

WEEKLY REPORT

12/02/2023



HOUSE OF REPRESENTATIVES PASSES BILL ABOUT CLINICAL TRIALS IN BRAZIL

The House of Representatives passed, on Wednesday (29), the bill 7.082/2017, that creates rules for clinical trials with humans and control of good practices through research ethics committees (CEPs). According to the text, the researcher must submit the request (clinical trial protocol) to the ethics committee linked to the institution that will carry out the research. The CEP of each research institution will be monitored by a technical body to be created by the Executive Branch. The bill also establishes that the researcher, after hearing the sponsor and the participant of the clinical trial, evaluate the need for post-trial access to the treatment of the experimental drug. Unlike the currently guaranteed by the infralegal standards, the supplied medicinal product may be discontinued when at least one of the following occurs: - decision of the participant; - if there is cure of the disease or worsening of health or introduction of effective therapeutic alternatives; - when the continuous use did not bring benefit, considering the cost / benefit ratio; - if there is an adversary event that, in areas of the researcher, derails the continuity of the experimental drug; - inability to obtain or manufacture of experimental medicinal products for technical or safety reasons; - five years after the commercial availability of the drug in the country; or - if the experimental medicinal product is available in the Unified Health System (SUS). The bill will now be sent to analysis of the Federal Senate. [Read more.](#)

BRAZIL IS EXPECTED TO REGISTER 704 THOUSAND CASES OF CANCER PER YEAR BETWEEN 2023 AND 2025

Brazil is expected to register 704 thousand cases of cancer per year between 2023 and 2025 disease, highlighted an article from Agência Brasil. The forecast is from the National Cancer Institute (Inca). This Monday (27th), National Day to Combat Cancer is celebrated. "The estimate is the main planning and management tool in the oncology area in Brazil, providing fundamental information for the definition of public policies", highlighted Inca, when refer to the publication Estimativa 2023 – Incidence of Cancer in Brazil. The material provides estimates for the occurrence of the 21 most common types of cancer in the country. The survey shows that the most common malignant tumor in Brazil is that of non-melanoma skin (31.3% of total cases), followed by those of the female breast (10.5%), prostate (10.2%), colon and rectum (6.5%), lung (4.6%) and stomach (3.1%). In men, prostate cancer is predominant in all regions, totaling 72 thousand new cases estimated each year in the fixed three-year period – second only to non-melanoma skin cancer. [Read more.](#)

PUBLIC HEARING DEBATES THE IMPORTANCE OF CARING FOR MEN'S HEALTH

This Tuesday (28), a public hearing on men's health was held in the Chamber of Deputies, focusing on research to combat cancer. The debate was led by deputy Weliton Prado (Solidariedade-MG). [Read more.](#)

PUBLIC HEARING DEBATES BILL ABOUT ORAL DRUGS ON HEALTH INSURANCE PLANS

In a public hearing held this Tuesday (28), in the Committee of Legislative Participation (CLP) of the House of Representatives, was discussed the implementation of Bill 4871/2023, which

deals with the inclusion of specific target oral medicines for the treatment of diseases immune-mediated in the list of minimum mandatory coverage of health insurance plans. The debate was requested by deputy Erika Kokay (PT-DF), sponsor of the bill. [Read more.](#)

COMMITTEE PASSES BILL THAT OBLIGES THE SUS AND HEALTH INSURANCE PLANS AND INSURANCE TO PROVIDE COMPREHENSIVE AND ADEQUATE TREATMENT FOR URINARY INCONTINENCE

The Social Security, Social Assistance, Childhood, Adolescence and Family Committee (CPASF) of the House of Representatives passed, on Wednesday (29), the Bill 5922 /2013, which obliges the Unified Health System and private health care plans and insurance to provide comprehensive and adequate treatment for urinary incontinence. The bill will be analyzed to the Finance and Taxation Committee. [Read more.](#)

COMMITTEE APPROVES BILL TO INCLUDE IMMUNOTHERAPY IN PROTOCOLS AND GUIDELINES FOR CANCER

At a meeting of the Finance and Taxation Committee (CFT) of the House of Representatives held this Wednesday (29), parliamentarians approved Bill 2371/2021, which proposes changes to the Organic Health Law, to include immunotherapy in protocols and guidelines for cancer. [Read more.](#)

COMMITTEE PASSES BILL FOR THE USE OF DIFFERENT CRITERIA FOR SETTING PRICES FOR GENE, CELLULAR AND STEM CELL THERAPIES

The Consumer Protection Committee (CDC) of the House of Representatives passed, this Wednesday (29), the Bill 3499/2021, which provides for the use of different criteria for setting prices for gene, cellular and stem cell therapies. The text will be analyzed by the Constitution Committee (CCJC) of the House. [Read more.](#)

CONTRACT OF THE MINISTRY OF HEALTH TO PURCHASE IMMUNOGLOBULIN GENERATES CONTROVERSY

The contract with a pharmaceutical company for the purchase of immunoglobulin by the Ministry of Health is generating suspicions of fraud. This is because the contract was established without a bidding process and the company in question had only one employee until last March, highlighted an article on the Panorama Farmacêutico portal, with information from Diário do Poder. According to the publication, questioned during a hearing at the Financial Inspection and Control Commission (CFFC) last Tuesday, the 28th, Minister Nísia Trindade did not discuss the matter. According to the person responsible for the department, the suspicions were raised by the opposition, with the aim of generating panic among the population and encouraging a discourse contrary to science. Furthermore, the minister only said that the link with Nanjing Pharmacare, represented by Auramed, for the purchase of immunoglobulin was more economical for the government and that the Federal Audit Court (TCU) is investigating the case. The agreed amount is R\$285.8 million. [Read more.](#)

NEW SUS INFORMATION SYSTEM WILL SUPPORT THE CREATION OF PUBLIC POLICIES

The Ministry of Health launched the National Health Work Information Center (Cenits), which compiles data for the production of information to support managers and professionals in the formulation and implementation of public health policies. According to a statement on the ministry's portal, the launch took place during the International Meeting of Decent, Dignified, Humanized and Democratic Work in the SUS, held on November 30th and December 1st, in Brasília. The new portal presents data on health and safety, career, regulation and census of the SUS workforce. With the platform, it is possible to access management support panels,

which systematize data and information about health professionals, covering the four government spheres: federal, state, district and municipal. The survey is carried out using different databases and official government systems, such as the National Registry of Health Establishments; Notifiable Diseases Information System; and the Brazilian Institute of Geography and Statistics. [Read more.](#)

AFTER MORE THAN 2 YEARS OF DELAY, SUS STARTS OFFERING NEW TREATMENT FOR SEVERE ISCHEMIC STROKE

With more than two years of delay, the SUS (Unified Health System) will begin offering MT (mechanical thrombectomy), a treatment that promises to improve quality of life, motor capacity and memory, in addition to providing independence to patients who have suffered Severe acute ischemic stroke (cerebrovascular accident), reported Folha de S. Paulo. This type of stroke occurs when an artery is blocked, preventing the passage of oxygen to brain cells, which die. This obstruction can happen due to thrombosis or embolism. The adoption of the procedure had already been communicated in an ordinance published in February 2021, but without implementation. Now, another ordinance, GM/MS No. 1,996, of November 24, 2023, published in the Official Gazette of the Union this week, informs about the inclusion of TM in the table of procedures, medicines, orthoses, prostheses and special materials of the SUS, and the 12 Brazilian hospitals qualified to offer mechanical thrombectomy. [Read more.](#)

PHARMA COMPANIES WITHDRAWN GROWTH HORMONE FROM THE MARKET IN BRAZIL

Two multinational pharmaceutical companies recently announced a cut in the supply of somatropin, known as growth hormone, to the Brazilian market, Folha de S.Paulo reported. The drug produced by Novo Nordisk has been unavailable since July, with no restocking date yet. Merck will stop distribution in January 2024, also for an indefinite period. The medicine is indicated for the treatment of growth disorders in children and adolescents. Patients should seek medical advice to replace the medication with another with the same active ingredient. The therapeutic alternatives available in the country are in regular supply, according to the manufacturers. When questioned, pharmaceutical companies attributed the shortage to logistical and production difficulties, and said that other countries were also being affected. The cut in supply by multinationals should not affect the distribution of the hormone by the SUS (Unified Health System). The public medication is produced by the Brazilian laboratory Cristália in partnership with the BioManguinhos institute, from Fiocruz (Fundação Oswaldo Cruz). Free treatment is guaranteed to children and adolescents with proven growth hormone deficiency and girls with Turner syndrome. Around 30 thousand patients are currently served by the SUS. [Read more.](#)

OTHER HIGHLIGHTS

[Congresswoman sponsors request for official applause for the Blue November Campaign](#)

[Public hearing debates the abandonment of women by their partners during cancer treatment](#)

[Resolution published with new distribution of Anvisa's board of directors](#)

[Anvisa approves public consultation on electronic cigarette](#)

BRAZIL NEWS

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[Brazil's Lula appoints his justice minister to Supreme Court](#)

[Argentina's Milei invites Brazil's Lula to inauguration, travels to US](#)

[Argentina's Milei seeks foreign policy, IMF reset in Washington trip](#)

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[Brazil proposes global forest conservation fund at COP28](#)

[Brazilian state launches mandatory tracking of cattle to stop deforestation](#)

[Amazon rainforest destruction slows sharply year to date, report says](#)

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[Nestle to invest \\$1.2 bln in Brazil by 2025](#)



Relações Governamentais