WEEKLY REPORT 11/09/2024



SENATOR REQUESTS PUBLIC HEARING ABOUT BLUE NOVEMBER

Senator Nelsinho Trad (PSD-MS) sponsored request 105/2024 to the Social Affairs Committee (CAS), proposing holding a public hearing on 'Men's Health - Every Step Counts'. He emphasized that the goal is to raise awareness about men's health, promoting access to information and reducing stigmas. He highlighted that lack of information and prejudice are some of the reasons why many men neglect simple, quick, and essential procedures to detect diseases in their early stages. Therefore, he stated that the debate seeks to draw attention to the importance of carrying out preventive exams regularly. <u>Read more</u>.

CONGRESSMAN SUGGESTS THAT THE MINISTRY OF HEALTH EXPAND AWARENESS CAMPAIGNS ON PROSTATE CANCER

Congressman Captain Alberto Neto (PL-AM) sponsored indication 1517/2024, which suggests that the Minister of Health, Nísia Trindade, expand awareness campaigns and counter prejudice for early diagnosis of prostate cancer. In his text, the congressman highlighted that there is a stigma related to men's health and seeking medical care, especially when it comes to urological exams. According to him, this can lead men to avoid talking about health issues or postpone preventive exams. This stigma represents a significant obstacle to the early detection of diseases. Therefore, he highlighted that the Blue November campaign plays a crucial role in encouraging preventive exams, which are essential for the early detection of cancer. <u>Read</u> more.

BRAZILIAN VACCINE FOR PROSTATE CANCER IS APPROVED BY THE FDA FOR CLINICAL TRIALS

A therapeutic vaccine against prostate cancer developed by Brazilian researchers has been approved for clinical trials by the FDA (Food and Drug Administration, the regulatory agency of the United States). It is the first time that a technology of this type has reached this stage. Created from the patient's own tumor cells, the vaccine aims to strengthen the immune system against cancer and reduce recurrence, in addition to conventional treatments. According to preliminary data, personalized immunotherapy reduces the recurrence of the disease from 37% to 12%. Mortality among treated patients fell from 12.8% to 4.3%. <u>Read more</u>.

BRAZILIAN RESEARCH REVEALS THAT AROUND 10% OF MEN DO NOT KNOW WHAT THE PROSTATE IS

A survey conducted by the Brazilian Society of Urology (SBU), with the support of Adium and conducted by the Ideia Institute, reveals surprising data. With the theme "The male perspective on men's health", the survey involved the participation of 1,500 men over 40 years old, from all regions of the country, who responded via mobile application. Despite the neglect, misinformation, fear, and anxiety are still part of the male universe when they think about their health. <u>Read more</u>.

TAX REFORM: SENATORS DOUBLE AMENDMENTS AND 40% FAVOR FOOD AND HEALTH

Senators have already submitted 1,622 proposed amendments to the proposed tax reform regulation, double the 805 suggested by the House of Representatives. The amendments, a term used behind the scenes by some senators to point out flaws in the proposal, reflect the interests of different sectors of the economy, which seek to reduce the impact on prices for

consumers due to an alleged increase in the tax burden. There are two groups that lead: amendments related to health and those that affect Brazilians' diets. Together, they total 623, almost 40% (38.4%) of the total. <u>Read more</u>.

ANS SIGNS AGREEMENT WITH CFM THAT MAY RESTRICT PROCEDURES FOR ASD

The National Supplementary Health Agency (ANS) signed a technical cooperation agreement with the Federal Council of Medicine (CFM) last Tuesday (5/11). As JOTA revealed, the proposal of the president of ANS, Paulo Rebello Filho, is to use this agreement to create usage guidelines for operators in procedures aimed at beneficiaries with autism spectrum disorder (ASD). The president of ANS also wants to sign a technical cooperation agreement with the National Council of Justice (CNJ) to facilitate the creation of a type of Technical Support Center for the Judiciary (Natjus) for supplementary health demands, which currently does not exist. Rebello's proposal is that these centers be funded with 1% of the revenue from Supplemental Health Fees (TSSs). The president of ANS submitted a proposal for a provisional measure to the Minister of Institutional Relations, Alexandre Padilha, to facilitate this sharing and the creation of these centers. When contacted, Padilha did not comment. <u>Read more</u>.

ANS SIGNS PARTNERSHIP TO CONSOLIDATE VALUE-BASED REMUNERATION MODELS IN HEALTHCARE

In order to improve the Value-Based Remuneration Program, the National Supplementary Health Agency (ANS) signed a technical cooperation agreement with the Brazilian Institute of Value in Health (IBRAVS), the Federal Council of Physiotherapy and Occupational Therapy (COFFITO) and the Regional Councils of Physiotherapy and Occupational Therapy (CREFITO) of the 3rd and 4th Regions. The agreement was signed on Thursday, October 31, and will last for five years. It is motivated by the need to consolidate, qualify and expand the Value-Based Compensation Models Program, an initiative promoted by ANS in supplementary healthcare. With this cooperation, it is expected that private health plan operators, in partnership with providers, will opt for payment models that emphasize the importance of health outcomes for the patient and that favor the efficient allocation of resources, avoiding waste and promoting sustainability. <u>Read more</u>.

PUBLIC DEFENDER SEES POSSIBLE OMISSION AND REQUESTS AUDIT AT ANS FOR PLAN CANCELLATIONS

The DPU (Public Defender's Office of the Union) sent letters to committees in the House of Representatives and the Senate with a report on the unilateral cancellations of health plans by operators to support a possible request for an audit at the ANS (National Supplementary Health Agency) due to possible failure to carry out inspections. The audit request would be made to the TCU (Federal Court of Auditors). In the report, the DPU details its actions to try to ensure the maintenance of contracts terminated with signs of irregularities and the recommendation that there should be continued coverage of treatments for the elderly, people with disabilities, people with rare diseases, pregnant women and people with disorders considered serious, regardless of whether they are hospitalized. <u>Read more</u>.

THE 50 LARGEST HEALTH PLANS IN BRAZIL

Bradesco Saúde, Hapvida and SulAmérica Saúde are the three largest health plan operators in Brazil, according to the Valor 1000 ranking. Just like last year, the companies continue to lead and occupy the same positions as in the list released the previous year. <u>Read more</u>.

AFTER CRITICISM, CGU MINISTER STATES THAT REGULATORY AGENCIES ARE NOT EXEMPT FROM CONTROL

The minister of the CGU (Comptroller General of the Union), Vinícius Marques, questioned this Friday (1) criticisms about government intervention in regulatory agencies after opening proceedings to investigate Aneel (National Electric Energy Agency). "The CGU has 240 audits of regulatory agencies. Aneel alone has 18," he said. "None of this is intervention. If we start

reading any discussion about agencies as intervention, we are going down the wrong path. No one is exempt from any type of control. No autonomy is unrestricted." <u>Read more</u>.

REPRESENTATIVE SPONSORS BILL THAT GRANTS THE HOUSE THE POSSIBILITY TO MONITOR REGULATORY AGENCIES

Representative Danilo Forte (União-CE) presented in an interview at the House of Representatives the bill that grants the House the possibility to monitor regulatory agencies. The PEC has not yet been officially filed, but the text developed by the parliamentarian seeks to add a new paragraph to article 51 of the Federal Constitution, granting the House of Representatives the power to monitor and monitor the activities and normative acts of regulatory agencies. According to the proposal, the committees of the House will be able to establish deadlines for the agencies to adopt the necessary measures to comply with the law. In addition, if intentional unlawful conduct is identified, whether by action or omission, such conduct must be forwarded to the Public Prosecutor's Office, the Attorney General's Office and the Federal Court of Auditors, so that the appropriate actions can be taken regarding the administrative, civil or criminal liability of the offenders. <u>Read more</u>.

ANVISA ADOPTS STRATEGY BASED ON ARTIFICIAL INTELLIGENCE TO OPTIMIZE DRUG ANALYSIS

As part of its commitment and ongoing effort to provide quality and efficient services, Anvisa has adopted several strategies to optimize its work processes. Among these strategies is the use of technological solutions, such as the application of Artificial Intelligence (AI) models. In this sense, the Agency developed an AI-based tool to optimize the analysis of qualification studies of the limits of impurities and degradation products of synthetic drugs, classified as new, innovative, generic, and similar. The qualification analysis of impurities and degradation products is an integral part of the safety analysis within the scope of the registration and post-registration of medicines. The activity is mandatory when the limits found in the products are higher than the limits established by Resolution RDC 53/2015, by international guides on the subject and by pharmacopoeias recognized by Anvisa. <u>Read more</u>.

ANVISA AND ABDI SIGN AGREEMENT TO MODERNIZE SYSTEMS

Anvisa and the Brazilian Agency for Industrial Development (ABDI) signed, this Friday (11/8), a technical cooperation agreement aimed at modernizing the regulatory agency's information systems. The main objective of the two institutions with this agreement is to enable investment in information technology (IT) tools capable of optimizing Anvisa's performance, promoting automation and reducing dependence on qualified labor for minimum data structuring, which should allow for an acceleration in the decision-making process. The partnership should enable the modernization of Anvisa's technology park and the improvement of its internal processes, in order to meet the deadlines, set forth in the legislation. One of the expected effects is the increase in competitiveness and innovation in the Brazilian pharmaceutical sector, especially due to the adoption of information standards already used by the main drug regulatory agencies in the world. <u>Read more</u>.

AFTER BACK AND FORTH, HEALTH DEPARTMENT REJECTS OFFER OF UPDATED COVID VACCINE DUE TO LACK OF ANVISA REGISTRATION

The exchange of expired Covid vaccines, the result of a delivery with a different expiration date than that agreed with the pharmaceutical company Moderna, involved a back-and-forth at the Ministry of Health. After saying that it would accept an offer of 3 million updated vaccines, that is, adapted to the JN.1 variant, the ministry changed its position and refused the vaccines. The doses were supposed to arrive in the country by December. Instead, the ministry headed by Nísia Trindade demanded the delivery of the older vaccine, the model currently available in the SUS (Unified Health System), aimed at the XBB strain. It also opened an administrative process against the company, which says it is unable to follow the Health Department's order because it no longer manufactures vaccines against the XBB variant. <u>Read more</u>.

MORE HIGHLIGHTS

ANS approves the inclusion of treatment for leukemia and recommends not incorporating treatments for prostate and lung cancers, diabetes, and lymphoma

<u>Judge suspends CFM rule requiring use of platform to issue certificates</u>

<u>Statement of repudiation to the STF regarding the provision of high-cost medicines</u> to patients with serious illnesses approved

<u>Pharmaceutica company stops production of rivotril 0.5 mg, and pharmacies no</u> longer have stock

BRAZIL NEWS

Brazil annual inflation forecast at 1-year high in Oct

Brazil Finance minister cancels trip to Europe amid pressure to present fiscal measures

Brazil denies CNN report that upcoming spending cuts limited to \$2.6 bln

Brazil looks at curbing health, education spending in fiscal package, sources say

Brazil finalizes talks on new fiscal measures amid volatility post US election

Trump victory a boost for Brazil's right-wing politics

Brazilian firms tout U.S. plants, leaning into Trump trade wars

US soybean trade with China already strained before Trump's return

Biden's Amazon visit comes as US climate policy to shift under Trump

Brazil announces new climate change pledge ahead of COP29 summit

Brazil lifts coal imports to record as hydro hit lingers

EU-Mercosur trade deal should reward conservation, says Stanford professor

EU official expects Mercosur trade deal this year, dismisses changes on deforestation law

Brazil funding of green projects from sustainable bonds off to a slow start

Sweden selects Embraer cargo plane; Brazil plans to buy more Saab fighters

Brazil aid to airlines on the way, says airports minister

Brazil sues Italy's Enel for power outage reparations

Petrobras posts 22% increase in quarterly profit, announces \$3 billion in dividends