

# WEEKLY REPORT

08/31/2024



## **MINISTER OF HEALTH DEFENDS LULA AMIDST THE CONFLICT WITH ANVISA, BUT REINFORCES THE AGENCY'S AUTONOMY**

Health Minister Nísia Trindade came to the defense of President Luiz Inácio Lula da Silva when asked about the government's recent conflict with the National Health Surveillance Agency (Anvisa). In a conversation with journalists, the minister argued that Lula had merely made public a demand from the pharmaceutical industry for faster release of medications but reaffirmed the agency's autonomy. The minister criticized, however, the "backward step" in the agencies' relationship with national policies. According to Nísia, Lula had merely echoed what he had heard from representatives of the pharmaceutical industry and justified the sector's concern with the pace of the agency's decisions. "If you're going to have a product for diabetes, if you're going to have cutting-edge products in Brazil, and that will impact the sustainability of the SUS [Unified Health System] itself," she said, regarding Lula's demand for speed. "I think that was the president's motivation, which was the context of his speech," she added. [Read more.](#)

## **MINISTRY OF HEALTH WILL DRAFT A DECREE TO REGULATE THE LAW ON RESEARCH INVOLVING HUMAN BEINGS**

Law No. 14,874/2024, which establishes the new legal framework for research involving human beings by public and private institutions, has just come into force last week. The law also creates the National System of Ethics in Research Involving Human Beings, as well as the National Research Ethics Body as an Interdisciplinary and Independent Board under the coordination of the Ministry of Health, through the Secretariat of Science, Technology and Innovation and the Health Economic-Industrial Complex (Sectics). According to the new law, the commitment to ethics and independence in the analysis of research protocols will be guaranteed. The regulation of the law will be done by an act of the Executive Branch, which will provide institutional stability with the purpose of guaranteeing that ongoing clinical research has an environment conducive to its realization. [Read more.](#)

## **CFM ESTABLISHES NEW RULES FOR THE RELATIONSHIP BETWEEN DOCTORS AND PHARMACEUTICAL COMPANIES**

The Federal Council of Medicine (CFM) released a resolution that determines that all doctors who have any type of link with sectors of the healthcare industry, such as drugstores, pharmaceutical and device companies, must inform this "partnership" through the CRM-Virtual platform — an exclusive digital platform for the category. The links range from formal employment contracts to consultancies, participation in research and acting as paid speakers. Resolution No. 2,386/2024 was approved at a plenary meeting on August 21 and released on Wednesday (28). The main objective of the measure, according to the CFM, is to increase transparency and prevent conflicts of interest that may influence clinical decisions, "ensuring that medical practices in Brazil are conducted within ethical and legal parameters". The president of the CFM explains that the rule allows information to be recorded and monitored. Later, it can also be disclosed to the public, "promoting greater clarity in the relationships between doctors and companies", says José Hiran Gallo. [Read more.](#)

## **BRAZIL TODAY IS A DISNEYLAND FOR THE PHARMACEUTICAL INDUSTRY, SAYS ANS PRESIDENT**

The president of the National Supplementary Health Agency (ANS), Paulo Rebello, highlights that the revenue that the pharmaceutical industry has obtained at the expense of other links in the health chain has been a problem for the sector, as well as the high claims rate and cost problems that the sector has already had to deal with. The president of ANS believes that in Brazil today, litigation is intense and different from other countries, and in recent years we have seen changes that have increased pressure on the sector. He believes that the country has now become a very favorable environment for the pharmaceutical industry. "Today, the country is a Disneyland for the pharmaceutical industry, they earn a lot. If there is a prescription, the operator must provide the medication, without the need for a prior assessment of its safety. This is a challenge that we need to address," says Rabello. [Read more.](#)

### **ARTHUR LIRA ARGUES THAT THE HOUSE OF REPRESENTATIVES HAS INVESTIGATIONS PRIOR TO THE ONE AGAINST HEALTH PLANS**

The president of the House of Representatives, Arthur Lira (PP-AL), stated that the House already has at least eight requests to open Parliamentary Commissions of Inquiry (CPIs) that precede the investigation into health plans. This would be, according to Lira, the reason for not opening the committee. Lira's statement was a response to the minister of the Federal Supreme Court (STF), Flávio Dino, who requested a statement from the president of the House regarding the non-installation of the collegiate to investigate health plans, targets of consumer complaints due to terminations or unilateral changes to contracts. Lira argued that, due to the limit of five CPIs operating simultaneously, the CPI of Health Plans, last in the order of requests, cannot be installed at the moment. [Read more.](#)

### **STF SUSPENDS DECISIONS REQUIRING THE PURCHASE OF ELEVIDYS AND PROPOSES AN AGRÉMENT**

The Minister of the Federal Supreme Court (STF) Gilmar Mendes suspended the preliminary decisions that oblige the Union to acquire the drug Elevidys, indicated for the treatment of Duchenne Muscular Dystrophy (DMD). The determination will be valid until the conclusion of the conciliation in progress, within the scope of Complaint (RCL) 68709. The decisions of the ministers of the STF also remain valid and those that are favorable to children about to turn 7 years old. Gilmar Mendes clarified that the decision does not revoke the injunctions granted, but merely suspends their effectiveness until negotiations with the laboratory are concluded, which could benefit not only the plaintiffs, but all children with DMD in the country. [Read more.](#)

### **CANCER: GROUNDBREAKING TREATMENT FOR MULTIPLE MYELOMA ARRIVES IN BRAZIL**

Patients with multiple myeloma, a rare type of blood cancer, now have access to a treatment that is unprecedented in the country. It is called cilta-cel, a CAR-T cell therapy under the trade name Carvykti, from Janssen-Cilag, a pharmaceutical company owned by Johnson & Johnson. Carvykti was the second CAR-T cell therapy approved in Brazil, with its use authorized by the National Health Surveillance Agency (Anvisa) in March 2022. However, it only actually reached patients this year. [Read more.](#)

### **PHARMACEUTICAL INDUSTRY WANTS TO END LIST OF EXEMPT DRUGS IN TAX REFORM**

Among the various sectors dissatisfied with the proposed regulation of tax reform that has just reached the Senate, the pharmaceutical industry wants to take advantage of the discussion to put an end once and for all to the current model of taxes on medicines, considered obsolete and inadequate. The main controversy concerns the pharmaceuticals that will be exempt from the new Tax on Goods and Services (IBS) and Contribution on Goods and Services (CBS). According to the substitute for the Complementary Bill (PLP) 68/2024 approved by the Chamber of Deputies, 383 items included in a list attached to the legislation will be entitled to the zero rate of the new taxes. "Even to be exempt, you have to follow a list, and that is a big problem," says Sergio Mena Barreto, president of the Brazilian Association of Pharmacies and Drugstores (Abrafarma). "If a new formulation is launched for a disease that already has a medicine on

the list, you will have one medicine that is exempt, and another, competing, that is not," he explains. "Just because a product is innovative, it will not be exempt. That is why we are fighting to end these lists," says the representative of Abrafarma, whose claim is also supported by the Pharmaceutical Industry Union (Sindusfarma) and the Association of the Research Pharmaceutical Industry (Interfarma). [Read more.](#)

## **DENGUE FEVER DRIVES GROWTH IN PRIVATE VACCINE MARKET WITH 261.1% INCREASE**

The private vaccine market showed heterogeneous growth in the period from May 2023 to May 2024, with some vaccines standing out significantly. According to data released by IQVIA Non-Retail Pro, the market reached a total value of R\$ 1.63 billion during this period. However, this growth was not uniform across all vaccines. Vaccines against Dengue, HPV, Herpes Zoster and Pneumococcal stood out with the highest growth. The Dengue vaccine registered an impressive increase of 261.1% in the short term, comparing the period from 2024 to 2023, in addition to a compound annual growth (CAGR) of 3,827.9% since 2020. Vaccines against HPV and Herpes Zoster also showed significant growth, with increases of 30.1% and 83.9%, respectively, in the same comparative period. The Pneumococcal vaccine, in turn, had a growth of 117.7% in the short term. [Read more.](#)

## **THE VACCINE WILL NOT BE THE GOVERNMENT'S MAIN STRATEGY FOR DENGUE FEVER, WHICH FOCUSES ON COMBATING THE MOSQUITO**

The new plan to combat dengue fever in Brazil is expected to be launched by the Ministry of Health by September 10, focusing on combating the mosquito and using new technologies. In 2024, cases of the disease caused a crisis in the ministry and peaked between January and April. Vaccination will not be the main strategy to contain the spread of the disease in 2025, but it may become one in 2026, according to the Minister of Health, Nísia Trindade. [Read more.](#)

## **AGREEMENT ON AMENDMENTS COULD REDUCE PRESSURE ON HEALTH, SAYS NÍSIA**

The agreement reached last week between the Executive, Judiciary and Legislative branches on parliamentary amendments could bring relief to the pressures that the Ministry of Health traditionally faces, assessed the Minister of Health, Nísia Trindade. In a coffee organized for journalists on the morning of this Wednesday (28), Nísia attributed the siege to which she was subjected at the beginning of the year in part to the dispute over the destination of the resources. "A problem that now seems to have a solution", she said. Nísia, however, is aware that the difficulties are not over. And she herself adds: the fact that health receives half of the resources from the mandatory amendments means that the area continues to be essential in political relations and in the federative relationship. [Read more.](#)

## **CIMED PLANS R\$3.5BN INVESTMENT TO EXPAND MARKET PRESENCE**

Cimed, a leading pharmaceutical company in Brazil, plans to invest R\$2 billion in expanding its production capacity and R\$1.5 billion in marketing over the next five years, aiming to increase its presence in the consumer goods industry. CEO João Adibe has decided not to pursue the acquisition of Jequití, the cosmetics brand owned by the Silvio Santos Group but remains actively searching for assets in this sector. The goal is ambitious. "We want to become the Brazilian Procter & Gamble," Mr. Adibe told Valor. [Read more.](#)

## **BRAZILIANS PERFORMED 2.4 BILLION TESTS IN 2023, AN INCREASE OF 11%**

Brazilians used the Unified Health System (SUS) and supplementary healthcare to perform 2.4 billion exams in 2023, an increase of 11% compared to the previous year. The data are part of the ABRAMED Panel, presented by the entity during the International Health Leadership Forum (FILIS). Half of the exams (1.2 billion) were performed by the private sector – an increase of 10% compared to 2022. Over the past six years, the period in which the entity has been monitoring, the upward trend in demand for tests was only not seen in 2020, at the height of the pandemic. Between 2018 and 2023, the volume of tests performed in the private sector grew by 40%. [Read more.](#)

## **28% OF CONSUMERS ADMIT TO TAKING MEDICATION WITHOUT GUIDANCE**

The Consulta Remédios (CR) platform, a pharmaceutical retail platform in Brazil, released data from a survey conducted with more than 2,000 consumers. The survey, conducted in July 2024, sought to identify some common behaviors among users of pharmacy products, including self-medication, the level of trust in the pharmacist, frequency of visits to the pharmacy, among others. "We have always been concerned about the issue of self-medication, as we know it is a reality. So, we wanted to identify this issue and understand more about the behavior of our audience. There were about 15 questions that revolved around the most varied subjects and that brought relevant data, such as, for example, that 28% of people self-medicate when they have mild symptoms", said Paulo Vion, CEO of the platform, which commissioned the survey conducted online. [Read more.](#)

### **MORE HIGHLIGHTS**

[Suspected mpox case at Brazilian airport likely chickenpox, hospital says.](#)

[Global Regional Forum discusses Oncology in the Federal District](#)

[Public Hearing at the Legislative Assembly of São Paulo debates rare diseases and access to treatments in the state](#)

[Final draft of bill establishing identification card for people with rare diseases in Minas Gerais is approved](#)

### **BRAZIL NEWS**

[Brazil watchdog moves to block access to Elon Musk's X after court order](#)

[Brazil judge takes on Musk's X as 'fake news' crusade ramps up](#)

[What is Elon Musk's feud with a Brazilian Supreme Court justice about?](#)

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[Brazil's government to end 2024 within fiscal target tolerance band, finance minister says](#)

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