WEEKLY REPORT

CONSULTORES
Relações Governamentais

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PHARMACEUTICAL INDUSTRY WARNS OF CONCRETE RISK OF MEDICINE SHORTAGES AND SEEKS POSTPONEMENT OF TAX REFORM

Brazil's pharmaceutical industry has warned of a "concrete risk" of medicine shortages during the transition to the country's new tax system and is asking the government to postpone the implementation of the changes affecting the sector. Industry representatives argue that companies need more time to adapt invoicing systems, tax calculations, pricing procedures and supply-chain operations to the new rules. The concern is particularly relevant for medicines, whose prices are regulated and whose distribution involves complex inventories and multiple intermediaries. The sector argues that operational failures during the transition could disrupt the supply of drugs to pharmacies, hospitals and healthcare providers. Read more.

BRAZIL'S FEDERAL REVENUE SERVICE RECEIVES LIST OF MEDICINES ELIGIBLE FOR ZERO CBS AND IBS RATES

Brazil's Federal Revenue Service has received the list of medicines proposed for zero rates under the country's new federal and subnational consumption taxes, the Contribution on Goods and Services (CBS) and the Tax on Goods and Services (IBS). The list was prepared by the Chamber of Drug Market Regulation (CMED) and delivered for review by the Ministry of Health. The process is part of the implementation of the tax reform provisions establishing preferential treatment for medicines. The definition of the products eligible for the zero rate is an important step for the pharmaceutical industry, which is seeking clarity on the tax treatment of medicines and the impact of the transition on prices and supply. Questions remain about how inventories and products already circulating in the market will be treated as the new system takes effect in 2026 and 2027. Read more.

BRAZIL'S PRESIDENT LULA SIGNS LAW ESTABLISHING A NATIONAL MEDICAL PROFICIENCY EXAMINATION

President Luiz Inácio Lula da Silva has signed legislation establishing the National Medical Proficiency Examination (Enamed), a new assessment framework for medical education in Brazil. The examination will evaluate students at different stages of medical school, with assessments planned for the fourth, eighth and twelfth semesters. The final assessment will carry greater weight in the overall evaluation. The law also establishes professional proficiency requirements for students who entered medical school from June 19, 2019. The measure comes amid concerns about the quality of medical education: in the 2025 assessment, 107 of the 351 medical schools evaluated received scores of 1 or 2, the lowest levels. Read more.

BRAZIL'S MINISTRY OF HEALTH ISSUES NEW INTERNAL REGULATIONS FOCUSED ON INNOVATION AND DIGITAL HEALTH

Brazil's Ministry of Health has published a new internal regulation reorganizing its administrative structure and setting out priorities across 22 sections and 874 articles. The regulation reinforces the role of digital health, telehealth, data integration, technological innovation and the responsible use of artificial intelligence in the organization and delivery of public healthcare services. The new framework also addresses transparency and coordination across the Ministry's departments. Its provisions reflect the government's broader effort to modernize health administration and strengthen the use of information systems and digital tools in public policy planning and implementation. Read more.

BRAZILIAN GOVERNMENT SEEKS TO ADVANCE HEALTHCARE AGENDA BEFORE NEW CONGRESS TAKES OFFICE

The Brazilian government is working to move forward with its healthcare legislative agenda before the new Congress takes office in 2027. Among the issues under discussion are the 2027 federal budget, the legal framework for artificial intelligence, interoperability between health information systems and the inclusion of certain home-use medicines in the coverage obligations of private health insurance providers. The effort reflects the government's attempt to secure progress on health-related priorities while the current congressional composition remains in place. The proposals involve different areas of healthcare policy, from digital transformation and access to medicines to the allocation of public resources and the regulation of emerging technologies. Read more.

BRAZIL'S NATIONAL COUNCIL OF JUSTICE LAUNCHES AI TOOL TO COMPARE TECHNICAL OPINIONS AND SCIENTIFIC EVIDENCE IN HEALTHCARE LITIGATION

Brazil's National Council of Justice (CNJ) has launched an artificial intelligence tool designed to compare technical opinions and scientific evidence in healthcare-related lawsuits. The system is intended to support the work of the country's judicial technical support units (NatJus) and judges by facilitating the analysis of medical evidence and the technical recommendations available in individual cases. The initiative seeks to improve the quality and consistency of judicial decisions involving access to healthcare technologies and treatments. Read more.

JUDICIALIZATION EXPOSES ACCESS FAILURES FOR TREATMENTS INCORPORATED INTO BRAZIL'S PUBLIC HEALTHCARE SYSTEM

The judicialization of healthcare in Brazil is increasingly being used by patients seeking treatments that have already been incorporated into the Unified Health System (SUS). The cases highlight a gap between the formal inclusion of medicines and technologies in public policy and their effective availability to patients. Administrative barriers, delays in implementation and difficulties in organizing care pathways can lead patients to seek court orders to obtain treatments that should already be accessible. The issue raises questions about the implementation of health technology incorporation decisions and the responsibilities of public authorities in ensuring timely access. Read more.

CNJ ASSESSMENT IDENTIFIES RISING DEMAND AND STRUCTURAL CHALLENGES FACING NATJUS UNITS

A diagnostic assessment by Brazil's National Council of Justice (CNJ) has identified growing demand and structural difficulties affecting the country's judicial technical support units (NatJus), which provide scientific and technical information for healthcare-related court cases. The findings point to challenges involving staffing, operational capacity and the ability to respond to an expanding volume of requests. NatJus units play an important role in supporting judges who must assess claims involving medicines, procedures and other health technologies. Strengthening their capacity is considered relevant to improving the technical basis of judicial decisions and addressing the growing pressure created by healthcare litigation. Read more.

DENIALS OF ACCESS TO HEALTHCARE TECHNOLOGIES HAVE INCREASED SIGNIFICANTLY, DPU COORDINATOR SAYS

The coordinator of the health division at Brazil's Federal Public Defender's Office (DPU) says denials of access to healthcare technologies have increased significantly. The assessment draws attention to the difficulties faced by patients seeking medicines, procedures and other treatments through public healthcare services, including cases in which administrative decisions or implementation problems prevent access. The issue is closely linked to the broader debate over healthcare judicialization and the effectiveness of public policies. The DPU's concerns reinforce the need to improve administrative procedures, ensure the implementation of treatments already incorporated into the SUS and strengthen mechanisms that allow patients to obtain timely access without having to resort to the courts. Read more.

BRAZIL'S ANS AND IESS SIGN AGREEMENT TO IMPROVE VALUE-BASED PAYMENT MODELS IN PRIVATE HEALTHCARE

Brazil's National Supplementary Health Agency (ANS) and the Institute for Supplementary Health Studies (IESS) have signed a cooperation agreement to advance value-based healthcare models and improve payment arrangements in the private health insurance sector. The partnership includes the exchange of information, international benchmarking and professional training focused on payment models that consider healthcare outcomes and quality, rather than relying exclusively on the volume of services provided. The initiative seeks to encourage changes in the way healthcare providers and insurers organize and finance care. The discussion is part of a broader effort in Brazil's supplementary health system, where traditional fee-for-service arrangements remain prevalent. Read more.

ANS CONSIDERS HEALTHCARE DISCOUNT-CARD MARKET OPAQUE AND HAS NO REGULATORY PROPOSAL YET

Brazil's National Supplementary Health Agency (ANS) considers the healthcare discount-card market opaque and has not yet developed a regulatory proposal for the sector. The agency has received responses from 38 companies and is continuing its assessment through information requests and other investigative measures to better understand how the businesses operate and what services they provide. The debate concerns products that offer discounts on consultations, examinations and healthcare services but do not provide the same contractual guarantees as regulated health insurance plans. ANS is seeking to clarify the market's structure and identify potential risks to consumers before deciding whether and how regulatory intervention may be appropriate. Read more.

BRAZIL'S HEALTH INSURANCE PORTFOLIO IS AGING, BUT INCREASE IN CONSULTATIONS AMONG OLDER BENEFICIARIES IS CONCENTRATED

Brazil's supplementary health insurance portfolio is becoming older, reflecting the country's broader demographic transition. However, an increase in medical consultations among older beneficiaries has been observed mainly in specific segments rather than uniformly across the entire population. The data suggest that the relationship between aging and healthcare utilization is more complex than a simple across-the-board rise in demand. The trend has implications for insurers, healthcare providers and policymakers as the sector adapts to an older beneficiary population. Read more.

POPULATION AGING IS EXPECTED TO ADD R$121.6 BILLION TO BRAZIL'S HEALTHCARE SPENDING BY 2036

Population aging is projected to generate an accumulated impact of R$121.6 billion on Brazil's healthcare spending between 2026 and 2036, according to estimates by the Ministry of Finance. The projection, calculated at 2025 prices, highlights the growing fiscal implications of demographic change as the share of older people in the population increases and demand for healthcare services evolves. The trend is expected to put additional pressure on both public and private healthcare systems, reinforcing the need for policies focused on prevention, chronic disease management, primary care and more efficient service delivery. The figures also underscore the importance of incorporating demographic projections into medium- and long-term health financing and planning. Read more.

LULA COULD APPOINT ALL DIRECTORS OF BRAZIL'S 12 REGULATORY AGENCIES BY 2030

President Luiz Inácio Lula da Silva could appoint the directors of all 12 of Brazil's federal regulatory agencies by 2030, with 59 board positions expected to become available over the period. Eighteen positions are already vacant, creating an opportunity for the government to reshape the leadership of agencies responsible for overseeing strategic sectors, including healthcare and pharmaceuticals. The appointment process is particularly relevant for the health sector because Anvisa and ANS decisions have a direct impact on pharmaceutical regulation, market access, healthcare services and the supplementary health system. Read more.

REGULATORY AGENCIES: ORGANIZATIONS URGE CONGRESS TO PROTECT BUDGETS FROM CUTS

A group of 41 organizations representing regulated sectors has called on Brazil's Congress to protect the budgets of federal regulatory agencies against further cuts and ensure adequate funding in the 2027 budget. The entities include industry associations representing pharmaceutical companies, medical devices and other healthcare-related businesses. They argue that insufficient resources undermine the agencies' ability to carry out inspections, review applications and maintain regulatory capacity. The organizations have also raised concerns about staffing shortages at agencies such as Anvisa and the National Supplementary Health Agency (ANS). Read more.

ANVISA PUBLISHES NEW GUIDANCE ON DRUG INTERACTION STUDIES

Brazil's Health Regulatory Agency (Anvisa) has published Guide No. 89/2026, providing recommendations for studies assessing drug interactions. The document incorporates international technical references, including guidance developed by the International Council for Harmonisation (ICH), and is intended to support the design and evaluation of studies examining how medicines may affect one another when used together. The guide is recommendatory rather than legally binding. Anvisa has opened the document to public contributions until April 26, 2027, allowing companies, researchers and other stakeholders to provide feedback on the proposed technical approach. The initiative is part of the agency's efforts to align Brazilian regulatory practices with international standards and improve the scientific basis for medicine evaluation. Read more.

BRAZIL'S MINISTRY OF HEALTH LAUNCHES CALL TO ESTABLISH NATIONAL REGISTRY OF CLINICAL RESEARCH CENTERS

Brazil's Ministry of Health has launched a public call to establish a National Registry of Clinical Research Centers. The initiative is intended to map institutions conducting clinical studies across the country, collecting information on infrastructure, research teams, areas of expertise and operational capabilities. The registry is expected to provide a clearer picture of Brazil's clinical research capacity and help identify institutions that could participate in future studies. The initiative may support the development of the country's clinical research ecosystem, improve coordination among research centers and help attract investment in clinical trials. Read more.

ANVISA APPROVES FIRST ORAL SEMAGLUTIDE FORMULATION FOR OBESITY IN BRAZIL

Brazil's Health Regulatory Agency (Anvisa) has approved the first oral semaglutide formulation for the treatment of obesity in the country. The product, marketed as an oral version of Wegovy, is taken once daily and represents a new administration option in a market where semaglutide-based treatments have gained significant attention. The approval is supported by clinical evidence from the Phase 3 OASIS 4 trial, which evaluated the 25 mg daily dose over 64 weeks and reported average weight loss of more than 13%. The new formulation expands the range of treatment options for obesity in Brazil, although access will also depend on pricing, availability and the conditions under which the medicine is prescribed. Read more.

COURT BLOCKS MUNICIPALITY'S COMPOUNDED MOUNJARO PROGRAM IN SÃO PAULO STATE

A court has suspended a municipal program in Urupês, in the state of São Paulo, that provided compounded tirzepatide to residents. The decision followed legal action by Eli Lilly, the manufacturer of Mounjaro, which challenged the municipality's initiative involving a compounded version of the medicine. The ruling is preliminary and applies to the local program. The court imposed a daily fine of R$10,000 in the event of non-compliance. The case brings renewed attention to the regulatory and legal debate surrounding compounded versions of GLP-1 medicines and other products used for weight management, particularly in relation to

intellectual property, quality controls and the rules governing pharmaceutical compounding. Read more.

NEW SEMACLIQUE WEIGHT-LOSS PEN REACHES BRAZILIAN PHARMACIES, WITH PRICES STARTING AT R$333

Semaclique, a semaglutide-based injectable medicine developed by Germed, Brace Pharma and EMS, has reached Brazilian pharmacies, with prices starting at R$333 per unit when purchased in a three-unit package. The product is a new entry in Brazil's expanding market for GLP-1 medicines used in weight management and is administered once a week. The medicine was approved by Anvisa in August. Its arrival adds another branded option to a market experiencing growing demand for semaglutide-based treatments. Pricing and distribution will be important factors in determining its competitiveness and the extent to which it can expand access among Brazilian consumers. Read more.

IN SÃO PAULO, 72% OF PROSTATE CANCER PATIENTS WAIT MORE THAN 60 DAYS TO START TREATMENT

A study in the state of São Paulo found that 72% of patients diagnosed with prostate cancer begin treatment more than 60 days after diagnosis. The median waiting time was 110 days, and only 45% of patients received treatment in the municipality where they lived. The findings point to persistent delays and geographic barriers in access to cancer care. The results highlight challenges in the organization of oncology services and the referral of patients across healthcare networks. Timely treatment is a key component of cancer care, and reducing delays requires coordination between diagnosis, specialist assessment, hospital capacity and access to appropriate therapies. Read more.

MORE HIGHLIGHTS

Anvisa's e-Notivisa system to begin receiving technical complaints about medicines

Anvisa extends transition period for Brazil's National Prescription Control System until March 2027

Anvisa establishes working group to discuss regulatory framework for traditional health products

Anvisa opens call to assess active pharmaceutical ingredients manufactured in Brazil

Sindusfarma announces pharmaceutical industry census

CADE conditions EMS-Medley acquisition on divestment of drug brands

CADE convicts pharmaceutical companies of international cartel

Brazil's SUS incorporates drug for chronic autoimmune liver disease

Speakers question use of social organizations in healthcare contracts

Senate approves "September in Bloom" campaign against gynecological cancer

Senate Human Rights Committee rejects House amendments to Tourette syndrome bill, sending text to presidential approval

Senate committee approves incentives for investment in health research

BRAZIL NEWS

Industrial trade group lobbies Senate to lower CBS tax rate

Under pressure, Lula calls for fiscal responsibility to draw foreign capital

Lula government sees Trump's midterm setback as chance to mend US ties

Rate-cut hopes fade in Brazil as Lula's reelection fans inflation fears

Brazil's Lula not weighing proposal to slash interest rates, minister says

Lula's election win dashes US hopes of quick access to Brazil's rare earths

Brazil extends oil export tax through year end, advances US reciprocity process

Brazil economists raise inflation, rate forecasts after Lula reelection

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