

WEEKLY REPORT

05/04/2024



BRAZILIAN GOVERNMENT ACCELERATES APPROVAL OF HEALTH AMENDMENTS TO THE BUDGET TO CONTAIN TENSION WITH THE NATIONAL CONGRESS

In a new crisis in the relationship with the National Congress, the government accelerated the release of parliamentary amendments and has encouraged ministers' personal meetings with representatives and senators to hear their demands. One of those selected for the mission was the Minister of Health, Nísia Trindade, who intensified her agendas with politicians in recent weeks and made her department the record holder in allocating resources to congressmen's electoral strongholds. Of the R\$8.5 billion in individual amendments committed by the government until the beginning of the week, 92% came from Health, which has responded to parliamentarians' requests more quickly than other ministries. The commitment is the first stage of payment, when the amount is reserved in the Budget. The pace that the government imposed for sending resources is the result of pressure from parliamentarians to fill the funds of allied city halls in time for the October municipal elections. The R\$8.5 billion committed so far represents 34% of the R\$25 billion in amendments planned for the year. In 2020, the year of the last municipal dispute, the federal government had released R\$7.8 billion by April 30, equivalent to 22% of the total. [Read more.](#)

TAX REFORM: WHAT THE TAX ON HEALTH PLANS WILL BE LIKE

The tax reform regulatory bill provides for a differentiated regime for health plans, with a 60% discount on federal contribution rates and state and municipal taxes on goods and services. If the general rate is 26.5%, as estimated by the Brazilian government, the taxation of plans could be 10.6%. The offer of plans by private companies to employees is seen by the government as indirect remuneration. Therefore, companies' spending on these services will not generate credit to deduct taxes. The argument of the extraordinary secretary for Tax Reform at the Ministry of Finance, Bernard Appy, is that citizens who take out a health plan on their own do not receive tax credits and the same should apply to companies. The government defends equality as a principle of neutrality. "It's an indirect salary that we are giving to our employees. If instead of paying him this benefit, I were paying the same amount in his salary, he would be paying the tax", said Appy in the project presentation interview. This point in the proposal is likely to generate controversy during discussions of the proposal in the National Congress and has already been criticized by tax experts. [Read more.](#)

SOLEMN SESSION AT THE HOUSE OF REPRESENTATIVES EMPHASIZES THE IMPORTANCE OF REGISTERING INTELLECTUAL PROPERTY

A solemn session in the Plenary of the House of Representatives on Tuesday (30) celebrated the World Intellectual Property Day. The president of the National Intellectual Property Institute (INPI), Julio César Moreira, told congressmen that 75% of patents registered in the country belong to foreigners. He explained that it is necessary not only to stimulate innovation, but to increase people's knowledge about the need for correct registration of inventions. Representative Julio Lopes (PP-RJ), who suggested the session, explained the importance of registering intellectual property. "It not only ensures that creators receive recognition and fair

reward for their innovations, but also encourages continued investment in research and development, thus fueling the virtuous circle of innovation in the country." [Read more.](#)

SUBCOMMITTEE ON RARE DISEASES APPROVES WORK PLAN FOR 2024

The Permanent Subcommittee on the Rights of People with Rare Diseases (CASRaras) approved, this Tuesday (30), its work plan for 2024. The ten years of the National Policy for Comprehensive Care for People with Rare Diseases, established by Ordinance 199, from 2014, from the Ministry of Health, is the main focus of the collegiate for this year. The Subcommittee — chaired by Senator Mara Gabrielli (PSD-SP), with vice-presidency by Senator Damares Alves (Republicanos-DF) — monitors public policies aimed at people with rare diseases in the various aspects concerning the topic, especially those dedicated to care provided by the Unified Health System (SUS) and within the scope of supplementary health. With five public hearings planned (others may be suggested by members of the subcommittee), the panel intends to propose a possible update of the standard at the end of the work. To execute the work plan, the following debates are being proposed: Accreditation, financing, operation and evaluation of reference centers and services for rare diseases in the country (May); Standardization of access for people with rare diseases to medicines, medical devices and technologies within the scope of the SUS (June); Advances and access to advanced cell therapies (August); Observance and adequacy of current clinical protocols and therapeutic guidelines for rare diseases, as well as the need for their updating and expansion to diseases not yet covered (September); It is Debate on legislative proposals in the National Congress that prioritize people with rare diseases (October). [Read more.](#)

ANVISA MUST COMPLETE REGISTRATION OF GENE THERAPY FOR A RARE DISEASE BY JUNE, SAYS AGENCY REPRESENTATIVE

In a public hearing at the House of Representatives about the registration of the drug Elevidys, the representative of the National Health Surveillance Agency (Anvisa), João Batista da Silva Júnior, announced that the process should be completed by June. From then on, he stated, release will depend on the company that produces the drug. Elevidys is a gene therapy used to treat Duchenne muscular dystrophy. [Read more.](#)

ANVISA WILL PREPARE PUBLIC CONSULTATION FOR REGULATION ON CLINICAL TRIALS FOR DRUG REGISTRATION

The National Health Surveillance Agency (Anvisa) approved today, during the 7th Ordinary Public Meeting of the Collegiate Board (ROP 7/2024), the opening of the Public Consultation (CP) to review Collegiate Board Resolution No. 9, of 2015. This Resolution deals with the Regulation for conducting clinical trials aimed at registering medicines in Brazil. For the director reporting on the topic, Meiruze Freitas, "the guiding pillar for the review of RDC nº 9, of 2015, was to improve Anvisa's regulatory performance in the approval and monitoring of clinical trials, based on health risk". During the same meeting, the Regulatory Impact Analysis Report (AIR) was presented, which, after an in-depth analysis, confirmed the need to review current legislation, aiming to adapt it to innovation scenarios and ensure the harmonization of Brazilian regulations with international standards. [Read more.](#)

ANVISA WILL USE ANALYSIS FROM EQUIVALENT FOREIGN AUTHORITIES FOR THE GMP INSPECTION AND CERTIFICATION PROCESS

The National Health Surveillance Agency (Anvisa) published, in the Official Gazette of the Union this Friday (3/4), Normative Instruction (IN) 292/2024, which establishes the optimized procedure for the purposes of analyzing the certification of Good Practices of Manufacturing and the criteria for defining Equivalent Foreign Regulatory Authorities (AREE) for the inspection process of medicines, biological products, cannabis products for medicinal purposes and active

pharmaceutical ingredients (IFA). Regulatory trust - reliance - will bring more agility to the entire certification process. [Read more.](#)

ADOPTION OF THE DIGITAL LEAFLET GENERATES DISCUSSION IN THE CHAMBER

The adoption of the digital leaflet by some laboratories became a subject of debate in the Chamber of Deputies. Bill 715/24 proposes that Anvisa will no longer be the body responsible for defining medicines that will be sold with only one leaflet format, whether digital or physical. The information is from Agência Câmara de Notícias. [Read more.](#)

BRAZIL ALREADY REACHES THE MARK OF 2,000 DEATHS FROM DENGUE IN 2024

The country surpassed the mark of 4.3 million probable cases of dengue in 2024, according to data from the Ministry of Health 's Arbovirus Monitoring Panel, updated this Friday (03). 2,197 deaths from the disease were recorded. In addition to the confirmed deaths, there are still 2,276 under investigation. These are the highest numbers in the historical series, recorded by the Health department since 2000. The country has recorded three consecutive years of record dengue cases, after a period with lower incidence during the pandemic. [Read more.](#)

MORE HIGHLIGHTS

[Favorable opinion presented to the project that creates the parliamentary front for the development of the pharmaceutical industry](#)

[Representatives request a public hearing on the schedule for implementing the expansion of the Neonatal Screening Test](#)

[Ministry of Health provides information about the creation of a national bank of epidemiological information on rare diseases](#)

[Representative presents favorable opinion to the project that includes patient associations in Conitec](#)

BRAZIL NEWS

[Portugal's government rejects paying reparations for colonial, slavery legacy](#)

[Brazil bets on Japanese PM's visit to unlock beef sales](#)

[Latin America's seven largest economies to grow 1.4% this year, OECD forecasts](#)

[Congress, companies react to suspension of payroll relief](#)

[CNS, ABIMAQ defend payroll tax exemption at Supreme Court](#)

[Brazil Congress approves bill to keep tax incentives for events industry](#)

[Brazil's Lula asserts no tax exemptions for the wealthy, pledges relief for workers](#)

[Brazil posts strong job figures, signals stronger activity; inflation a concern](#)

[Brazil economists split over size of likely rate cut on May 8](#)

[Moody's raises outlook for Brazil's rating](#)

[Development Bank plans to foster naval industry projects](#)

[Brazil rains cloud national soy outlook as big farm state submerges](#)