WEEKLY REPORT

CONSULTORES
Relações Governamentais

08/09/2025

NEW TREATMENT FOR ADVANCED PROSTATE CANCER APPROVED IN BRAZIL
A new treatment for advanced prostate cancer, when there is metastasis, was approved in June by Anvisa (National Health Surveillance Agency). The combination therapy of talazoparib and enzalutamide is indicated for cases where the tumor continues to grow even after hormonal blockade. According to oncologists, up to 20% of patients develop the metastatic and hormone-resistant form (mCRPC). Another, even more serious, type is prostate cancer with a mutation in the homologous recombination repair (HRR) gene, also resistant to hormonal blockade, which affects approximately 4% of patients, according to medical literature. These alterations impair the cells' ability to repair themselves, leading to cancer progression. Produced by Pfizer under the name Talzenna, talazoparib is a PARP (poly ADP-ribose polymerase) enzyme inhibitor. Enzalutamide, commercially known as Xtandi and manufactured by Astellas, blocks the action of testosterone and other male hormones (androgens). The drug had been used as the basis for standard treatment of prostate cancer in cases of metastasis, just as Talzenna was already used in treatments for breast and ovarian cancer with the HRR mutation. Read more.

ANS DENIES RESOURCES FOR PROSTATE CANCER AND PSORIASIS TREATMENTS
The National Supplementary Health Agency (ANS) held the 626th Regular Meeting of the Board of Directors (DICOL) on Monday (4). At the beginning of the meeting, Director Eliane Medeiros commented on the health campaigns held in August: breastfeeding (Golden August), lung cancer (White August), multiple sclerosis (Orange August), vascular health (Blue and Red August), and men's health (Blue August). The directors decided not to grant the appeal filed by Astellas Farma Brasil Importação e Distribuição de Medicamentos Ltda., which challenged the non-inclusion of the UAT143 technology (enzalutamide in combination with leuprorelin for the treatment of non-metastatic hormone-sensitive prostate cancer in high-risk biochemical recurrence) in the ANS List of Health Procedures and Events. Read more.

NEW DRAFT IS PRESENTED ON BILL ABOUT CLIMACTERIC TREATMENT IN THE UNIFIED HEALTH SYSTEM (SUS)
Representative Rogéria Santos (Republicans-BA) presented, in the Health Committee, a substitute bill to Bill 876/2025, which addresses the development of a Clinical Protocol and Therapeutic Guideline (PCDT) for climacteric and the offer of hormone treatments in the Unified Health System (SUS). Authored by Representative Ana Paula Lima (Workers' Party-SC), the initial text aimed to ensure the incorporation of hormone treatments for climacteric in the SUS. However, the rapporteur noted that, upon analyzing the original text, she observed that the author stipulates that the offer of hormone treatment must occur not only under medical indication, but also "in accordance with Law No. 8,080 of September 19, 1990." She emphasized that the proposed substitute bill seeks to give greater depth and clarity to this provision. Therefore, the amendment aims to ensure the development of a Clinical Protocol and Therapeutic Guideline (PCDT) specific to menopause. Read more.

BRAZIL TO TELL U.S. IT WILL SHORTEN PATENT REVIEW PERIOD FOR MEDICINES
Delays in granting pharmaceutical patents to U.S. companies by Brazil are one of the central issues in an investigation launched by the United States Trade Representative (USTR) under Section 301 of the U.S. Trade Act, according to a report by O Globo. Sources familiar with the matter said the Brazilian government intends to respond that the current review period — which

the U.S. claims can take up to six years — will be reduced to two years by 2026. The investigation focuses on alleged unfair trade practices by the Brazilian government. U.S. authorities argue that the lengthy approval time significantly reduces the effective period of patent exclusivity, which is legally set at 20 years. Brazil's National Institute of Industrial Property (INPI), which oversees patents, stated that the current average time to analyze a patent application — after the examination is requested — is 2.9 years overall, and 3.7 years specifically for pharmaceutical products. Read more.

PADILHA: ANVISA REGISTRATIONS AND PATENT GRANTING NEED TO BE FASTER

The executive order signed by U.S. President Donald Trump, raising tariffs on Brazilian products to 50%, has accelerated the Ministry of Health's efforts to reduce dependence on foreign markets. Strategies that were previously under consideration, such as faster registration of medicines and products considered essential for the sector, are now receiving increased emphasis, Health Minister Alexandre Padilha told JOTA. Items highlighted as priorities for registration include medicines, vaccines, and products for chronic diseases. Padilha also stated that discussions are underway to mitigate the impact on the healthcare equipment sector, one of the sectors most affected by the tariff hike. One option is to increase the participation of Brazilian products in the Pan American Health Organization's Revolving Fund. Read more.

DOMESTIC COMPETITORS TO OZEMPIC WILL HAVE DIFFERENT STRENGTHS, EXPLAINS DOCTOR

Starting this Monday (4), new national medications will arrive in Brazilian pharmacies that compete with products such as Ozempic, Wegovy and Mounjaro. In an interview with CNN, endocrinologist Deborah Beranger explains that, although these medications have a more affordable cost, they have a different potency to their imported counterparts. The Brazilian production of these medications represents an important alternative for patients with lower purchasing power. However, it is important to emphasize that the reduced potency affects both the effectiveness of weight loss and glycemic control. Read more.

BRAZIL'S HEALTH MINISTER AND PHARMACEUTICAL INDUSTRY DISCUSS CLINICAL TRIALS RULES AND DRUG PRICING

Brazil's Health Minister, Alexandre Padilha, met on Thursday afternoon (7) with the Pharmaceutical Research Industry Association (Interfarma), which represents international companies in Brazil. The meeting took place during the entity's Board of Directors meeting in São Paulo and aimed to discuss industry demands and government initiatives. "We talked about how this partnership will help Brazil occupy an increasingly prominent position in production, technological innovation, and access to medicines here in our country," said the minister. This was not Padilha's first meeting with the pharmaceutical industry. On May 7, the minister had already met with various organizations at a sector dinner in Brasília. Also, on Wednesday (6), the government representative took part in the Health Forum, an event organized by Esfera Brasil in partnership with EMS. Padilha highlighted that one of the main topics discussed was the new regulatory framework for clinical research, an instrument that could boost the sector and b— a discussion within the scope of the Drug Market Regulation Chamber (CMED), which was under public consultation until July 10 — was another topic on the agenda. The "Agora Tem Especialistas" program was also mentioned because, according to Padilha, it creates new demand for medicines. Read more.

BRAZIL OPENS PUBLIC CONSULTATION ON CHALLENGES TO STRENGTHENING CLINICAL TRIALS

Brazil's Ministry of Health has launched a public consultation to gather input from civil society on the main challenges and barriers to strengthening the clinical research environment in the country. The consultation was published in the Official Gazette on Friday (August 1). It seeks to map out the current state of clinical trial in Brazil, including the capacity of research centers, and identify key structural and operational issues that limit growth in the sector. According to the Ministry, the collected data will support the development of public policies aimed at: -

Strengthening the national clinical research ecosystem, - Promoting technological innovation, - Expanding public access to new treatments. Read more.

BRAZIL'S SENATE TO HOLD CONFIRMATION HEARINGS FOR ANVISA AND ANS LEADERSHIP NOMINEES

Brazil's Senate Social Affairs Committee (CAS) will hold confirmation hearings on Wednesday, August 13, for four nominees to lead the country's two main health regulatory agencies — Anvisa (National Health Surveillance Agency) and ANS (National Supplementary Health Agency). The nominees include candidates for the presidency of both agencies. The CAS received the reports on their nominations on Wednesday (6) and granted a collective request for further review before scheduling the hearings. For Anvisa, the nominee for director-president is Leandro Pinheiro Safatle, an economist, who would replace Antônio Barra Torres. His nomination (MSF 91/2024) is being reviewed by Senator Mara Gabrilli (PSD-SP). Read more.

BRAZILIAN REGULATORY AGENCIES ADVOCATE FOR FINANCIAL AUTONOMY THROUGH USE OF OWN REVENUES

On Tuesday (5), a joint public hearing held by four committees in the House of Representatives discussed the main challenges faced by federal regulatory agencies, such as staff shortages and budget cuts, according to a report by Futuro da Saúde. In this context, the Committee of Federal Regulatory Agencies (COARF) requested support from the National Congress for legislative changes aimed at ensuring the financial autonomy of the agencies and the use of the revenues collected by the regulatory bodies themselves. As established by Law No. 13,848/2019 — which governs the management, organization, decision-making process, and social oversight of regulatory agencies — functional, decision-making, administrative, and financial autonomy are guaranteed. However, according to COARF, the financial component is not being fully implemented. Read more.

WITH TARIFF HIKE, GOVERNMENT WILL PRIORITIZE DOMESTIC INDUSTRY

Amid the tariff hike crisis and concerns about its impact on industry, the government has decided to purchase R$2.4 billion in equipment for the Unified Health System (SUS). Domestic manufacturers will receive preference even if their prices are 10% to 20% higher than those of international competitors. The first bidding process begins this week, the Ministry of Development, Industry, Commerce, and Services (MDIC) announced. The list of equipment was published last Thursday (31) in the Official Gazette. Read more.

ORDINANCE PUBLISHED CREATES WORKING GROUP ON COMPLIANCE WITH COURT ORDERS FOR THE SUPPLY OF MEDICATION

Ordinance 7.800/2025 was published in the Official Gazette of the Union on Tuesday (5), establishing a permanent Working Group within the Ministry of Health to improve and regulate inter-federal reimbursement for amounts spent by federative entities in compliance with court orders for the supply of medication. The Working Group will aim to contribute to the continuous improvement of inter-federal reimbursement processes, propose guidelines that strengthen integration between the entities involved, assist in resolving disagreements, and suggest improvements to regulatory acts related to procedural rules. Read more.

ORDINANCE PUBLISHED ESTABLISHES WORKING GROUP TO DEVELOP A MONITORING AND EVALUATION PLAN FOR PDPS

The Secretary of Science, Technology and Innovation and the Economic-Industrial Complex of the Ministry of Health published in the Official Gazette of the Union this Tuesday (05), the ordinance that aims to establish the Working Group, of a propositional nature, to develop a monitoring and evaluation plan for PDPs. Read more.

CONGRESS ANALYZES CREATION OF FEDERAL DRUG MARKETPLACE

Bill 2133/2023, which proposes the creation of a federal drug marketplace, is currently under consideration in the National Congress. Dubbed the Express Purchasing System (Sicx), the innovation was authored by the Rio de Janeiro State Secretary of Health and Deputy Daniel Soranz (PSD/RJ). This information comes from the Futuro da Saúde website. After being approved by the Constitution and Justice Committee (CCJ) of the Chamber of Deputies in early July, the bill will be analyzed by the Federal Senate. Read more.

IN A DEBATE IN THE HOUSE OF REPRESENTATIVES, EXPERTS DEFEND THE SAFE USE OF AI IN HEALTHCARE

The Health Committee of the Chamber of Deputies held a public hearing on Tuesday (5) to discuss a bill regulating the use of artificial intelligence (AI) in the health sector. The meeting brought together deputies, representatives of the Ministry of Health and experts from the medical technology sector. Artificial intelligence is already used in medicine to support diagnoses and assist in surgeries using robots. The expectation is that, in the future, technology will transform patient care and the healthcare industry itself. Read more.

MORE HIGHLIGHTS

Adult patients with acute lymphoblastic leukemia (ALL) will have a new medication option on the SUS

Ministry of Health may provide information on actions to regulate the National Policy for Cancer Prevention and Control

Representative proposes solemn session in allusion to Pink October

Public hearing scheduled to discuss strengthening regulatory agencies

Bill aimed at diagnosing hereditary malignant neoplasms was sponsored to the São Paulo State Legislative Assembly

Bill aiming to create the State Preventive Genetics Program is sponsored to the Legislative Assembly of Goiás

Blue August Campaign reinforces actions dedicated to men's health in the Paraná State Legislative Assembly

BRAZIL NEWS

Brazil's Bolsonaro arrested, adding to tensions with Trump

Brazil's Supreme Court caught off guard by order to arrest Bolsonaro, sources say

Lula says Bolsonaro should face charges for inciting US against Brazil

'I won't humiliate myself': Lula sees no point in tariff talks with Trump

Lula says he will discuss tariffs with BRICS group

Lula plans new 'national sovereignty' policy for strategic minerals

Brazil files WTO request for consultation over US tariffs

Lula signs bill to ease Brazil environmental licenses but vetoes key provisions

Brazil weighs pulling $5.5 billion from development bank fund to prop up tariff-hit businesses

Brazil economy starting to see impact of high rates, official says

Brazil central bank warns on US tariffs, vows to anchor inflation expectations

Brazil central bank did not pause but halted tightening cycle, official says

Brazil interest rate overly restrictive, room for earlier cuts, minister says

Brazil auto exports to jump driven by Argentina; tariffs affect local sales

Standard Chartered inks deal to sell jurisdictional forest credits in Brazil

Brazil dismisses calls to relocate COP30 amid Amazon city price surge