

# WEEKLY REPORT

09/30/2023



## **GOVERNMENT PLANS TO PRODUCE 70% OF HEALTH SUPPLIES BY 10 YEARS**

Brazilian Health Minister Nísia Trindade said Tuesday (Sep. 26) that the government is working to produce 70 percent of all health supplies used in the country within ten years. "The steps will be taken from now on, resuming efforts that began 20 years ago," she said, referring to the launch of strategies to bolster the Health Economic and Industrial Complex, scheduled for today. "Planned investments total BRL 42.1 billion. A portion of this will come under the PAC [Growth Acceleration Program], where we will have investments in public laboratories, with a focus on Hemobrás, to quadruple the production of vaccines—a great tool for health on a regular basis and for pandemic situations," the minister noted on *Conversa com o Presidente*, aired on Canal Gov. According to the minister, the total amount planned stand at BRL 23 billion in investments from the private sector, as well as funding from the National Bank for Economic and Social Development (BNDES) and the Financier of Studies and Projects (Finep). "These add up to BRL 42.1 billion. It's the biggest investment in recent years because we've created a favorable system". [Read more.](#)

## **STRATEGIES FOR STRENGTHENING THE HEALTH ECONOMIC AND INDUSTRIAL COMPLEX ARE PRESENTED IN A CEREMONY AT PLANALTO PALACE**

The strategy presented will include 6 structuring programs of the National Strategy for the Development of the Health Economic-Industrial Complex (CEIS):

- The Partnership Program for Productive Development, which involves the government's coordination with the private sector for the transfer of technology, in the well-known PDPs, but is now even more oriented towards reducing SUS vulnerabilities and expanding the population's access to healthcare. The estimate is that public authorities will attract around R\$23 billion from the private sector by 2026;
- The Local Development and Innovation Program foresees the resumption of investments in local initiatives with a technological and innovative focus, such as artificial intelligence for the early detection of diseases, for example. It is also aimed at the main challenges of the SUS, considering the need to reduce productive and technological vulnerabilities, promote sustainability and access to healthcare;
- The Program for Preparation in Vaccines, Serums and Blood Products aims at self-sufficiency in products essential to the lives of Brazilians and brings together the efforts of public authorities and the private sector. It stimulates the national production of technologies, expanding access and guaranteeing the supply of vaccines, serums and blood products. The idea is that initiatives are monitored and involve local innovation, in addition to technology transfer;
- The Program for Neglected Populations and Diseases is a resumption of the initial strategy for public production in the country, focusing on diseases such as tuberculosis, dengue, schistosomiasis, and leprosy. This is one of the most prominent points of the new CEIS strategy, which aims at equity. It encompasses encouraging the production of technologies to improve the prevention, diagnosis and treatment of the population affected by neglected diseases, and includes cooperation between the public and private sectors;
- The Assistance Modernization and Innovation Program particularly covers philanthropic entities. The proposal is that the expansion of the CEIS is linked to modernization and innovation in assistance by these institutions providing services to the SUS. It is expected that incentive mechanisms will be established as well as commitments to adhere to this

program. Philanthropic hospitals are responsible for 60% of all highly complex care in the public health network; and

- The CEIS Infrastructure Expansion and Modernization Program combines public and private investments for the productive and infrastructure expansion of the Complex itself. The objective is to enable the production, technological and innovation capacity of the CEIS, something necessary for the execution of the other five programs listed.

### **PUBLIC HEARING SCHEDULED TO DISCUSS BILL THAT ADDRESSES WOMEN'S HEALTH DURING CLIMACTERIC AND MENOPAUSE**

The Commission for the Defense of Women's Rights (CMULHER) of the House of Representatives scheduled for October 5th, at 10 am, the public hearing to discuss Bill 5602/2019, which addresses women's health in the climacteric and menopause. [Read more.](#)

### **PUBLIC HEARING SCHEDULED WILL DEBATE BILL THAT ESTABLISHES REGULATORY STANDARDS FOR THE PHARMACEUTICAL SECTOR RELATED TO GENE THERAPIES**

The Consumer Protection Committee of the House of Representatives scheduled a public hearing for October 4th, at 9:30 am, to debate the project that establishes regulatory standards in the pharmaceutical sector regarding gene therapies. [Read more.](#)

### **SUBCOMMITTEE ON RARE DISEASES OF THE FEDERAL SENATE HOLDS A PUBLIC HEARING ON NEONATAL SCREENING**

The Subcommittee on People with Rare Diseases of the Federal Senate held this Wednesday (27), a public hearing on the current stage of implementation of the National Neonatal Screening Program in accordance with Law No. 14,154, of May 26, 2021. The request was made by Senator Mara Gabrilli (PSD-SP), through Request 84/2023 and Request 94/2023, both from the Social Affairs Committee. [Read more.](#)

### **IN A PUBLIC HEARING ON TAX REFORM, A REPRESENTATIVE OF THE PHARMACEUTICAL INDUSTRY DEFENDS A DIFFERENT APPROACH TO THE HEALTH SECTOR**

The sixth public hearing of the Constitution and Justice Commission (CCJ) on tax reform (PEC 45/2019), this Tuesday (26), dealt with specific and favored regimes, relating to goods and services that will be exempt or reduced tax rate, which must be defined later, by complementary law. The executive president of Sindusfarma, Nelson Mussolini, defended that there should be no increase in the tax burden on areas such as health and education. He highlighted the need for tax reform, and exemplified that when a pharmaceutical company starts a construction project until the production of the first product, it already pays tax, and it is necessary to have a different look at health and education in this construction of what is intended as the future for the country. [Read more.](#)

### **COMMITTEE PASSES BILL ABOUT TRANSPARENCY OF CLINICAL TRIALS FOR THE TREATMENT OF CANCER**

At a meeting of the Constitution, Justice, and Citizenship Committee (CCJC) of the House of Representatives held this Tuesday (26), parliamentarians passed the Bill 4615 /2019, which provides for transparency and broad publicity of clinical trials authorized and under development in the national territory involving medicines for the treatment of cancer. The matter will be sent to the Federal Senate for analysis. [Read more.](#)

### **SUPREME COURT CONVENES SPECIAL COMMISSION TO DISCUSS MEDICINES FINANCING BY SUS**

Minister Gilmar Mendes, of the Federal Supreme Court (STF), convened a special commission to debate the structure of financing and medicines by the Unified Health System (SUS) and the judicialization of the issue and its consequences, the court's portal reported. The initial deadline for the work is 12/18. The decision was taken within the scope of Extraordinary Appeal (RE) 1366243, with general repercussion (Theme 1,234), filed by the government of Santa Catarina.

The state seeks to decide whether the Union is jointly responsible in actions against state governments requesting the supply of medicines registered with the National Health Surveillance Agency (Anvisa), but which are not part of the SUS standardized list. The commission must be formed by four representatives of the Union, four members appointed by the National Health Fund, the National Health Council, Conitec and Anvisa, four representatives from the states and four representatives from the municipalities. The Federal Senate, the House of Representatives and the Federal Audit Court may also nominate representatives, as observers or consultants. The minister considers that adequately addressing the issue requires an approach that encompasses the entire process of providing health actions and services by the State, from funding to financial compensation between federative entities. The rapporteur proposes that debates and proposals be scaled according to four points: responsibility, funding and reimbursement for the supply of medication incorporated or not incorporated by the SUS; monitoring SUS users; extrajudicial methods of resolving disputes, including at the administrative level of the SUS; and any other topics that arise in the debates.

[Read more.](#)

### **DIABETES CONTROL AND ANTIDEPRESSANTS ARE THE MOST JUDICIALIZED MEDICATIONS**

Medications for diabetes control, antidepressants and geriatric diapers are some of the main demands of Brazilians who seek legal action against the Unified Health System (SUS), highlighted an article in the newspaper O Globo. In the last five years, the lack of inputs available by public authorities was the subject of 13,914 legal proceedings, according to Judiciary data extracted by Deep Legal, an artificial intelligence company. The numbers indicate that 63% of the cases raised are judged valid or partially valid by the Judiciary, forcing the SUS to provide medicines for the patients' health treatment. Those affected by diabetes are responsible, for example, for 24% of these actions. Orders are made to ensure basic sugar control medication. Requests for medicines aimed at depression, anxiety and mood disorders also appear recurrently, comprising 13% of legal complaints. Also, according to the survey, around 3% of lawsuits are related to geriatric diapers. Despite the product being provided by the SUS, patients argue in their requests that "the quantity" offered by the system "is insufficient." [Read more.](#)

Relações Governamentais

### **ANVISA APPROVES PUBLIC CONSULTATION ON BIOSIMILAR MEDICINES**

Anvisa approved, this Wednesday (27/9), a public consultation on the Resolution of the Collegiate Board (RDC) to change the national regulation of biosimilar medicines and revoke chapter V of RDC 55/2010, which provides for registration of biological products through comparability (biosimilars). The proposal seeks to simplify the process of developing and registering biosimilars, recognizing the possibility of dispensing with specific steps or studies, when technically feasible. [Read more.](#)

### **ANVISA PUBLISHES REAL WORLD EVIDENCE GUIDE AND ANNOUNCES WORKING GROUP FOR OCTOBER**

Anvisa has released a guide-to-guide companies in conducting real-world evidence studies (RMSs) to be used in support of the development of new medicines or new indications. As explained in a statement on the agency's portal, the guide defines the technical requirements to prove the safety and effectiveness of medicines based on real-world data, providing important data collection and analysis guidelines for the pharmaceutical industry. Including the possibility of using EMRs in the drug development process can bring important benefits to innovation and development in the pharmaceutical area. EMRs can be used to support the assessment of the safety and effectiveness of medicines in broader populations and in real-world conditions. In parallel with the release of the guide, Anvisa announced the creation of a working group (GT-EMR) that will be established in October. The GT-EMR will play an important role in evaluating EMR study designs, issuing technical opinions and collaborating to improve the regulatory environment, aiming to improve the quality of health research in Brazil. [Read more.](#)

## PSD CONGRESSMEN TARGET HEALTH FUNDS: 'IF WE DANCE, NÍSIA (MINISTER OF HEALTH) WILL DANCE TOO

A group of federal PSD congressmen literally blocked the Minister of Institutional Relations, Alexandre Padilha, after an event in the main hall of Palácio do Planalto this Tuesday (26), reported the G1. Parliamentarians surrounded the minister on the side wall of the main hall and began to make demands on a series of issues. The circle was made up of PSD representatives, including Pedro Paulo and Laura Carneiro, both from Rio de Janeiro. The party leader in the House, Antônio Britto (BA), was also in the group. The representatives demanded from Padilha that the PSD be included in appointments in charge of the National Health Foundation (Funasa). The state-owned company entered the ministerial reform that Lula's government is conducting to accommodate the center parties. Republicanos, União Brasil and even the PL want to occupy spaces at Funasa. Another demand in question is the transfer of federal resources in the health area to the state of Rio de Janeiro. These are funds that have already been authorized for the state, but the resource has not yet been released. This money is in the budget of the Ministry of Health under the heading RP2/A4, which are the funds that the Lula government inherited from the extinct secret budget. During the conversation, deputy Laura Carneiro mentioned the Minister of Health, Nísia Trindade. 'If we dance, Nísia will dance too'. The dialogue was recorded by reporter Isa Stacciarini, from CBN radio. [Read more](#).

### MORE HIGHLIGHTS

[Public hearing scheduled on the inclusion of rare diseases in the curriculum of higher education health courses](#)

[Breast cancer treatment presents different results in the SUS and in supplementary health](#)

[Health plans maintain denial of treatment coverage even after new law on the list of procedures](#)

['Blood is not a commodity', says Nísia; Congress evaluates PEC that allows sale of plasma](#)

[Ministry of Health may provide information on the creation of assisted therapy centers in the SUS](#)

### POLITICAL NEWS

[President Lula awake and well after hip surgery, say doctors](#)

[Central-bank chief warns inflation expectations may not converge amid fiscal concerns](#)

[Brazil's jobless rate drops to 7.8% in quarter through August](#)

[Supreme Court's new chief justice faces stormy ties with Congress](#)

[Brazil farm sector battles Supreme Court on Indigenous land rights](#)