WEEKLY REPORT

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BRAZIL APPROVES FIRST INNOVATIVE TREATMENT FOR PHENYLKETONURIA, EXPANDING CARE OPTIONS

Brazil approves a new innovative treatment for phenylketonuria (PKU), a rare genetic disorder traditionally managed through strict dietary restrictions. The drug, recently authorized by the Brazilian Health Regulatory Agency (Anvisa), works by reducing phenylalanine levels in the blood, potentially allowing patients greater dietary flexibility and improved quality of life. Clinical data indicate the therapy is safe and effective in lowering toxic amino acid levels, which, if untreated, can lead to severe neurological damage, especially in children. While the new treatment does not replace dietary management entirely, experts highlight its potential to ease long-term disease control and reduce the burden on patients and families. Read more.

BRAZIL'S LULA SAYS STATE MUST GUARANTEE ACCESS TO MEDICINES

President Luiz Inácio Lula da Silva states that the Brazilian State has a duty to guarantee access to medicines, emphasizing that public investment in pharmaceutical access should not be viewed as a cost but as a fundamental measure to save lives. The remarks were made during a visit to a pharmaceutical industrial facility in Anápolis (GO), reinforcing the government's focus on access policies. Lula highlights the Popular Pharmacy Program as a key mechanism to ensure access to essential medicines, particularly for low-income populations. He argues that access to treatment constitutes a fundamental human right and signals continued prioritization of public policies aimed at expanding pharmaceutical assistance and reducing barriers to access within Brazil's healthcare system. Read more.

AUDIT FINDS INEFFICIENCIES IN BRAZIL'S HTA PROCESS AND POTENTIAL R$130 MILLION LOSS TO SUS

A federal audit conducted by the Federal Court of Accounts (TCU) identifies structural inefficiencies in Brazil's health technology assessment (HTA) process, highlighting delays, methodological gaps, and governance issues within the National Committee for Health Technology Incorporation (Conitec). The findings raise concerns about the effectiveness and sustainability of decision-making in the Unified Health System (SUS). The audit also points to inconsistencies between prices presented during HTA evaluations and those actually paid after incorporation, estimating that improved price monitoring could have generated savings of approximately R$130 million. The TCU issued multiple recommendations to the Ministry of Health to enhance transparency, strengthen economic evaluations, and improve compliance with regulatory timelines. Read more.

BRAZIL PREPARES PRICE NEGOTIATION COMMITTEE AND REFORMS TO HTA PROCESS

Brazil's Ministry of Health is preparing the creation of a formal price negotiation committee for the incorporation of medicines, vaccines, and other technologies into the Unified Health System (SUS), signaling a structural shift in how pricing is overseen within the health technology assessment (HTA) process. The proposal is expected to be formally presented in the coming weeks, according to officials from the Secretariat of Science, Technology and Innovation in Health. The initiative is part of broader reforms under discussion for the National Committee for Health Technology Incorporation (Conitec), aiming to strengthen cost-effectiveness evaluations, improve price transparency, and align reimbursement decisions with budget

impact considerations. The move follows growing scrutiny from oversight bodies and stakeholders regarding inefficiencies and price inconsistencies in current incorporation processes. Read more.

BRAZIL'S PHARMA INDUSTRY QUESTIONS BENEFITS OF SINGLE HTA AGENCY PROPOSAL

Brazil's pharmaceutical industry is raising concerns over a bill that proposes the creation of a single health technology assessment (HTA) agency, warning that there is no clear evidence the model would generate benefits for patients or the healthcare system. The proposal, currently under discussion in the National Congress, has triggered strong reactions from multiple industry stakeholders. According to Interfarma CEO Renato Porto, the unification of HTA processes could overlook structural differences between Brazil's public and private healthcare systems, including funding models, patient profiles, and access dynamics. Industry representatives argue that any reform should be preceded by a broad technical debate, emphasizing the need for regulatory predictability, legal certainty, and preservation of existing institutional frameworks such as the National Committee for Health Technology Incorporation (Conitec). Read more.

VALUE-BASED HEALTHCARE GAINS RELEVANCE IN TECHNOLOGY ASSESSMENT DEBATES IN BRAZIL

Value-based healthcare (VBHC) is gaining prominence in discussions on health technology assessment (HTA), as stakeholders seek more efficient and sustainable approaches to incorporating new treatments. The model emphasizes patient outcomes relative to costs, becoming increasingly relevant amid rising demand, limited budgets, and the growing complexity of innovative therapies. International momentum around VBHC is influencing policy and evaluation frameworks, with countries such as the United Kingdom, Canada, and the United States advancing initiatives to integrate value criteria into decision-making processes. In Brazil, the approach is expected to reshape HTA discussions by prioritizing outcome-based metrics and resource allocation efficiency, potentially impacting future incorporation decisions within the Unified Health System (SUS). Read more.

BRAZIL MOVES TO REMOVE ORIGIN-COUNTRY APPROVAL REQUIREMENT FOR DRUG REGISTRATION

Brazil's House of Representatives advances legislation removing the requirement for prior market authorization in the country of origin as a condition for drug registration in Brazil. The proposal shifts the regulatory focus toward compliance with Good Manufacturing Practices (GMP), regardless of where the product is manufactured. The measure aims to streamline market entry and reduce barriers for new medicines, while maintaining quality and safety standards under the Brazilian Health Regulatory Agency (Anvisa). Lawmakers argue the change aligns Brazil with international regulatory practices and may facilitate faster access to therapies, particularly in cases where products are not yet commercialized in their country of origin. Read more.

BRAZIL MOVES TO ALLOW PHARMACIES INSIDE SUPERMARKETS UNDER STRICT HEALTH RULES

Brazil moves forward with legislation allowing the installation of pharmacies and drugstores in supermarkets, provided they operate in fully segregated and dedicated areas that comply with all sanitary and regulatory requirements. The measure, approved by Congress and pending final implementation steps, maintains that medicines cannot be sold in regular aisles or checkout areas. The framework requires the presence of a licensed pharmacist during all operating hours and full compliance with storage, dispensing, and traceability standards. While supporters argue the initiative may expand access to medicines, particularly in underserved areas, critics warn about potential risks related to inappropriate use and increased commercial pressure on consumption. Read more.

BRAZIL EXEMPTS IMPORT TAXES ON WEIGHT-LOSS PEN COMPONENTS TO BOOST LOCAL PRODUCTION

Brazil exempts import taxes on components used in the manufacturing of weight-loss injection pens, aiming to support domestic production and expand access to GLP-1 therapies. The measure, approved by the Executive Management Committee of the Foreign Trade Chamber (Camex), covers up to 58 million units and is valid for 12 months. The decision comes as Brazilian pharmaceutical company EMS prepares to launch a semaglutide-based product, following the recent patent expiration of the molecule. The exemption applies to structural components such as pen bodies, glass, and caps—excluding the active ingredient itself—and reflects a broader government strategy to localize production, increase competition, and reduce prices in a rapidly expanding obesity treatment market. Read more.

PATENT CLIFF COULD DRIVE US$230 BILLION REVENUE LOSS IN GLOBAL PHARMA BY 2030

The global pharmaceutical industry faces a significant "patent cliff" through the end of the decade, with revenue losses projected to exceed US$230 billion between 2025 and 2030, according to industry estimates. The expiration of exclusivity for blockbuster drugs is expected to intensify competition and accelerate the entry of generics and biosimilars across key markets. Major pharmaceutical companies such as Bristol Myers Squibb, MSD, and Pfizer are among the most exposed, with high-revenue products losing patent protection starting in 2026. In Brazil, the end of exclusivity for semaglutide-based drugs already signals increased competition and potential price reductions, reinforcing the country's role as a relevant market in the post-patent landscape. Read more.

BRAZIL'S HOUSE OF REPRESENTATIVES APPROVES BILL MANDATING SUS ACCESS TO ADVANCED CANCER THERAPIES

Brazil's House of Representatives approves a bill requiring the Unified Health System (SUS) to provide free access to advanced cancer therapies, including immunotherapy vaccines and other innovative technologies. The proposal, originally from the Senate, now moves to presidential sanction and expands the National Cancer Control Policy to ensure access across prevention, diagnosis, treatment, and monitoring. The legislation establishes principles such as universal and equitable access, prioritization of innovative treatments, and criteria based on patients' clinical and immunological profiles. It also promotes domestic production, technology transfer, and faster regulatory review timelines, signaling a broader strategy to strengthen innovation and reduce dependence on imports in Brazil's oncology landscape. Read more.

BRAZIL ENDS EXCEPTIONAL IMPORT PATHWAY FOR RADIOPHARMACEUTICALS, SIGNALING REGULATORY SHIFT

The Brazilian Health Regulatory Agency (Anvisa) ends the exceptional import authorization pathway for radiopharmaceuticals, marking a transition toward a more structured and predictable regulatory framework in the country. The measure reflects the agency's effort to normalize market conditions and strengthen reliance on standard approval and distribution channels. Radiopharmaceuticals remain critical for the diagnosis and treatment of cancer and other diseases, and the policy shift is expected to increase pressure on domestic production capacity and regulatory timelines. Stakeholders highlight that ensuring supply continuity and expanding local manufacturing will be essential to avoid shortages and maintain patient access during the transition. Read more.

BRAZIL'S ANVISA SEEKS TO ACCELERATE AI REGULATION AFTER CHINA HOSPITAL VISITS

The Brazilian Health Regulatory Agency (Anvisa) is moving to accelerate the regulation of artificial intelligence in healthcare following a technical mission to China, where officials visited hospitals already integrating AI into clinical workflows. The initiative aims to use international best practices to support the development of "smart hospitals" in Brazil. The effort is aligned with the federal government's plan to create a national network of AI-enabled hospitals, backed

by an estimated US$300 million investment, and expected to include the first such unit within the public system by 2029. Anvisa is also considering incorporating AI tools into its own regulatory processes to increase efficiency, while addressing the current fragmentation of rules across different health authorities. Read more.

BRAZIL'S ANVISA SUSPENDS MAJOR COMPOUNDING PHARMACY OVER IRREGULAR HORMONE PRODUCTS

The Brazilian Health Regulatory Agency (Anvisa) suspends the operations of Bio Meds Pharmaceutica, one of the country's largest compounding pharmacies focused on hormone implants, after identifying serious regulatory violations in the production and commercialization of medicines. The measure includes the recall of all liquid preparations and the prohibition of manufacturing, sales, advertising, and use of its products. According to Anvisa, the company marketed standardized compounded medicines without individualized prescriptions, a practice that violates Brazilian sanitary regulations requiring patient-specific formulations. The case also raises broader concerns over the safety and scientific validity of hormone implants—popularly known as "beauty chips"—and manipulated injectable drugs, reinforcing regulatory scrutiny over this segment. Read more.

BRAZIL'S ANVISA SIGNALS STRICTER RULES FOR COMPOUNDING PHARMACIES AMID MARKET EXPANSION

The Brazilian Health Regulatory Agency (Anvisa) is preparing stricter regulations for compounding pharmacies, as the rapid expansion of the sector—particularly in high-demand therapies—raises concerns over quality, traceability, and regulatory gaps. According to Anvisa director Daniel Pereira, current rules dating from 2007 no longer reflect the scale and complexity of today's market. A key priority will be tightening controls on sterile and injectable formulations, including products based on substances such as tirzepatide, which have seen a surge in demand and imports. The agency also plans to address issues such as large-scale production without individualized prescriptions, online sales via apps and marketplaces, and the lack of clear rules for private-label medicines sold by pharmacy chains. The regulatory overhaul aims to strengthen enforcement, ensure product safety, and adapt oversight to new distribution models. Read more.

BRAZIL TO OFFER HIGH-COST CANCER DRUG THROUGH SUS FOLLOWING LOCAL PRODUCTION STRATEGY

Brazil will expand access to pembrolizumab, an advanced immunotherapy that can cost over R$20,000 per dose in the private market, through the Unified Health System (SUS), Health Minister Alexandre Padilha announces. The initiative is part of a strategy to localize production via a technology transfer partnership between the Ministry of Health, the Butantan Institute, and Merck Sharp & Dohme. Currently available in SUS only for melanoma, the therapy is expected to be expanded to additional cancer types pending evaluation by the National Committee for Health Technology Incorporation (Conitec). The localization strategy aims to reduce costs, increase supply security, and significantly broaden patient access to one of the most advanced immunotherapies currently available. Read more.

BRAZIL DELIVERS FIRST FULLY DOMESTIC TRANSPLANT DRUG AND INVESTS IN HEALTH INNOVATION

Brazil delivers the first fully domestically produced batch of tacrolimus, a critical immunosuppressive drug used to prevent organ rejection in transplant patients, marking a milestone in the country's health industrial policy. The initiative enables full national control over the production chain, from active pharmaceutical ingredient (API) to final product, strengthening supply security within the Unified Health System (SUS). The announcement also includes R$90 million in investments to boost health innovation, covering areas such as mRNA technologies, biopharmaceuticals, medical devices, and digital health. The measures are part of Brazil's strategy to reinforce its Health Economic-Industrial Complex (CEIS), reduce external dependence, and improve system resilience amid global supply disruptions. Read more.

LACK OF SANITATION COVERAGE CONTINUES TO PRESSURE BRAZIL'S PUBLIC HEALTH SYSTEM

Limited access to basic sanitation services continues to place a significant burden on Brazil's public health system, with experts warning that preventable diseases linked to poor sanitation drive avoidable hospitalizations and healthcare costs. The issue disproportionately affects low-income regions, where infrastructure gaps remain persistent. Specialists highlight that expanding sanitation coverage is critical not only for improving public health outcomes but also for reducing long-term expenditures within the Unified Health System (SUS). Despite regulatory advances and investment commitments, progress remains uneven across regions, reinforcing structural inequalities in access to healthcare and prevention. Read more.

MORE HIGHLIGHTS

Brazil's medical devices market grows above industry average in 2025

Brazil calls for integrated public policy to strengthen medical devices sector

Brazil's Anvisa suspends 30 medical devices over GMP violations

French pharmaceutical company Boiron partners for local production in Brazil

HPV vaccination advances in Brazil, but cervical cancer deaths remain a concern

Cervical cancer kills 20 women per day in Brazil despite preventable nature

Brazil expands colorectal cancer testing, but late diagnosis remains a major challenge

BRAZIL NEWS

Brazil's Bolsonaro discharged from hospital, placed under house arrest

Brazil audit court sidesteps Banco Master ruling as parallel investigations unfold

Canada eyes Mercosur pact by autumn

Brazil central bank opposes credit-card rate caps as Lula frets over household debt

Brazil awards first Amazon reforestation concession to startup Re.green

Brazil's Americanas files motion to exit bankruptcy protection proceedings

Brazil unveils first supersonic fighter jet assembled in country