WEEKLY REPORT

CONSULTORES
Relações Governamentais

09/20/2025

BRAZIL DEBATE INTENSIFIES OVER DRUG PATENT EXTENSIONS

A recent survey shows there are currently 67 lawsuits in Brazil seeking to extend patent rights for medications. Experts warn that prolonging patent durations could undermine access to generics and increase costs for the health system. The concern arises despite the 2021 ruling by the Supreme Court, which struck down the paragraph of Article 40 of the Industrial Property Law that allowed automatic extensions of patents in cases of delays at the National Institute of Industrial Property (INPI). Specialists, including professors, legal experts, and public health advocates, argue that new mechanisms now under discussion may recreate similar effects to the invalidated rule. The debate also points to the risk of so-called "patent walls," when companies file minor modifications or additional requests to artificially extend exclusivity without meaningful innovation. Recommendations emerging from these discussions include stricter criteria for patent approval, greater transparency in examination processes, and strengthening the institutional capacity of INPI to reduce backlogs. The issue is gaining momentum across legal, academic, and public health sectors, highlighting the balance between encouraging innovation, and ensuring affordable access to essential medicines. Read more.

BRAZIL PHARMA INDUSTRY DIVIDED OVER PRIORITY FOR NATIONAL OZEMPIC PRODUCTION

The recent decision by Anvisa to prioritize registration of Ozempic-type pens manufactured by Brazilian companies has sparked debate in the pharmaceutical industry. The measure is intended to expand competition and prevent supply shortages, giving preference to firms that carry out at least part of the production process in Brazil. Novo Nordisk, the patent holder for Ozempic (semaglutide), filed a lawsuit to block the policy. The company argues there is no current risk of supply disruption and criticizes what it considers a lack of technical criteria in the decision. Domestic manufacturers, however, claim the measure could reduce prices and increase access. A study commissioned by Instituto Esfera indicates that when multiple Brazilian producers enter a market, regulated minimum prices for oncology drugs fall by an average of 20%, with reductions reaching 35% in highly competitive segments. Read more.

BRAZIL'S SUPREME COURT SETS STRICT CRITERIA FOR HEALTH PLANS TO COVER TREATMENTS OUTSIDE ANS LIST

The Supreme Court has ruled that private health plans in Brazil may be required to cover medical treatments or procedures not listed in the ANS's mandatory list, but only if all of the following five conditions are met: 1 - The treatment must be prescribed by a qualified physician or dentist; 2 - There must be no formal refusal by ANS to include the procedure, nor an ongoing update process concerning that treatment; 3 - There must be no adequate and effective alternative treatment already included in the ANS list; 4 - The treatment must be supported by robust scientific evidence of efficacy and safety, such as randomized clinical trials, systematic reviews or meta-analyses; and 5 - The drug or technology must be registered and approved by Anvisa. The court emphasized that the ANS list remains the main reference, but with "mitigated taxativity," meaning exceptions are possible under strict conditions. Judicial decisions must also comply with these criteria, taking into account prior requests to health plans and data from technical bodies such as NATJUS. The ruling relates to Law 14.454/2022, which altered Law 9.656/1998 to make the list more open and flexible. While patient advocates warn that access to treatments may become more restrictive, health plan operators expect the

decision will reduce litigation and generate cost savings estimated at around R$ 25 billion. Read more.

NEW LEADERS AT ANS ARE OFFICIALLY SWORN IN

Health Minister Alexandre Padilha on Wednesday (17) swore in the new members of the collegiate board of the National Supplementary Health Agency (ANS), with Wadih Damous taking office as President and Lenise Secchin as Director of Norms and Product Licensing (DIPRO). In his speech, Padilha stressed the need for greater integration between SUS and the supplementary health sector, framing the relationship as complementary. He stated that any notion of separation or antagonism between the two systems is unfounded, since they depend on each other to grow and to ensure comprehensive care. Read more.

ANVISA APPOINTS NEW EXECUTIVE SECRETARY OF CMED

The Federal Official Gazette of Tuesday, September 16, published Ordinance No. 1.101 of September 15, 2025, issued by the National Health Surveillance Agency (Anvisa), appointing Mateus Amâncio Vitorino de Paulo as the new Executive Secretary of the Drug Market Regulation Chamber (CMED). Mateus Amâncio Vitorino de Paulo holds a degree in Economics from the Institute of Economics of the Federal University of Rio de Janeiro (UFRJ), where he graduated with honors, and a master's degree in Economic Theory from the University of São Paulo (USP). He has solid academic and professional experience in economic regulation, econometric simulations, and public policy impact analysis. Throughout his career, he has worked as a researcher at the Central Bank of Brazil, in consulting firms, and in specialized research groups. He also completed an internship at the National Bank for Economic and Social Development (BNDES). In his master's dissertation, he analyzed the direct and distributive effects of regulatory changes in the Brazilian electricity sector, applying causal inference models and partial equilibrium analysis. During his academic training, he also worked as a teaching assistant in Microeconomics, Statistics, and Econometrics, in addition to publishing articles and presenting papers at national and international conferences. Read more.

HOUSE OF REPRESENTATIVES HOLDS SOLEMN SESSION MARKING INTERFARMA'S 35TH ANNIVERSARY

Brazil's House of Representatives held on Wednesday (16) a solemn session celebrating the 35th anniversary of Interfarma, requested by Congressman Doutor Luizinho (PP-RJ). Congressman Pedro Westphalen (PP-RS) highlighted the importance of clinical research in Brazil and the pivotal role of Interfarma, calling for greater investment and regulatory frameworks to retain talent and expand innovation. Interfarma's executive president, Renato Porto, celebrated the association's trajectory, which represents 42 laboratories focused on innovation, and emphasized advances such as treatments for HIV and Covid-19. Amanda Spina, chair of the Board of Directors, reinforced the need for a favorable ecosystem to ensure equitable access to advanced therapies. Co-founder Jorge Raimundo recalled the entity's early efforts to strengthen intellectual property rights and support the creation of regulatory frameworks such as the patent law and Anvisa. Health Minister Alexandre Padilha praised Interfarma's contribution to the SUS and announced the adoption of the CPF as the official number for the National Health Card, as well as new measures to strengthen clinical research and expand access to modern therapies. He also anticipated the release of a new breast cancer treatment protocol. Anvisa's president, Leandro Safatle, recognized Interfarma's strategic role in promoting innovation and reaffirmed the agency's commitment to regulatory predictability. Representing Vice President Geraldo Alckmin, Pedro Guerra stressed the government's priority of strengthening the health industrial complex. The solemn session was attended by several lawmakers, including Congressman Zé Neto (PT-BA), who emphasized the importance of the clinical research framework, and Congressman Luiz Carlos Hauly (Pode-RR), who recalled his participation in the creation of the SUS and highlighted the role of prevention and access to quality medicines and vaccines. Read more.

REPRESENTATIVE REQUESTS INCLUSION OF GUESTS AT PUBLIC HEARING ON MENOPAUSE

Representative Romero Rodrigues (PODE-PB) submitted Request 248/2025, which proposes an amendment to his earlier Request 134/2025, in order to include new guests at the public hearing to discuss the National Policy for Comprehensive Health Care and Quality of Life for Women in Menopause: Challenges and Pathways to Implementation. The request adds two names: Dr. André Malavasi Longo de Oliveira, gynecologist and obstetrician from the University of São Paulo, and Dr. Lizandra Paravidine Sasaki, president of the Brasília Gynecology Society. Lizandra's inclusion was suggested by Astellas to the representative. The debate is scheduled for October 16, with the specific time yet to be determined. Read more.

HOUSE OF REPRESENTATIVES' HEALTH COMMITTEE PASSES SUBSTITUTE BILL ON MENOPAUSE AND CLIMACTERIC TREATMENT IN SUS

The Health Committee of the House of Representatives approved on Wednesday (17) the substitute bill presented by Representative Rogéria Santos (Republicanos-BA) to Bill 876/2025, which addresses the development of Clinical Protocols and Therapeutic Guidelines (PCDTs) for climacteric care and the provision of hormonal treatments within the Unified Health System (SUS). The proposal was originally authored by Representative Ana Paula Lima (PT-SC). The initial draft required the incorporation of hormonal treatments for symptoms of menopause and climacteric, based on medical prescription. The substitute text expands the scope of the measure and establishes that SUS may provide different therapeutic approaches, including hormonal therapies, in accordance with Law No. 8.080/1990. It also allows for the development of clinical guidelines or equivalent documents to guide care during the climacteric period, ensuring individualized clinical assessment, rational use of medicines, and improved quality of care. Read more.

SENATE COMMITTEE PASSES BILL SETTING DEADLINE FOR SUS TO PROVIDE NEW TECHNOLOGIES

The Senate's Social Affairs Committee (CAS) approved on Wednesday (17) Bill 6172/2023, which amends the Organic Health Law to establish a maximum period of 180 days for the Unified Health System (SUS) to provide newly incorporated medicines, products, procedures, as well as clinical protocols and therapeutic guidelines (PCDTs), counted from the date of the incorporation decision. The proposal, authored by Senator Mara Gabrilli (PSD-SP), stipulates that the incorporation of new health technologies must occur within 180 days after the publication of the decision, with the possibility of extension for an additional 90 days in exceptional cases. The same timeframe will apply to situations involving the exclusion of health technologies. Read more.

BRAZIL CLINICAL TRIAL LAW REGULATION RAISES EXPECTATIONS IN SECTOR

Expectations for the regulation of Brazil's Clinical Trials Law (Law 14.874/2024) have increased following recent statements by Health Minister Alexandre Padilha that regulatory details could be released soon. Stakeholders anticipate about 30 items of the law to receive clear definitions, particularly in areas like process agility, strengthening of ethics committees, and classification of trial risk. Projections from Interfarma and IQVIA estimate Brazil could move from 20th to 10th place in global rankings of clinical studies, accompanied by an annual economic boost of about R$ 6.3 billion, creation of 56,000 qualified jobs, and benefits for 286,000 patients per year. Critical expected regulatory elements include establishment of the National Ethics Instance in Research (INAEP), risk classification of studies to define whether they fall under accredited or credentialed Ethics Committees, and rapid accreditation of more ethics committees for faster approval. Read more.

BRAZIL WORKSHOP DISCUSSES REGULATORY REQUIREMENTS FOR CLINICAL TRIALS AND DRUG REGISTRATION

Anvisa and the Pharmaceutical Industry Union (Sindusfarma) held the 2nd Workshop Points of attention on regulatory requirements for clinical development and registration of drugs on

September 15, in a hybrid format, with about 450 participants. Representatives from Anvisa's clinical research and drug registration areas reviewed common deficiencies found in dossiers, especially in documents such as the Investigator's Brochure, Experimental Drug Dossier, Specific Clinical Trial Dossier, and Statistical Analysis Plans. The discussions were based on RDC 948/2024 (sanitary requirements for human-use medicines) and RDC 753/2022 together with IN 184/2022 (on synthetic and semi-synthetic drug registration), also noting the impact of RDC 945/2024, IN 338/2024 and Law 14.874/2024 since their enforcement starting in January 2025. Anvisa will consolidate the workshop's outcomes into a Q&A document to guide the regulated sector. Read more.

BRAZIL SUPERMARKETS AND DRUGSTORES REACH CONSENSUS ON OTC DRUG SALES

After weeks of public divergences, supermarket and drugstore associations signaled consensus on a model for selling medicines in food retail stores. On Wednesday (17), the Senate's Committee on Social Affairs approved a new text allowing the commercialization of over-the-counter medicines in supermarkets, provided they are sold in a separate area within the store and in full compliance with ANVISA sanitary rules. Both sectors supported the approved wording. The proposal requires a pharmacist to be present during all opening hours, establishes rules for drugs subject to special control, and authorizes the use of digital sales channels only for delivery, as long as sanitary regulations are observed. The bill amends the 52-year-old Sanitary Control of Medicines Law. The original proposal allowed OTC drugs to be freely displayed on supermarket shelves, with only in-person or virtual pharmacist support. Following three public hearings, Senator Humberto Costa (PT-PE) revised the text, partially accepting an amendment by Senator Efraim Filho (União-PB). Unless a request for a floor vote in the Senate is filed, the proposal will proceed directly to the House of Representatives. To become law, it must be sanctioned by the Executive. Read more.

BRAZIL SUS PATIENTS WAIT ON AVERAGE MORE THAN ONE MONTH BEYOND LEGAL DEADLINE FOR CANCER DIAGNOSIS AND TREATMENT

Patients in the SUS (Unified Health System) are waiting on average 50 days to have a cancer diagnosis confirmed, and 75 days for the start of treatment — well beyond the legal limits of 30 days for diagnosis and 60 days for therapy initiation. The delays vary significantly by region: in the North, the wait for treatment averages 82 days; in the Northeast and Center-West, 67 days; in the South 54 days; and in the Southeast 40 days. Patient advocates and health experts warn that exceeding the deadlines harms prognosis, as later diagnosis often means more advanced disease and reduced chances of cure. Read more.

BRAZIL RESEARCH REVEALS DELAYS AND REGIONAL DISPARITIES IN FIRST YEAR OF NATIONAL CANCER POLICY

A survey by the Movimento Todos Juntos Contra o Câncer (TJCC), presented at the 12th TJCC Congress in São Paulo, reveals that despite the enactment of Law 14.758/2023 establishing the National Policy for Prevention and Control of Cancer (PNPCC), implementation remains inconsistent across Brazil. Key findings include: - No state complies with the law's deadline of 30 days for cancer diagnosis; the national average is 50 days from suspicion to confirmation; - In treatment initiation, only the South region meets the 60-day legal deadline; in the North, waits average 85 days; - About 50% of states report they do not yet have a defined implementation schedule for the PNPCC; - Governing coordination differs sharply by region, producing gaps in defining patient navigation of care and structuring care pathways. Some health administrators reported unclear understanding of primary health care's role under the new policy; - Progress is visible: approximately 45% of states have reviewed their oncology protocols, and half are updating them to align local practice with the PNPCC; and - Data systems remain fragmented. Only 38% of states and capitals have structured patient navigation programs; many do not track performance of the 60-day treatment standard. Read more.

BRAZIL NEW PHARMACEUTICAL ASSISTANCE ORDINANCE FOR CANCER TO BE ANNOUNCED IN CONSINCA MEETING

The Ministry of Health, under Minister Alexandre Padilha, will introduce the fourth ordinance regulating pharmaceutical assistance under the National Policy for Prevention and Cancer Control (PNPCC) during the Consinca meeting on September 23. The ordinance will establish criteria for the centralization of procurement and the distribution of oncology medications in the SUS. It aims to increase efficiency, promote cost savings, guarantee patient rights, and expand access to treatment. It also proposes a maximum deadline of 180 days for medications to be made available after a favorable incorporation decision. Read more.

LAW ESTABLISHES NEW STANDARDS FOR SUS EQUIPMENT PROCUREMENT

The newly sanctioned Law 15.210/2025 mandates that purchases of medical equipment for exams and treatments in the Unified Health System (SUS) must consider the effective use of the equipment throughout its useful life. The law requires that public bidding processes include either proof of installed capacity to operate the equipment or a plan ensuring that all operational requirements will be met. These provisions have been incorporated into the Updated Public Procurement Law. Law 15.210/2025 originated from Bill 2641/2019, submitted by Senator Alessandro Vieira (MDB-SE), and was inspired by a proposal from a high school student from Sergipe who participated in the House of Representatives' Parlamento Jovem. Its main objective is to prevent waste of expensive equipment that often remains unused in health facilities due to lack of infrastructure. The new standards apply to equipment whose cost exceeds the threshold exempting purchases from bidding. Read more.

BRAZIL GOVERNMENT ADOPTS CPF IN SUS REGISTRATION AND WILL ELIMINATE INACTIVE RECORDS

The Ministry of Health announced on Tuesday (16) that the CPF (Individual Taxpayer Registry) will become the unique identifier for all users of the Unified Health System (SUS). This measure is part of a major data clean-up process that foresees the exclusion of 111 million inactive or duplicate records by April 2026. Since July, about 54 million records have already been deactivated. The ministry explained that the SUS database, which in July had 340 million entries, now registers 286.8 million active records. Of this total, 246 million are already linked to a CPF, while 40.8 million are under review due to duplication or inconsistencies — many without an associated CPF. The change aims to standardize patient identification and eliminate multiple SUS cards for the same person. According to the government, the measure will facilitate the monitoring of medical history, vaccination, and drug dispensing, as well as reduce administrative inefficiencies. Read more.

MINISTRY OF HEALTH OPENS APPLICATIONS TO TRAIN 4,000 SPECIALISTS IN PRIORITY AREAS FOR SUS

The Ministry of Health has launched applications for institutions to train 4,000 specialist health professionals in priority areas for the SUS through two new calls. Institutions can apply until October 20, 2025 via the SIG-Residências system. Of the 4,000 fellowships: - 3,000 are for medical residency programs in specialties such as anesthesiology, radiology, and oncologic surgery; - 1,000 are for healthcare professional residency programs, including areas like women's health, mental health, obstetric nursing, among others. Universities, federal hospitals tied to the Ministries of Health and Education, public institutions at the municipal, state and district levels, and non-profit private entities may apply. This is the largest offering under Pró-Residência in the past 10 years. In 2025 alone, the Ministry will invest R$1.8 billion, a 32% increase compared to 2023. Bursaries will prioritize the states in the Legal Amazon to promote equity and reduce regional disparities. Read more.

BRAZIL MEDLEY ASSETS ATTRACT INTEREST FROM MAJOR NATIONAL PHARMA PLAYERS

At least four Brazilian pharmaceutical companies are preparing offers to acquire the generics manufacturer Medley, currently owned by French group Sanofi. The interested parties include

Aché, EMS, Hypera and União Química. Sanofi is seeking around US$ 1 billion for the sale, but market sources estimate the final price may be closer to US$ 500–600 million. The transaction is expected to be concluded in early 2026. The acquisition is seen as strategic for the companies involved, as Medley's portfolio includes generics in key therapeutic areas such as analgesics and cardiovascular drugs. Sanofi has engaged Lazard as financial advisor to separate Medley's operations and prepare it for the sale. Private equity funds are also being considered potential bidders. Sanofi acquired Medley in 2009 for approximately R$ 1.5 billion, which at the time reinforced its position in Brazil's generics market. Read more.

BRAZIL RANKS AS FIFTH LARGEST BIOSIMILARS MARKET GLOBALLY

Brazil is currently the fifth largest country in the world in number of registered biosimilars, consolidating its position as the leader in Latin America. Biologicals and biosimilars already account for 30% of the pharmaceutical sector's total revenue, moving R$ 48.5 billion in 2024, a 25.9% increase compared with 2023. According to PróGenéricos, its member companies increased their market share in units sold from 1.45% in 2020 to 7.33% in 2024, representing a growth of 1,589%. Brazil now has 63 biosimilars registered, distributed among 15 manufacturers, with 80 presentations available. Major producers active in the country include Aché, Brainfarma, Eurofarma, EMS, Fresenius Kabi and Sandoz, responsible for molecules such as adalimumab, enoxaparin, insulin glargine, filgrastim and trastuzumab. Read more.

MORE HIGHLIGHTS

Ministry of Health recommends testing all babies for early diagnosis of autism

Senator Dr. Eudócia presents requests for the Work Plan of the subcommittee on cancer

Senator requests public hearing to discuss bill creating Regulatory Framework for Vaccines and High-Cost Cancer Medications

Bill aims to ensure civil society participation in regulatory agency committees

A solemn session was held in honor of Muscular Dystrophy Awareness Day

Public hearing discusses the regulation of nuclear medicine in Brazil

Bill on disseminating information for prostate cancer prevention is received by the Education and Culture Committee

Parliamentary Front will act in defense of people with rare diseases in the Legislative Assembly of Rio Grande do Sul

BRAZIL NEWS

Brazil's Congress fast-tracks amnesty bill that could include Bolsonaro

Brazil central bank keeps rates steady, signaling extended hold

Brazil's finance minister sees rate cuts in coming months

Brazil economic activity falls more than expected in July

Brazil economists trim end-2026 interest rate forecast after seven months

Brazil will be first to invest in global forest fund, sources say

Brazil expects Mercosur-UAE trade deal by end of 2025, minister says

Swiss economy minister signs Mercosur agreement in Brazil

UN boosts financial support to poorer countries attending COP30 amid hotel crisis

Brazil launches proposals to attract data centers, regulate digital competition

Brazil leather price slumps, challenging $1.25 billion export industry

Brazil's beef exports to US to fall further in September after tariffs, industry group says