WEEKLY REPORT

10/05/2024

CONSULTORES
Relações Governamentais

STF PUBLISHES SUMMARY THAT ESTABLISHES CRITERIA FOR JUDICIAL CONCESSION OF HIGH-COST DRUGS

The Federal Supreme Court (STF) published in the Official Gazette of the Union (DOU) this Thursday (10/3) Binding Summary No. 61, which requires the Judiciary to adopt the criteria established in the judgment of Theme 6 of general repercussion, in RE 566,471, when analyzing requests for the supply of high-cost medicines not yet incorporated into the SUS. Based on the decision, judges must now follow this new understanding when analyzing demands for the judicial provision of drugs. "The judicial concession of a medicine registered with Anvisa, but not included in the dispensing lists of the Unified Health System, must observe the theses established in the judgment of Theme 6 of General Repercussion (RE 566,471)," says the summary statement. On September 9, the STF formed a majority in the judgment of RE 566.47 to introduce stricter criteria for the acquisition of high-cost medicines approved by the National Health Surveillance Agency (Anvisa), but not incorporated into the Unified Health System (SUS). According to the theses established by the rapporteur, Justice Gilmar Mendes , in Theme 6 , the Judiciary should only issue a court order for the supply of drug if the following requirements are cumulatively present: - Administrative refusal to supply the medication through official SUS channels; - Delay in assessing or absence of a request for incorporation into Conitec; - Impossibility of therapeutic substitution; - Proof of drug efficacy and safety through randomized clinical trials and systematic reviews or meta-analyses; - Clinical indispensability, demonstrated by a detailed medical report attesting why the medication is essential for the patient; and - Proof by the patient that he/she does not have the financial means to cover the costs of the medication. Read more.

PRESIDENT OF THE FEDERAL SENATE SUSPENDS LEGISLATIVE ACT ABOUT ANALYSIS OF BILL ON REQUIREMENTS FOR THE PROVISION OF DRUGS NOT INCORPORATED IN THE SUS

The Board of Directors of the Federal Senate withdrew the ruling of Complementary Bill 149/2024, which establishes the criteria for federative entities to provide drugs not incorporated in the standards of the Unified Health System (SUS) or not yet registered with the National Health Surveillance Agency (Anvisa). The Legislative act, previously published, sent the proposal for analysis by the Committee on Social Affairs; and Committee of Constitution, Justice, and Citizenship. However, in a very unusual decision, the President of the Federal Senate, Rodrigo Pacheco, canceled the Legislative act, considering a reassessment of the initial referral necessary. Read more.

PUBLIC HEARING WILL DEBATE COVERAGE OF RARE DISEASES BY THE SUS

Access to medicines and technologies in the Unified Health System (SUS) aimed at treating rare diseases will be the subject of a public hearing on Tuesday (8), at 2:30 pm. The debate is promoted by the Permanent Subcommittee on the Rights of People with Rare Diseases (CASRARAS), which operates within the Social Affairs Committee (CAS). The initiative for the public hearing is from the chair of the subcommittee, Senator Mara Gabrilli (PSD-SP). In the justification for her request (REQ 1/2024 — CASRARAS), she expressed hope that "expanding dialogue between the government, the pharmaceutical industry and civil society can result in more inclusive policies" for the segment, but people with rare diseases face problems such as unequal access to treatment and misinformation from health professionals. "Regulating access to medicines, medical devices and technologies in the SUS for people with rare diseases is

essential for the inclusion and guarantee of these people's rights", concludes the senator. Read more.

PUBLIC HEARING WILL DISCUSS DELAY ON ANVISA'S AUTHORIZATION OF DRUG FOR DUCHENNE MUSCULAR DYSTROPHY

The Committee for the Defense of the Rights of Persons with Disabilities (CPD) of the House of Representatives has scheduled a public hearing for October 15, at 4 pm, to discuss Anvisa's authorization of the drug Elevidys in the treatment of Duchenne Muscular Dystrophy. Representative Max Lemos (PDT-RJ), who proposed the debate, highlighted the importance of the discussion, explaining that he visited Anvisa this year to seek information about the authorization of the drug's registration, which has not yet been analyzed. According to the parliamentarian, it is essential that Anvisa prioritize the evaluation and approval process of this drug. Read more.

ANVISA AND FDA SIGN AGREEMENT FOR DATA EXCHANGE

On Monday (9/30), Anvisa's CEO, Antonio Barra Torres, signed a mutual confidentiality agreement between Anvisa and the Food and Drug Administration (FDA), the United States regulatory authority, represented by Dr. Robert Callif, FDA commissioner. The agreement allows the two agencies to share confidential and non-public commercial information about regulated drugs, both in pre -market and post-market phases. According to Anvisa, this is a major step forward in the relations established between the two authorities, which consolidates a partnership of trust that has been built over the last ten years. The exchange of information with the FDA, permitted by the new agreement, guarantees Anvisa access to strategic data on the safety, efficacy and quality of medicines already analyzed by the American agency, contributing to a more robust and agile evaluation in Brazil. Read more.

SENATOR PRESENTS FAVORABLE OPINION ON THE BILL THAT ESTABLISHES EXEMPTION FROM FEDERAL TAXES FOR THE DONATION OF MEDICINES

Senator Nelsinho Trad (PSD-MS) presented, in the Social Affairs Committee, a favorable opinion on Bill 4719/2020, which establishes the exemption from federal taxes for the donation of medicines to the Union, states, the Federal District and municipalities, to the Santas Casas de Misericórdia, the Brazilian Red Cross and certified charitable entities. The text, authored by former deputy General Peternelli, specifies that medicines received with the exemption provided may only be used for charitable and non-profit activities, prohibiting the marketing, or dispensing of medicines that use brands or signs that indicate companies or establishments not authorized as pharmaceutical industries. Read more.

ANS: IT IS NECESSARY TO ENCOURAGE THE PROVISION OF INDIVIDUAL HEALTH PLANS

The National Supplementary Health Agency (ANS) wants to promote a technical review of individual plans to encourage operators to offer the product again. With 8 million beneficiaries and representing 15% of the market, individual plans had an annual adjustment of 6.91% for the period from May 2024 to April 2025, authorized by ANS. The rest of the market is made up of collective plans and their adjustments are not determined by the regulatory agency. "The operators have no appetite to sell this product. We need to stimulate the market so that this can happen," said Paulo Rebello, CEO of ANS, at the second edition of the event "Health is Priceless. But It Has a Cost", held by Brazil Journal on October 26 in São Paulo. This topic and others under review will be taken to a public hearing held by the agency, scheduled for October 7. Read more.

LARGEST HEALTHCARE DISCOUNT COMPANY, CARTÃO DE TODOS WILL ATTEND ANS HEARING

Paulo Rebello, president of the National Supplementary Health Agency (ANS), proposed the inclusion of an item that was off the radar of the regulatory agency's "combo price" package, which will enter public discussion on the 7th: the debate on the rules for the sale of exclusively

outpatient plans. "Today, we know that there are around 60 million people using discount cards, which are cheap products, without any type of regulation or supervision, but which allow consultations and exams to be carried out", said Rebello, in his vote, at a meeting of the collegiate board held on Friday, 27th. "It is the way these people found to have access to health services." For him, however, it is necessary to review the rules of exclusively outpatient plans to "give these consumers the possibility of having health plans with lower prices, clear rules and guaranteed coverage, enabling health care and consultations and exams as a way of preventing diseases or identifying them in the early stages". Read more.

NOVO NORDISK TO INVEST $158 MILLION IN INSULIN PLANT IN BRAZIL

Danish drugmaker Novo Nordisk (NOVOb.CO), opens new tab will invest 864 million reais ($158.2 million) to revamp a plant in Brazil responsible for pumping out a quarter of its insulin production globally, the firm said on Friday. The funds will overhaul the Montes Claros factory, in the southeastern state of Minas Gerais, and implement sustainable projects there, Novo Nordisk said in a statement. The maker of Ozempic and Wegovy, which have exploded in popularity for their use as weight-loss drugs, made the announcement public as Brazilian President Luiz Inacio Lula da Silva met earlier in the day with Queen Mary Donaldson of Denmark, the Brazilian government said in a statement. Read more.

BRAZIL IS LEFT OUT OF AGREEMENT THAT ALLOWS PRODUCTION OF GENERIC VERSION OF INNOVATIVE HIV VACCINE

Drugmaker Gilead Sciences on Wednesday announced a plan to allow six generic drug companies in Asia and North Africa to manufacture and sell at a lower price its breakthrough drug lenacapavir, a twice-yearly injection that offers near-complete protection against HIV infection. These companies will be able to sell the drug in 120 countries, including all the countries with the highest HIV rates, which are in sub-Saharan Africa. Gilead will not charge generic drugmakers for the licenses. Gilead says the deal, made just weeks after clinical trial results showed the drug's effectiveness, will provide rapid and broad access to a medicine that has the potential to end the decades-long HIV pandemic. Read more.

MINISTRY OF HEALTH LAUNCHES PANELS TO MONITOR MPOX AND MALARIA

In September, the National Center for Epidemiological Intelligence (CNIE) of the Ministry of Health launched the Mpox Dashboard on the department's official website. Developed in partnership with the Department of HIV/AIDS, Tuberculosis, Viral Hepatitis and Sexually Transmitted Infections (Dathi), the tool allows you to view indicators on the incidence of the disease, demographic profile and a historical series covering the years 2022 to 2024. In addition to data on mpox, the Malaria Dashboard was also launched. The objective is to consolidate epidemiological data on the disease throughout the country, through a historical series of the last 12 years. The information includes the demographic profile of cases and the geographic distribution of malaria, among other relevant data. Read more.

WHO LAUNCHES DENGUE COMBAT PLAN WITH ESTIMATED COST OF R$301 MILLION

The WHO (World Health Organization) launched this Thursday (3) a global strategy plan to combat dengue and other arboviruses transmitted by mosquitoes of the Aedes family. The plan lists priority actions for controlling transmission and recommendations for countries affected by the diseases, listing five essential components for combating an epidemic. The step-by-step process listed by the WHO foresees the establishment of emergency coordination, with clear and coordinating leadership; collaborative surveillance, with the development and use of tools to detect the beginning of an outbreak early; community protection, encouraging local engagement with prevention and response actions; effective and progressive medical care, ensuring access to adequate treatment to prevent deaths; and access to measures such as vaccines and investment in research for new treatments for diseases. Read more.

MORE HIGHLIGHTS

Government prepares 1st stage of program to pay debts with regulatory agencies and expects to raise R$4 billion

ANS, the agency that oversees health plans, is in debt

Hospital Sírio-Libanês launches unprecedented study on drug risks

BRAZIL NEWS

Plane carrying Brazil president lands in Mexico after technical issue

Brazil rolls out minimum tax on profits of multinational firms

Fitch unlikely to raise Brazil's credit rating soon, director says

Brazil credit rating upgrade paves the way for reduced risk premium, officials say

Brazil posts larger-than-expected August deficit as government spending outpaces revenue

Brazil private economists forecast two 50-basis-point rate hikes this year

Brazil's top court says X paid pending fines to wrong bank

Brazilian state to host COP30 climate summit defends gold mining rules

EU proposes to delay landmark anti-deforestation law by 12 months

Brazil's coast eroding faster than ever as Atlantic advances

Brazil drought sinks Amazon rainforest port river level to 122-year low

Extreme drought isolates Amazon communities in Brazil

Bayer sees Intacta2 Xtend GMO seed covering 30% of Brazil's soybeans

Airbnb drives short-term rental boom in tourist haven Rio