

# WEEKLY REPORT

08/24/2024



## **LULA SAYS ANVISA WILL BE FASTER WHEN MEMBERS LOSE RELATIVES DUE TO LACK OF MEDICINE**

President Luiz Inácio Lula da Silva said this Friday that the National Health Surveillance Agency (Anvisa) will be faster to release medicines when one of its members loses a relative due to lack of medicine. He made the statement in Hortolândia (SP), at the inauguration of the EMS pharmaceutical factory. Lula was accused by businessman Carlos Sanchez because of Anvisa's procedures to release medicines in Brazil. "Our friend Sanchez made a demand, a provocation to the Minister of Health, the Vice President of the Republic and the President of the Republic, that Anvisa needs to move a little faster to approve the requests that are there, because it is not possible people can't buy medicine because Anvisa doesn't release it", said Lula. [Read more.](#)

## **IN RESPONSE TO LULA, DIRECTOR OF ANVISA SAYS THAT THE GOVERNMENT WAS WARNED REPEATEDLY ABOUT A LACK OF EMPLOYEES AT THE AGENCY**

The director-president of the National Health Surveillance Agency (Anvisa), Antonio Barra Torres, responded this Friday (23) to criticism made by President Luiz Inácio Lula da Silva about the agency's supposed slowness in releasing medicines. In an official note, Barra Torres stated that the federal government was repeatedly alerted about the lack of employees at Anvisa, which has directly impacted the speed of processes. The director of Anvisa highlighted that, since the 2022 election, the agency sent 26 letters to the federal government detailing staff shortages and participated in several meetings with ministers to discuss the topic. According to him, the only concrete measure received so far was the release of 50 of the 120 vacancies scheduled for public competition in 2023. "With an insufficient number of workers and tasks that only increase, the time to carry out such tasks can only become longer", argued Barra Torres. [Read more.](#)

## **REGULATORY AGENCY OFFICIALS APPROVE 27% ADJUSTMENT**

In an assembly with more than 2,800 participants, employees from regulatory agencies approved, this Tuesday (20), the adjustment proposal made by the federal government to the category. The information was released by the National Union of Employees of National Regulatory Agencies (Sinagencias), which represents employees of 11 bodies. With the acceptance of the proposal, the expectation is that the agreement will be formally signed this Wednesday, at the Ministry of Management and Innovation in Public Services (MGI), in Brasília. The adjustment offered is 27% for career civil servants and 15.5% for those in the Special Position Plan (PECs), in two installments (2025 and 2026). The proposal was approved by 69% of employees who participated in the assembly. In total, according to Sinagencias, there were 1,969 votes in favor, 868 against and 23 abstentions. [Read more.](#)

## **MINISTRY OF HEALTH PUBLISHES ORDINANCE TO STRENGTHEN ANVISA**

The Ministry of Health published this Friday (23/8), in the Official Gazette of the Union (DOU), an ordinance with support actions for the National Health Surveillance Agency (Anvisa). The objective is to modernize the institution, in order to guarantee the strengthening of the Health Industrial Economic Complex. The measure was announced last Wednesday (21/8) by the Minister of Health, Nísia Trindade, as JOTA had anticipated. Read here in full. The actions will be aimed at the development of technological programs, such as integrated digital platforms, in addition to qualification measures in the regulatory environment. The measure, according to

the Ministry of Health, recreates the figure of the management contract with the agencies, in order to improve coordination. [Read more.](#)

## **ORDINANCES ARE PUBLISHED REGARDING THE INCORPORATION OF TREATMENTS FOR PROSTATE CANCER INTO THE SUS**

The Secretariat of Science, Technology and Innovation and the Health Economic-Industrial Complex published in the Official Gazette of the Union, this Friday (23), the ordinances about incorporation of treatments for prostate cancer into the SUS. One ordinance incorporates abiraterone associated with androgen deprivation therapy (ADT) in patients with castration-resistant, metastatic, and chemotherapy-naïve prostate cancer, according to the protocol of the Ministry of Health. The ordinance also presents the decision not to incorporate enzalutamide for patients with chemotherapy-naïve metastatic castration-resistant prostate cancer; apalutamide, darolutamide and enzalutamide (associated with ADT) for patients with non-metastatic castration-resistant prostate cancer; and enzalutamide combined with TPA for patients with metastatic castration-resistant prostate cancer with prior use of docetaxel. [Read more.](#) The other ordinance incorporates abiraterone in monotherapy or in combination with docetaxel for the treatment of patients with castration-sensitive and metastatic prostate cancer (mSCPC), according to the protocol of the Ministry of Health, and not to incorporate the drugs enzalutamide, darolutamide and apalutamide for the treatment of patients with mSCPC. The technical areas will have a maximum period of 180 days to effectively offer the approved treatment in the SUS [Read more.](#)

## **AMENDMENTS RELATED TO THE HEALTH AREA ARE PRESENTED TO THE BILL REGULATING TAX REFORM IN THE FEDERAL SENATE**

The deadline for submitting amendments to the Federal Senate to Complementary Bill 68/2024, which establishes the Tax on Goods and Services (IBS), the Social Contribution on Goods and Services (CBS) and the Selective Tax (IS), has ended. The text includes all medicines registered with Anvisa or produced by compounding pharmacies, at a reduced or zero rate. In total, 1,233 medicines benefit in two categories: 850 with a 60% reduction and 383 with zero taxation. The 60% reduction also applies to the supply of compositions for enteral and parenteral nutrition, special compositions and nutritional formulas intended for people with inborn errors of metabolism. Basic menstrual health care products, accessibility devices for people with disabilities and 92 medical devices also entered the differentiated regime. The PLP establishes that the time for reassessing the list of medications covered by the reduced tax rate will be reviewed every 120 days. The matter, which is being processed by the Constitution, Justice, and Citizenship Committee in the Federal Senate, received a total of 1,095 amendments. Of these, 48 propose changes in the health area. [Read more.](#)

## **BRAZIL OPENS FACTORY FOR MEDICINES FOR DIABETES AND OBESITY**

President Luiz Inácio Lula da Silva and the Minister of Health, Nísia Trindade, participated this Friday (23) in the inauguration of a synthetic polypeptide factory, in Hortolândia (SP), dedicated to the production of medicines for diabetes and obesity. In a statement, the ministry informed that the factory will produce synthetic liraglutide, "an innovative product that was submitted for registration with the National Health Surveillance Agency (Anvisa) and is in the priority queue for evaluation". Operated by the pharmaceutical company EMS, the factory must also produce semaglutide, an ingredient for the drug Ozempic, whose patent is in force until March 2026 and whose registration application has already been submitted to Anvisa. "With an investment of R\$ 60 million, the space represents a historic milestone, as it is considered the first of its kind in the country and is part of the federal government's initiatives related to the Health Economic-Industrial Complex", assessed the ministry, in a note. [Read more.](#)

## **GENERIC WEIGHT-LOSS DRUGS WON'T BE AVAILABLE FOR YEARS**

Eli Lilly and Novo Nordisk enjoy the largest market values in the pharmaceutical industry, as investors expect years of high-volume sales and high prices for their weight-loss drugs that replicate the effects of the GLP-1 hormone: Lilly's Zepbound and Novo's Wegovy. One limit to

those prospects will be the arrival of generics. So, Guggenheim analyst Seamus Fernandez checked out what some of the big generic drugmakers have to say about the burgeoning GLP-1 category. Many are making plans, but according to the analyst's report, Novo and Lilly won't face substantial competition in the U.S. or Europe until the early 2030s. [Read more.](#)

## **HEALTH PLANS RECOVER IN THE 1ST QUARTER, ACCUMULATING R\$4.4 BILLION IN THE LAST 12 MONTHS**

The health plan sector demonstrated a significant recovery in the first quarter of 2024, consolidating a net result accumulated in 12 months of R\$4.4 billion. This performance marks the fourth consecutive quarter of positive results, an unprecedented sequence in the last two years. The operating result, with a value of R\$1.9 billion in the first quarter, was the main driver of this improvement, reaching a level close to that of the years before the covid-19 pandemic. Despite a decline of R\$2.4 billion in the 12-month period, this is the best result since the fourth quarter of 2021. The financial result, although it suffered a slight drop to R\$10.9 billion, remains the second best in the historical series. [Read more.](#)

## **RARAS BRASIL LAUNCHES FIRST NATIONAL REGISTRY OF PEOPLE WITH RARE DISEASES**

The result of a partnership between the University of Brasília (UnB) and the Ministry of Human Rights and Citizenship (MDHC), with the collaboration of the Ministry of Health, the Raras Brasil project launches, this Friday (23), the research "Profile biopsychosocial of people with rare diseases in Brazil". The project is coordinated by two professors from the university: Professor Maria Paula do Amaral Zaitune and Professor Natan Monsoro de Sá, both from the Department of Public Health at the University of Brasília (UnB). The objective is to understand the biopsychosocial profile of people with rare diseases in Brazil, based on the production of a situational diagnosis of the rare disease community. What sets Raras Brasil apart is the production of the first national registry of people with rare diseases with a biopsychosocial approach for civil society. Raras Brasil will provide a set of evidence that will support the formulation of support strategies and public policies for the population of people with rare diseases. [Read more.](#)

## **THE CHALLENGE FOR THE SUS IN THE COMING YEARS IS FINANCING, SAYS ALCKMIN**

Vice President Geraldo Alckmin drew attention to the challenge of financing the Unified Health System (SUS) in the coming years. According to him, three changes in the profile of the Brazilian population contribute to this. The reflection took place this Wednesday (21/8) at Fórum Saúde, an event organized by the pharmaceutical company EMS and Esfera, in Brasília. "We have a big challenge ahead: the cost. The demographic change, with the elderly population, the epidemiological change, with the different profile of diseases, and the incorporation of technology increase the cost. We need to have a lower cost and better results," comments Alckmin. The vice-president also recalled that, last year, the federal government enacted the annual adjustment of SUS funding. [Read more.](#)

### **MORE HIGHLIGHTS**

[Ministry of Health establishes Working Group to review ordinance that provides procedures for planning, acquisition, and management of strategic health supplies](#)

[Public hearing debates tax reform and its impacts on health](#)

[Project includes "Blue November" in the official calendar of Rio de Janeiro](#)

[Researchers and managers discuss the use of artificial intelligence to improve the SUS](#)

[Rapid aging of the population impacts health, education, and pensions, says ministry](#)

**BRAZIL NEWS**

[Brazilian population likely to start shrinking in 2042](#)

[Necessity drives most workers into micro entrepreneurship, study shows](#)

[Supreme Court stresses congressional role in resolving budget impasse](#)

[Brazil Senate OKs bill regulating payroll tax waivers](#)

[Senate unlikely to vote on Central Bank nomination before election](#)

[Brazil's grid caps power from wind and solar, threatening renewable projects](#)

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