

WEEKLY REPORT

11/30/2024



ANVISA APPROVES NEW FRAMEWORK FOR CLINICAL TRIALS IN BRAZIL

The Board of Directors of Anvisa approved, this Wednesday (27/11), a broad update of the standard that regulates clinical research in Brazil. The new rules should allow Brazil to be more attractive for investments in clinical research. The update of the standard was proposed by the Agency's own technical area and received 240 contributions during the public consultation phase, all of which were analyzed individually by the technical team. Clinical research encompasses a set of studies conducted on human beings, and the data generated during these studies serve to demonstrate the efficacy and safety of a drug that, during the research phase, is considered an investigational product. Clinical studies are one of the central pillars for the registration of new drugs and their arrival on the market. [Read more.](#)

REPRESENTATIVES OF REGULATORY POINT OUT A LACK OF PERSONNEL AND BUDGET TO ACT

Representatives of regulatory agencies have expressed concerns about budget cuts and staff shortages. The situation of these institutions was the subject of debate in the Economic Development Committee of the Chamber of Deputies on Thursday (28). The country has eleven regulatory agencies whose function is to create standards and monitor the quality of services provided in various market segments operated by the private sector. Regulated services include telecommunications, energy, transportation, water, fuel, and health. The Anvisa's CEO, Antônio Barra Torres, did not attend the hearing. [Read more.](#)

BILL AIMS TO ESTABLISH THE NATIONAL POLICY FOR COMPREHENSIVE HEALTH CARE AND QUALITY OF LIFE FOR WOMEN IN MENOPAUSE

Representative Silvye Alves (União-GO) presented Bill 4504/2024, which establishes the National Policy for Comprehensive Health Care and Quality of Life for Women in Menopause. The policy seeks to promote, ensure and integrate actions for the physical, emotional, and social health of women in menopause and climacteric, guaranteeing rights and improving quality of life. The guidelines include humanized care in the SUS, educational campaigns, integration between public sectors, encouragement of scientific research and strategies against discrimination and stigmas related to menopause. [Read more.](#)

ANVISA UPDATES RULES FOR THE SALE OF HORMONAL IMPLANTS

The National Health Surveillance Agency (Anvisa) published new rules for the handling and sale of hormonal implants in Brazil in the Official Gazette (DOU) this Tuesday. In October, the agency banned the use and sale of all products of this type. However, last week, it authorized those for medical purposes. Those for aesthetic purposes, sports performance, and muscle mass gain, such as "beauty chips", remain banned. Furthermore, advertising of any implant, regardless of its purpose, also remains prohibited in Brazil. The products are made with anabolic steroid-based hormones or androgenic hormones in compounding pharmacies with a prescription. They are inserted under the skin and used when hormone replacement therapy is indicated. [Read more.](#)

COMPLAINTS AGAINST DOCTORS FOR PRESCRIBING HORMONES INCREASED 120% IN ONE YEAR, SAYS CFM

The number of complaints and investigations against doctors who prescribed hormones grew 120% in one year, said Doctor Francisco Eduardo Cardoso Alves, representative of the CFM

(Federal Council of Medicine) during a debate in the Senate on the so-called "beauty chips". The data was presented after Anvisa backtracked on the total suspension of hormonal implants, on the 22nd. In October, the agency had prohibited the use for medical, aesthetic and performance purposes — the so-called anabolic steroids. This week, the agency established new rules to ensure greater rigor in the handling and sale of hormonal implants. Among the measures is the requirement of a prescription for the purchase of these products and information to the patient about the risks. [Read more.](#)

SUS EXPANDS TREATMENT OF POSTMENOPAUSAL WOMEN WITH SEVERE OSTEOPOROSIS AND TREATMENT FAILURE

The Ministry of Health agreed, this Thursday (28), during the 11th Ordinary Meeting of the Tripartite Intermanagerial Committee (CIT), the responsibility for financing and acquiring the drug romosozumab for the treatment of postmenopausal women with severe osteoporosis and treatment failure. The drug, already incorporated into the Unified Health System (SUS), will bring a better quality of life to thousands of women. In addition to expanding the lines of treatment for severe osteoporosis, the action also improves adherence and increases the effectiveness of treatment and reduces fractures. Approximately 11 thousand women throughout the country will benefit from the expansion. The drug was already available in the SUS for the treatment of women over 70 years of age and will now be available to patients who meet the criteria, with no age restrictions. The initiative not only expands treatment options for such a debilitating condition, but also increases the effectiveness in controlling the disease. Romosozumab stands out for strengthening bones, reducing the risk of fractures, and significantly improving treatment adherence, a common challenge among patients with osteoporosis. [Read more.](#)

MINISTRY OF HEALTH PUBLISHES ORDINANCE THAT PROMOTES CHANGES IN THE COMPOSITION OF CONITEC

The Ministry of Health published in the Official Gazette of the Union this Friday (29), the ordinance to amend the GM/MS Personnel Ordinance No. 149, of February 16, 2024, regarding the designation of indicated members who will compose the Committees of the National Commission for Incorporation of Technologies into the Unified Health System - Conitec. [Read more.](#)

GLOBAL FORUM 2024 DISCUSSES CANCER DIAGNOSIS AND TREATMENT, PUBLIC POLICIES AND HEALTHCARE FINANCING

The Global Forum – Frontiers of Health 2024 was held in Brasília on Tuesday (26), Wednesday (27) and Thursday (28). Promoted by the Lado a Lado Pela Vida Institute, the event discussed topics related to the fight against cancer, vaccination, SUS, and healthcare financing. During the opening of the event, Marlene Oliveira, founder and president of the Lado a Lado Pela Vida Institute, began her speech by highlighting the importance of prevention and vaccination. She emphasized that healthcare is something complex and most of the time we do not realize its size and importance. She then stated that public policies need to be made for the people who need access, diagnosis, and adequate treatment. Marlene explained that it is difficult to understand why health is not a top priority for the country, highlighting that everyone's commitment is needed to ensure that the Law that establishes the National Policy for Cancer Prevention and Control is implemented. [Read More.](#)

THE NUMBER OF PROSTATE CANCER DIAGNOSTIC TESTS IS INCREASING

A survey by Santa Catarina-based startup LifesHub , which specializes in data and market intelligence, shows that in recent years there has been a significant increase in the demand for PSA tests, used to diagnose prostate cancer, the second most common cancer in the country's male population , behind only non-melanoma skin tumors. Among those over 40 years old, there was a 97.2% increase in the total number of tests performed by the SUS between 2018 and 2023. There were 403.4 thousand evaluations six years ago, 795.6 thousand last year and 565.5 thousand until October 2024. [Read more.](#)

PUBLIC HEARING ADDRESSES PROSTATE CANCER PREVENTION AND EXPANSION OF HEALTH SERVICES IN RIO GRANDE DO SUL STATE

On Wednesday (27), the Health and Environment Committee of the Legislative Assembly of Rio Grande do Sul held a public hearing on prostate cancer prevention. The session was initiated by Congressman Kaká D'Ávila (PSDB). Approximately 70 thousand new cases of prostate cancer are detected each year in Brazil. It is the most common tumor in the male population. On the other hand, if diagnosed early, the chances of cure are over 90%. The data were presented by the honorary president of the National Prostate Institute, Marcos Dias Ferreira. [Read more.](#)

MORE HIGHLIGHTS

[Seminar at the House of Representatives discusses the Oncology Scenario in Brazil](#)

[Public hearing will discuss modernization of CMED's Internal Regulations](#)

[Government wants to diversify vaccine suppliers and create a platform to monitor stocks](#)

BRAZIL NEWS

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[Bolsonaro eyes comeback in Brazil with Trump's help](#)

[Brazil's income tax exemption plan sends currency to fresh lows](#)

[Brazil proposes income tax reform, frustrating investors focused on spending cuts](#)

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[Brazil's formal job creation falls short of expectations in October](#)

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