CMED's Executive Secretariat presented a roadmap outlining the adjustments companies will need to make as Brazil transitions to the new tax system established under the tax reform. The initiative aims to ensure that pharmaceutical companies are prepared to adapt pricing calculations, reporting obligations and regulatory compliance to the new tax framework. The discussions reflect the close interaction between tax policy and Brazil's medicine price regulation, with CMED expected to issue further operational guidance as implementation advances. Read more.

BRAZIL TO DEFINE FIRST MEDICINES ELIGIBLE FOR CONFIDENTIAL PRICING MODEL

Health Minister Alexandre Padilha said the Ministry of Health will work with pharmaceutical industry representatives to define the first medicines to be acquired under Brazil's planned confidential pricing model. The mechanism allows negotiated prices for high-cost medicines to remain undisclosed, enabling the government to secure larger discounts while preserving manufacturers' international pricing strategies. The Ministry expects to launch a pilot procurement later this year. According to Padilha, the model will initially focus on patented medicines supplied by a single manufacturer, particularly high-cost innovative therapies. This initiative is part of a broader effort to expand access to advanced treatments through the Unified Health System (SUS) while maintaining the financial sustainability of public pharmaceutical spending. Read more.

BRAZIL'S PHARMACEUTICAL IMPORTS RISE 14.3% IN 2026

Brazil's pharmaceutical imports increased 14.3% between January and May 2026 compared with the same period last year, reaching US$6.53 billion (approximately BRL 33.9 billion), according to data compiled by Valor Econômico based on trade statistics provided by Grupo FarmaBrasil. Pharmaceutical products accounted for 5.6% of the country's total imports, up from 5.1% in 2025 and 4.9% in 2024, reflecting a continued upward trend. The increase has been driven by factors including growing demand for innovative medicines, such as GLP-1 therapies, the aging population and Brazil's continued reliance on imported pharmaceutical products. The figures underscore the country's dependence on external suppliers for high-value medicines and active pharmaceutical ingredients, reinforcing the strategic importance of policies aimed at strengthening domestic pharmaceutical production and innovation. Read more.

CHINESE INVESTMENT TARGETS BRAZIL'S HEALTHCARE SECTOR

China's growing investment in Brazil is expected to increasingly reach the healthcare sector, according to industry experts cited by Futuro da Saúde. After Chinese investment in Brazil rose to US$6.1 billion in 2025—a 42% increase over the previous year—companies are now exploring opportunities in pharmaceuticals, medical devices, biotechnology, digital health, and healthcare infrastructure, driven by Brazil's large domestic market and expanding demand for healthcare services. The report highlights that partnerships between Brazilian and Chinese companies are likely to focus on technology transfer, local manufacturing, and innovation,

complementing broader bilateral cooperation initiatives in healthcare. Industry representatives believe these investments could strengthen Brazil's health industrial base while expanding access to advanced medical technologies and supporting the country's healthcare innovation ecosystem. Read more.

FIVE TRENDS ARE RESHAPING BRAZIL'S PHARMACEUTICAL INDUSTRY

Five strategic trends are expected to redefine the future of Brazil's pharmaceutical industry, according to a study highlighted by Panorama Farmacêutico. The report identifies artificial intelligence, patient experience, personalized medicine, data-driven decision-making, and sustainability as the main forces transforming business models across the sector. Together, these trends are shifting the industry's focus from products to more integrated, patient-centered healthcare solutions. The study notes that Brazil, which accounts for about 42% of Latin America's pharmaceutical revenue, is well positioned to lead this transformation. Companies that successfully integrate digital technologies, real-world data and personalized care strategies are expected to gain a competitive advantage as the industry adapts to changing patient expectations and advances in healthcare innovation. Read more.

INDUSTRY COALITION PROPOSES NEW FUNDING MODEL FOR HIGH-COST THERAPIES IN PRIVATE HEALTH INSURANCE

Brazil's Business Movement for Health (MES), an initiative led by the National Confederation of Industry (CNI), the National Industrial Training Service (Senai) and the Social Service of Industry (SESI), is developing proposals to improve the sustainability of the country's supplementary health sector. Among the main initiatives is the creation of a shared funding mechanism for high-cost therapies, particularly cancer treatments, with the aim of reducing the financial impact of these medicines on private health insurers while expanding patient access. The proposal, which has the support of the pharmaceutical industry association Sindusfarma, is still under discussion and could take the form of a dedicated fund or another risk-sharing arrangement involving insurers and manufacturers. The initiative reflects growing efforts by employers to participate more actively in discussions on healthcare costs, innovation and judicialization within Brazil's supplementary health system. Read more.

SENATE HEARING CALLS FOR STRONGER FOCUS ON EARLY DIAGNOSIS TO PREVENT BLINDNESS

Participants in a public hearing held by the Senate's Social Affairs Committee (CAS) called for stronger public policies focused on early diagnosis and equitable access to eye care to combat preventable blindness in Brazil. Experts emphasized the need to prioritize children's eye health, arguing that early detection and treatment can prevent permanent vision loss, while also highlighting barriers faced by people living in rural, underserved, and Indigenous communities. Speakers also stressed the importance of expanding access to ophthalmology services within the Unified Health System (SUS), noting that delayed diagnosis and unequal access to specialized care remain major obstacles to reducing avoidable blindness. The hearing reinforced calls for preventive eye health policies aimed at improving outcomes and reducing regional disparities. Read more.

GAPS IN NEWBORN SCREENING LEAVE BRAZILIAN CHILDREN AT RISK OF IRREVERSIBLE DISABILITIES

Failures in access to Brazil's newborn screening program (the "heel prick test") continue to expose children to irreversible health consequences despite the country's universal screening policy. According to a report by Folha de S.Paulo, national coverage reaches about 87% of live births, with significant regional disparities. The North and Northeast record the lowest screening rates, while delayed diagnosis of conditions such as phenylketonuria can result in permanent neurological damage that could otherwise be prevented through early treatment. The report also highlights the uneven implementation of the expansion of newborn screening established by Law No. 14,154/2021, which aims to gradually increase the number of diseases covered by the public health system. Although some states and municipalities have adopted broader

screening panels, nationwide implementation remains incomplete, underscoring ongoing challenges in ensuring equitable access to early diagnosis for rare diseases across Brazil. Read more.

HEALTH MINISTER SAYS REVIEW OF BUTANTAN DENGUE VACCINE WILL BE COMPLETED "AS QUICKLY AS POSSIBLE"

Health Minister Alexandre Padilha said the review of the Butantan Institute's dengue vaccine will be concluded "as quickly as possible," while emphasizing that there is no fixed timeline for resuming its use in Brazil's National Immunization Program (PNI). The vaccine was suspended after rare adverse events not identified during clinical trials were reported following its rollout, prompting an ongoing investigation by the Brazilian Health Regulatory Agency (Anvisa), the Butantan Institute and an expert panel convened by the Ministry of Health. Padilha said the investigation could support measures such as restricting the vaccine to specific population groups or regions, depending on the findings. He also confirmed that the Ministry of Health will maintain its agreement to purchase 18 million doses of Takeda's dengue vaccine over two years, with no changes to the current procurement strategy while the Butantan vaccine remains under review. Read more.

ANVISA REGULATES ROLLING SUBMISSIONS FOR CLINICAL TRIAL APPLICATIONS

The Brazilian Health Regulatory Agency (Anvisa) has approved a normative instruction establishing rules for the rolling submission of documents related to clinical trials involving medicines. The new procedure allows sponsors to submit specific sections of the Clinical Development Dossier (DDCM), such as drug stability data and analytical method validation, as they become available rather than waiting to complete the entire dossier before filing. The documents must be submitted before the clinical trial begins or before the implementation of a protocol modification. The measure is expected to streamline regulatory reviews, reduce development timelines and make Brazil a more attractive destination for clinical research. The rolling submission process implements provisions of RDC No. 945/2024 and is part of Anvisa's broader strategy to modernize clinical trial regulation and improve the country's competitiveness in pharmaceutical innovation. Read more.

ANVISA PRIORITIZES REDUCING DRUG APPROVAL BACKLOG AND STRENGTHENING INNOVATION

Eliminating the backlog of drug applications and fostering innovation are among the top priorities of the Brazilian Health Regulatory Agency (Anvisa), according to Acting Director-President Diogo Penha Soares. Speaking at the Amcham Brazil Health Forum, Soares said the agency is pursuing structural measures to improve regulatory predictability, including greater use of regulatory reliance, digital transformation, and mechanisms to accelerate the review of innovative products without compromising safety, quality, or efficacy. He also highlighted clinical research as a strategic priority for the agency. Soares emphasized that addressing the backlog will require long-term institutional strengthening, including increased funding, workforce expansion, and greater budget autonomy. He noted that Anvisa delivered a record number of regulatory approvals during the first half of 2026 and stressed that modernizing the agency is essential to support pharmaceutical innovation and attract investment in Brazil's life sciences sector. Read more.

ANVISA DIRECTOR BACKS REGULATORY SANDBOX FOR SMART HOSPITALS

Anvisa Director Thiago Campos has defended the use of a regulatory sandbox to support the development of Brazil's smart hospitals. The proposal would allow innovative healthcare technologies and operational models to be tested under temporary, controlled regulatory conditions before permanent rules are adopted, helping regulators adapt existing standards to emerging technologies such as artificial intelligence, automation and connected medical devices. According to Campos, the sandbox approach could accelerate innovation while ensuring patient safety and regulatory oversight. The initiative builds on Anvisa's previous experience with experimental regulatory environments and reflects the agency's broader efforts

to modernize health regulation in response to digital transformation across Brazil's healthcare system. Read more.

ANVISA DESIGNATES BRAZILIAN SEMAGLUTIDE AS REFERENCE PRODUCT FOR FUTURE GENERICS

The Brazilian Health Regulatory Agency (Anvisa) has added Ozivy, the country's first synthetic semaglutide developed by EMS, to its List of Reference Medicines (LMR). The decision makes Ozivy the official benchmark for the quality, safety and efficacy studies required for the registration of future generic and similar synthetic semaglutide medicines in Brazil. The product was approved earlier this year for the treatment of type 2 diabetes and entered the Brazilian market in June. The inclusion marks an important regulatory milestone following the expiration of the Ozempic patent in Brazil and is expected to accelerate competition in the semaglutide market. Because Ozempic is a biologic medicine, it cannot serve as a reference product for generics under Brazilian regulations, making Ozivy the first eligible reference for synthetic semaglutide products. Read more.

MEDICAL SOCIETIES WARN AGAINST USE OF MEDICINES NOT APPROVED BY ANVISA

Three leading Brazilian medical societies have issued a joint warning urging patients and healthcare professionals to use only medicines approved by the Brazilian Health Regulatory Agency (Anvisa). The alert comes amid the growing circulation of alternative versions of GLP-1 and GIP receptor agonists, including semaglutide and tirzepatide, often imported from Paraguay without authorization for commercialization in Brazil. The organizations stress that products approved abroad but not registered with Anvisa do not undergo the agency's quality, safety, and efficacy assessment. The statement emphasizes that biologic medicines require complex manufacturing processes and strict quality controls to ensure molecular integrity, sterility, and clinical performance. The medical societies warn that the use of unregistered products may expose patients to significant health risks and reinforce that only medicines authorized by Anvisa should be prescribed and dispensed in Brazil. Read more.

COURT ALLOWS EMS TO KEEP MARKETING OZIVY WHILE PATENT DISPUTE PROCEEDS

A court in Rio de Janeiro has denied Novo Nordisk's request for an injunction to halt the commercialization and marketing of Ozivy, EMS's synthetic semaglutide product for type 2 diabetes. The Danish pharmaceutical company argued that the product's name and branding could constitute unfair competition and create confusion with its Ozempic and Wegovy brands. However, the judge ruled that the allegations require further evidence and expert examination before any decision on the merits can be made. The decision allows EMS to continue selling Ozivy while the lawsuit moves forward and a court-appointed expert evaluates the claims. The case is being closely watched by the pharmaceutical industry as it marks one of the first legal disputes following the expiration of semaglutide patent protection in Brazil, with potentially significant implications for competition in the country's GLP-1 market. Read more.

BILLS SEEK TO EXTEND PHARMACEUTICAL PATENT TERMS IN BRAZIL

Two bills currently under discussion in Brazil's House of Representatives would introduce a patent term adjustment (PTA) mechanism to compensate patent holders for delays by the Brazilian Patent and Trademark Office (INPI) in examining patent applications. Supporters argue the proposals would increase legal certainty and strengthen incentives for research and development, while aligning Brazil with practices adopted in other jurisdictions. The proposals have sparked opposition from Brazil's domestic pharmaceutical industry, which argues they could delay the entry of generic and biosimilar medicines, increase costs for the Unified Health System (SUS) and revive a debate the Supreme Federal Court (STF) settled in 2021 when it struck down automatic patent term extensions. The measures remain under congressional review with no vote scheduled before the legislative recess. Read more.

STF PUBLISHES GUIDE ON JUDICIAL CLAIMS FOR MEDICINES UNDER BRAZIL'S PUBLIC HEALTH SYSTEM

Brazil's Supreme Federal Court (STF) has published a practical guide to help judges, lawyers, public officials, and citizens apply the Court's rulings on lawsuits seeking medicines through the Unified Health System (SUS). The document consolidates the legal principles established in three landmark cases (Themes 6, 500 and 1,234) and clarifies which level of government is responsible for providing medicines, as well as whether cases should be heard in federal or state courts. The initiative is intended to promote greater consistency in judicial decisions involving access to medicines, particularly high-cost therapies and treatments not incorporated into the SUS. By translating the Court's precedents into practical guidance, the STF aims to reduce legal uncertainty and improve the implementation of its healthcare-related rulings across Brazil's judicial system. Read more.

FAMILIES TURN TO COURTS TO SECURE COVERAGE OF NEW ALZHEIMER'S DRUG

Brazilian families are increasingly seeking court orders to require private health insurers to cover Kisunla (donanemab), a disease-modifying therapy for patients with early-stage Alzheimer's disease. Although the medicine was approved by the Brazilian Health Regulatory Agency (Anvisa) in 2025, it has not yet been incorporated into the list of mandatory procedures covered by the National Supplementary Health Agency (ANS). With treatment costing around BRL 30,000 per monthly infusion, courts have granted a growing number of injunctions ordering insurers to pay for the therapy. The wave of litigation highlights the ongoing challenges surrounding access to high-cost innovative therapies in Brazil's supplementary health sector. Legal experts note that recent court decisions have relied on the Supreme Federal Court's criteria allowing coverage of treatments outside the ANS reimbursement list under exceptional circumstances, provided specific legal and clinical requirements are met. Read more.

CANCER SURGERIES THROUGH BRAZIL'S PUBLIC HEALTH SYSTEM INCREASE BUT REMAIN BELOW DEMAND

The number of cancer surgeries performed through Brazil's Unified Health System (SUS) has increased in recent years but still falls short of the country's growing demand, according to data highlighted by Medicina S/A. Although surgical capacity has expanded following the COVID-19 pandemic, long waiting times, regional disparities, and shortages of specialized services continue to delay treatment for many patients, affecting clinical outcomes. The findings reinforce concerns over the need to strengthen Brazil's oncology care network by expanding surgical capacity and improving access to timely diagnosis and treatment. Experts argue that reducing delays in cancer surgery is essential to improving survival rates and ensuring equitable access to comprehensive cancer care across the country. Read more.

STUDY REVEALS RACIAL AND REGIONAL DISPARITIES IN ACCESS TO RADIOTHERAPY IN BRAZIL

A nationwide study has found significant racial and regional disparities in access to radiotherapy in Brazil, highlighting persistent barriers to cancer treatment. The analysis of more than 840,000 radiotherapy procedures performed between 2017 and 2022 showed that non-white patients travel an average of 145.6 kilometers to receive treatment (nearly 50% farther than white patients). Regional inequalities are even more pronounced, with patients in the North traveling an average of 442 kilometers, compared with about 74 kilometers in the Southeast. The findings underscore longstanding challenges in the distribution of radiotherapy services across the country and reinforce calls for expanding treatment capacity and improving geographic access. Experts argue that reducing these disparities is essential to ensuring equitable cancer care and improving clinical outcomes within Brazil's healthcare system. Read more.

STUDY HIGHLIGHTS SURVIVAL GAP FOR LUNG CANCER PATIENTS IN BRAZIL'S PUBLIC HEALTH SYSTEM

Patients with lung cancer treated through Brazil's public healthcare system (SUS) have significantly lower survival rates than those receiving care in the private sector, according to a new study highlighted by Folha de S.Paulo. The disparity is largely attributed to late diagnosis, with between 85% and 93% of SUS patients already presenting with advanced-stage disease when treatment begins, substantially reducing their chances of long-term survival. The findings underscore persistent challenges in timely diagnosis and access to innovative treatments in Brazil's oncology care network. Although the Ministry of Health has incorporated targeted therapies for advanced lung cancer into the SUS, experts argue that expanding early detection and accelerating access to diagnosis remain critical to improving patient outcomes. Read more.

MORE HIGHLIGHTS

Brazil prepares regulation for AI-enabled medical devices

Anvisa updates COVID-19 vaccine composition to target circulating variants

Anvisa expands indication for HER2-positive breast cancer therapy

Federal District expands access to genetic testing for hereditary cancers

Cyberattack exposes data of 500,000 patients in Brazil's public healthcare network

Brazil launches third National Health Survey

Brazil launches call for research to evaluate public health policies

Brazilian research center to use smartwatches for AI-driven disease detection

BRAZIL NEWS

Brazil's first-half inflation hits highest since 2022

Brazil keeps 12% oil export tax, to review measure in 30 days

Growing number of Brazilian companies seek out-of-court debt fixes amid high rates

Farm-debt decree will enable R$100bn renegotiation, minister says

Lula broadens inner campaign circle as race intensifies

In race against Lula, Flavio Bolsonaro lobbies Washington to delay Brazil tariff

Brazil's Senator Bolsonaro argues against 25% US tariff on its exports

US coffee industry asks Trump to keep tariff exemption on Brazil beans

Brazil police target executive linked to Banco Master's communication efforts

Brazil to impose strict advertising rules on online betting firms