

WEEKLY REPORT

04/27/2024



SENATE PASSES BILL WITH NEW RULES FOR CLINICAL TRIALS IN BRAZIL

The Federal Senate passed this Tuesday (23) the bill (PL 6007/2023) that creates rules for clinical trials in Brazil. The version approved is based on the one passed by the House of Representatives in 2023. The President will now review the bill and decide whether he signs into law or vetoes the text. The bill was initially sponsored by former senators Ana Amélia (RS), Waldemir Moka (MS) and Walter Pinheiro (BA) in 2015. The sponsors' objective was to accelerate the authorizations for clinical trials in Brazil. The approved text in the Federal Senate was the report of senator Dr. Hiran Gonçalves (PP-RR), rapporteur at the Constitution Committee. During the voting this Tuesday, Senator Hiran emphasized the regulation will bring more incentives to the sector. He added that the new rules will allow trials that today, due to flaws in the legislation, cannot be conducted in Brazil. The approval, said the rapporteur, will help people who suffer from difficult-to-treat illnesses, such as cancer and rare diseases. [Read more.](#)

GOVERNMENT FORESEES 60% REDUCTION AND EVEN ZERO RATE FOR HEALTH SERVICES AND DRUGS

The presentation on the text of the tax reform regulations made available this Thursday (25) by the Ministry of Finance clarifies that, in the health sector, there will be a 60% reduction or even zero rate for numerous services and medicines. The text sent to Congress provides for 27 services with reduced rates, 850 types of medicines, 71 types of enteral and parenteral compositions, 92 types of medical devices, 6 types of personal hygiene and cleaning products and some basic menstrual health care products. [Read more.](#)

ANVISA PUBLISHES NEW PANEL FOR CONSULTING DRUG PRICES

Anvisa (National Health Surveillance Agency) released this Wednesday (24) a panel to consult the maximum prices of medicines sold in the country. The objective of the tool is to facilitate the Brazilian population's access to the maximum prices of medicines authorized by Cmed (Chamber of Medicines Market Regulation). The initiative was announced in a note from the agency through the action of Scmed (Executive Secretariat of the Medicines Market Regulation Chamber). Pharmacies and drugstores, as well as laboratories, distributors and importers, cannot charge an amount for medicines above the price allowed by Cmed. Currently, the list of maximum prices allowed for the sale of pharmaceuticals is made available on the Anvisa portal for consumer consultation, with monthly updates. [Read more.](#)

PUBLIC HEARINGS IN BRASÍLIA DISCUSS THE REGULATION FOR THE POLICY FOR NATIONAL CANCER PREVENTION AND CONTROL

The third special edition of the Global Forum was held in Brasília, on Wednesday (24) and Thursday (25). In this edition, the event promoted by the Lado a Lado Pela Vida Institute debated the implementation of the Policy for National Cancer Prevention and Control, established by Law No. 14,758 of December 19, 2023 ([read more](#)). On Tuesday (23), it was held, at Special Committee on Combating Cancer in Brazil of the House of Representatives, public hearing to debate the implementation and regulation of the National Cancer Prevention and Control Policy within the scope of the Unified Health System ([read more](#)).

COMMITTEE PASSES BILL ABOUT DEADLINE FOR THE OFFERING OF TREATMENTS AND DRUGS APPROVED IN THE HEALTH PUBLIC SYSTEM

The Science and Technology Committee (CCT) approved this Wednesday (24) PL 6,172/2023, which establishes a maximum period of six months for the offering of new drugs, products, procedures, clinical protocols and therapeutic guidelines through the Unified System of Health (SUS). The bill went to a final vote in the Social Affairs Committee (CAS). Presented by Senator Mara Gabrielli (PSD-SP), the proposal includes in Law 8,080/1990, known as the Organic Health Law, the determination of compliance with the deadline for incorporating technologies into the SUS. Decree 7,646, of 2011, already provides for a period of 180 days for the incorporation, exclusion and alteration of medicines, products, procedures, clinical protocols and therapeutic guidelines by the SUS. [Read more.](#)

APPOINTED RAPPORTEUR OF THE BILL THAT ESTABLISHES DEADLINE FOR DIAGNOSIS AND TREATMENT OF PROSTATE CANCER

The Health Committee of the House of Representatives appointed Weliton Prado (Solidariedade-MG) the rapporteur of Bill 202/2024, which amends Federal Law No. 10,289, of September 20, 2001, to guarantee, through the System Unified Health System, adequate deadline for starting prostate cancer treatment and provides other measures. The matter was presented by representative Fábio Teruel (MDB-SP). In his text, he intends to determine that the units that are part of the Unified Health System are obliged to conduct tests for the early detection of prostate cancer, within a period of up to 30 days, whenever, at medical discretion, such a procedure is considered necessary. The bill also proposes the same deadline for the patient undergoing the first treatment, starting from the day the diagnosis is confirmed in a pathological report. [Read more.](#)

PUBLIC HEARING WILL DEBATE THE BILL ON THE TREATMENT OF CLIMACTERIC AND MENOPAUSE BY THE SUS

Senator Teresa Leitão (PT-PE) presented, at the Social Affairs Committee, Request 49/2024, which requests the holding of a public hearing, with the aim of debating Bill 3933/2023, which provides for the treatment of menopause and climacteric by the Unified Health System and establishes the National Awareness Week for women in menopause or in climacteric. The parliamentarian is the rapporteur of the proposal at the committee. Bill 3933/2023 was sponsored by Senator Mecias de Jesus (Republicanos-RR), and guarantees the availability of hormonal and non-hormonal medications for women in menopause or climacteric; carrying out diagnostic tests; training doctors to diagnose and treat climacteric and menopause; specialized psychological and multidisciplinary support for women, from diagnosis onwards; and availability of continuous and individualized treatment. The proposal also establishes National Awareness Week for menopausal or climacteric women, to be held annually in March. [Read more.](#)

CONSUMER PROTECTION ASSOCIATIONS MOBILIZE TO CHANGE THE LAW THAT REGULATES COLLECTIVE HEALTH INSURANCE PLANS

Consumer protection associations started a national movement calling for new regulation of group health plans, which represent more than 82% of the supplementary health market. They defend changes to current rules, such as those that allow annual adjustments without prior authorization from the ANS (National Supplementary Health Agency), which leads to rates much higher than those for individual/family plans, and unilateral and unmotivated terminations of contracts. [Read more.](#)

LULA AND NÍSIA TRINDADE PARTICIPATE IN THE INAUGURATION OF A PRIVATE INSULIN FACTORY IN MINAS GERAIS STATE

A new factory for the pharmaceutical company Biomm was inaugurated this Friday (26), in Nova Lima (MG), about 22 kilometers from the capital Belo Horizonte. President Luiz Inácio Lula da Silva (PT) and Minister Nísia Trindade, of Health, were present at the inauguration ceremony. The headquarters will resume the national production of insulin, a necessary ingredient for the treatment of diabetes. The governor of Minas Gerais, Romeu Zema (Novo), opposition to Lula, said he was not invited. In addition to Trindade, there were also the Ministers of Finance, Fernando Haddad (PT), Alexandre Silveira (PSD), of Mines and Energy, Alexandre Padilha (PT), of Institutional Relations, and Luciana Santos (PCdoB), of the Ministry of Science, Technology and innovation. First lady Rosângela Silva, known as Janja, was also present. Zema's predecessor in the position, Fernando Pimentel (PT), current president of EMGEA, was also present at the ceremony and received praise from Biomm's executive director, Walfrido dos Mares Guia Neto. [Read more.](#)

AMID THE DENGUE EPIDEMIC, HEALTH BECOMES THE MAIN CONCERN OF BRAZILIANS, ACCORDING TO AN IPSOS SURVEY

Public health has once again become the population's number 1 concern, as shown by a new survey by the Ipsos institute released this Thursday exclusively by GLOBO. Today, 42% of Brazilians indicate the issue as the country's main challenge, a figure that was 37% in March. The current percentage of mentions of the subject is the highest recorded by the "What Worries the World" survey since the end of the pandemic, in 2021. [Read more.](#)

MORE HIGHLIGHTS

[Subcommittee on Rare Diseases votes on work plan on Tuesday](#)

[Senator Hiran Gonçalves is appointed rapporteur of the project that defines rules to accelerate patent applications to INPI](#)

[Appointed rapporteur of the project that aims to establish standards for the use, acquisition and pricing of biosimilar drugs](#)

[Pharma investments blocked by health regulator's lack of analysts](#)

[Anvisa publishes regulation that toughens the ban on electronic cigarettes in Brazil](#)

[Government establishes Technical Committee to promote "One Health"](#)

BRAZIL NEWS

[Portugal must 'pay costs' of slavery and colonial crimes, president says](#)

[Brazil judge gives X five days to explain alleged non-compliance with court ruling](#)

[Brazil Justice says no evidence Bolsonaro sought asylum in Hungarian embassy](#)

[Lula's South American summit plan unlikely in tense region, diplomats say](#)

[Tax reform rules to hit Congress this Wednesday](#)

["Everything is treated as spending" in Brazil, Lula says](#)

[Parliament expands control over investments, affecting federal budget](#)

[Brazil again considered good destination for direct investment](#)

[Brazil's inflation slows to 0.21% in mid-April](#)

[Brazil aims to boost credit for small businesses, real estate loans](#)

[Brazil's central bank chief says no mechanical relationship between uncertainties and policy](#)

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