

# WEEKLY REPORT

09/14/2024



## **SUPREME COURT INTERRUPTS TRIAL ON HIGH-COST MEDICINES**

The trial at the Supreme Federal Court (STF) regarding the state's obligation to provide high-cost medications, even those not listed in the Unified Health System (SUS), was interrupted after Justice Kassio Nunes Marques requested for examination of the case. The case discusses whether the state should fund these expensive treatments for patients with severe illnesses in exceptional circumstances. The STF had already formed a majority opinion stating that the state is not obligated to provide medications not incorporated into the SUS unless specific criteria are met, such as the lack of alternative treatments and proven efficacy by regulatory agencies. However, Nunes Marques' request for a review temporarily halted the conclusion of the trial. [Read more.](#)

## **VOTES INCREASE RISK OF LEGAL ACTION, SAYS INTERFARMA PRESIDENT**

What are the possible consequences and criticisms of the joint vote cast by ministers Gilmar Mendes and Luís Roberto Barroso, of the Federal Supreme Court (STF), on the State's duty to provide medicines not incorporated into the Unified Health System? The two established strict criteria for the Judiciary to determine the granting of medications not included in the official SUS lists, creating a filter so that only in exceptional cases, with cumulative proof, patients have access to these treatments via a court decision. Among the requirements are proof of administrative denial, the lack of an alternative in the SUS and the presentation of robust scientific evidence supporting the efficacy and safety of the requested medication. But the joint vote, despite having greater institutional weight, as it is signed and agreed upon by two ministers, is receiving criticism. The president of Interfarma, Renato Porto, is one of the first to raise objections in this interview with JOTA. The eventual decision, he argues, could impose a barrier to patients' access to essential treatments. This is because Conitec, the agency responsible for analyzing the incorporation of medications into the SUS, is raised to a new status so that the medications can be provided. But does Conitec have sufficient structure and agility to meet the growing demand for new treatments? This is one of the questions. [Read more.](#)

## **REPRESENTATIVE PRESENTS OPINION TO REJECT BILLS ABOUT CONITEC'S DELIBERATION PROCESSES**

Representative Flávio Nogueira (PT-PI) presented, in the Health Committee of the House of Representatives, a report for the rejection of Bill 7870/2017, which seeks to amend the Organic Health Law. The proposal establishes a period of 120 days, extendable for another 60 days, for the incorporation, exclusion or modification of medicines, products, and procedures in the SUS, in addition to the creation or modification of clinical protocols and therapeutic guidelines. The rapporteur also voted to reject the other three attached proposals, which deal with related topics. Among them, Bill 4361/2021, by Congresswoman Silvia Cristina (PP-RO), which proposes mandatory public hearings in cases of unfavorable preliminary recommendations from Conitec. Furthermore, Bill 3543/2023, which suggested reducing the deadline for incorporating health technologies from 180 days (extendable for another 90 days) to 30 days, without extension, and Bill 2410/2023, which proposed that the incorporation of medicines should consider the number of beneficiaries, with the aim of maximizing social welfare and efficiently allocating public resources, should be rejected according to the report yet to be analyzed by the Health Committee. [Read more.](#)

**SENATOR SUGGESTS CREATING POSITIONS AT ANVISA**

Senator Mara Gabrilli (PSD-SP) presented Indication 71/2024, suggesting that the President of the Republic send a Bill proposing the creation of new positions at the National Health Surveillance Agency (Anvisa). The parliamentarian justified the proposal by pointing out the lack of sufficient professionals at Anvisa, which represents a risk to both public health and the country's economy. She also highlighted that, although a public selection process was held in April 2024 to fill 50 permanent positions at Anvisa, the number of employees is still insufficient to meet the growing demand for work, making it necessary to create new positions through legislation. [Read more.](#)

**ANVISA CREATES TECHNICAL CHAMBER FOR CLINICAL TRIALS OF DRUGS AND MEDICAL DEVICES**

Joint Ordinance 2, of September 9, 2024, was published this Friday (9/13), creating the Technical Chamber for Clinical Research on Medicines and Medical Devices, Catepec. Catepec's objective is to provide technical and scientific support to the Coordination of Clinical Research on Medicines and Biological Products (Copec) and the Coordination of Clinical Research on Health Products (CPPRO) of Anvisa. This support will enable the fulfillment of the regulatory duties of these Coordinations, related to the processes of regulation and evaluation of clinical research on medicines and medical devices. Another purpose of the Chamber is to monitor scientific and technological development in health surveillance, to modernize, rationalize and streamline Anvisa's regulatory action in the health control of clinical research, subsidizing the registration and post-registration of medicines and medical devices. [Read more.](#)

**LULA SAYS UNIVERSALIZATION OF SUS 'HAS A PRICE': MORE RESOURCES AND A DROP IN QUALITY**

President Luiz Inácio Lula da Silva stated that universalizing the health system has a "price" and, while it offers treatment to an entire population, there is a decline in the quality of the work provided. In a speech criticizing the administration of former president Jair Bolsonaro, Lula said, however, that he will not accept the discrediting of the Unified Health System (SUS). "Since the SUS was created, a war has been waged in an attempt to discredit the SUS, claiming that the service was not of good quality, that people were poorly served, that they were seen being treated in emergency room corridors," said Lula, during the ceremony to award the Oswaldo Cruz Medal of Merit this Wednesday, the 11th, at the Planalto Palace. One of the recipients was the First Lady, Rosângela da Silva. According to the president, however, these criticisms do not take into account that "every time we try to ensure that everyone has the right, the treatment is not the same as when we treat half a dozen people". "Universalization has a price. The first is the good one, that of serving all humanity. The second is that it requires more resources, more work and often, with the number of people, the quality drops a little. But that was never a reason for us to accept the discredit of the SUS", added the head of the federal Executive. [Read more.](#)

**HEALTH REPRESENTATIVES DEFEND ADJUSTMENTS TO TAX REFORM**

Even though they are included in the special taxation regime provided for in the tax reform, with a 60% reduction in taxes, representatives of the health sector defend changes in the complementary bill that regulates the tax reform (PLP 68/2024). This position was presented this Thursday (12), during another round of debates promoted by the Economic Affairs Committee (CAE). Representatives of health services stated that, if the text is approved as it stands, the activity will see an increase in general taxation of around 27%. Representatives of the education system, while recognizing the text as "balanced" and "fair", warned of the risk of an increase in taxation for companies that grant scholarships to employees. [Read more.](#)

**R\$2 MILLION MEDICINE FOR CHILDHOOD CANCER STILL HAS NO DATE TO ARRIVE AT SUS**

Qarziba, a medicine against neuroblastoma, a rare and aggressive type of cancer whose treatment can cost more than R\$2 million, was approved to be incorporated into the SUS

(Unified Health System) on Monday (2), but the Ministry of Health has not yet said how long it will take for the medicine to reach the population. In a statement, the ministry said it is awaiting the conclusion of a report by Conitec (National Commission for the Incorporation of Technologies) before formalizing the inclusion of the drug in the SUS. After the document is concluded, the ministry still has 180 days, extendable by another 90, to analyze the report. According to Health, the document is in its final phase but does not detail how long it will take for it to be completed for evaluation. [Read more](#).

### **THE FIGHT AGAINST COUNTERFEIT MEDICINES INTENSIFIES AND MOBILIZES NATIONAL AND INTERNATIONAL BODIES**

Counterfeit medicines have become a growing concern. With impacts on public health and the global economy, the increase in counterfeit medicines in recent years has been driven by the expansion of online commerce, with the proliferation of illegal websites and unregulated sales platforms. Data collected by the Federal Police (PF) show that, in 2023, 119,138 units of medicines and 21.35 liters of liquids were seized in Brazil - the agency clarifies that they are not necessarily all classified as counterfeit, but that they are retained by the authorities on suspicion of violating laws or regulations. In June, the PF launched an operation to investigate a criminal network that sold R\$11 million in counterfeit medicines to government agencies. Suspects were investigated in Mato Grosso do Sul, Curitiba, Francisco Beltrão (Paraná), Birigui, São Caetano do Sul (São Paulo), Rio de Janeiro, Nova Iguaçu (Rio de Janeiro) and Jacobina (Bahia). [Read more](#).

### **BRAZIL VACCINE PROVIDER BEEP RAISES \$18 MILLION, TURNS PROFITABLE**

Brazilian mobile vaccine provider Beep Saude said on Thursday it had turned profitable and announced a 100 million reais (\$17.64 million) investment from a U.S. climate-focused firm, as rising global temperatures may increase demand for vaccines. Beep Saude, a Rio de Janeiro-based firm founded in 2016, provides vaccines and diagnostic examinations at home in more than 100 cities. It serves consumers with private health insurance or who are willing to pay for home delivery and administration of vaccines, which generally are free from Brazil's public system. The firm said the new investment round was led by New York-based firm Lightsmith. Lightsmith Managing Director Jay Koh, who will join Beep's board, said climate change is likely to cause more mosquito-borne illnesses and increase the need for vaccinations. [Read more](#).

#### **MORE HIGHLIGHTS**

[House of Representatives holds 2nd Gynecological Cancer Awareness Fórum](#)

[House of Representatives holds 1st Brazilian Forum on Rare and Neglected Diseases](#)

[Committee appoints rapporteur for the bill that aims to create the National Day of Awareness about Phenylketonuria](#)

[Ministry of Health may provide information on the increase in the waiting list for cancer treatment](#)

[Health insurance plan must compensate patient for delay in release of chemotherapy](#)

## **BRAZIL NEWS**

[Brazil sees GDP accelerating in 2024 to 3.2% growth](#)

[Brazil central bank to hike rates by 25 basis points on Sept 18](#)

[Income tax reform proposals now with Lula, minister says](#)

[Brazil top court lifts Starlink, X bank account freeze after \\$3 mln transfer](#)

[Ukraine's Zelenskiy dismisses 'destructive' China-Brazil peace initiative](#)

[Brazil asks EU to hold off on implementing deforestation law](#)

[South America surpasses record for fires](#)

[Brazil's Lula backs highway through Amazon that could drive deforestation](#)

[Brazil says it has nearly cleared gold miners from Amazon Yanomami reservation](#)

[Brazil officially welcomes return of sacred Indigenous cloak from Denmark](#)



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**Relações Governamentais**