

# WEEKLY REPORT



03/07/2026

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## **BRAZIL HEALTH MINISTER DEFENDS DOMESTIC PRODUCTION OF OBESITY DRUGS TO REDUCE PRICES**

Brazil's health minister Alexandre Padilha defended expanding domestic production of obesity medicines as a strategy to reduce prices and broaden access to treatment. According to Padilha, while medications play an important role in tackling obesity, the current cost of new weight-loss drugs remains excessively high for most patients. The minister argued that Brazil should strengthen the technological capacity of public laboratories and national companies to produce peptide-based medicines such as semaglutide and liraglutide, widely used in treatments for obesity and diabetes. He said the goal is for the country to "master the technology" behind these drugs, increasing competition and helping bring prices down. Padilha also noted that the government is evaluating the targeted use of semaglutide within Brazil's Unified Health System (SUS) for patients with severe obesity and related conditions, while maintaining prevention policies focused on diet and physical activity. [Read more.](#)

## **BRAZIL APPOINTS RAPPOREUR FOR BILL DECLARING TIRZEPATIDE DRUGS OF PUBLIC INTEREST**

The House of Representatives has appointed Congressman Mersinho Lucena (PP-PB) as rapporteur of Bill 68/2026, which proposes to classify the medicines Mounjaro and Zepbound, based on tirzepatide, as being of public interest in Brazil. Authored by Deputy Mário Heringer (PDT-MG), the proposal aims to enable the mechanisms provided under Article 71 of Brazil's Industrial Property Law, amended by Law 14,200/2021, which allows compulsory licensing in cases of public interest. The bill recognizes tirzepatide-based medicines as relevant for the treatment and control of type 2 diabetes and obesity, also referred to as adiposity-based chronic disease. The text also foresees that specific regulations could define the use of these medicines in patients with overweight conditions that do not meet the obesity threshold but present proven cardiovascular, lipid or metabolic health risks. With the rapporteur designated, Lucena is now responsible for preparing the legislative opinion that will guide the next steps of the proposal's discussion and possible vote in the House. [Read more.](#)

## **BRAZIL LAWMAKER DEFENDS PATENT WAIVER FOR TIRZEPATIDE DRUGS SUCH AS MOUNJARO**

Congressman Mário Heringer (PDT-MG) has defended a legislative proposal that could enable the patent waiver of medicines based on tirzepatide, including the diabetes and obesity drug Mounjaro. The bill aims to declare these medicines of public interest, opening the possibility for compulsory licensing and the production of lower-cost versions in Brazil. According to Heringer, the high cost of tirzepatide therapies limits access for most patients and encourages unsafe alternatives in the parallel market. The lawmaker argues that allowing domestic production after a patent waiver could significantly reduce prices and curb illegal trade in the medication. In Brazil, a single Mounjaro injection pen can cost roughly R\$1,400 to R\$3,000, depending on the dosage. The proposal advances in Congress under an urgency regime, which allows the bill to be voted directly in the House of Representatives plenary without passing through committees. Supporters frame the measure as a public health strategy to expand access to treatments for diabetes and obesity, while critics warn that weakening patent protections could create legal uncertainty and discourage pharmaceutical innovation and investment. [Read more.](#)

## **ANVISA REPORTS PROGRESS IN PLAN TO REDUCE REGULATORY BACKLOGS IN BRAZIL**

Brazil's National Health Surveillance Agency (Anvisa) reports early progress in its action plan aimed at reducing regulatory backlogs for medicines, vaccines, medical devices, and inspections. The initiative, launched in November 2025, seeks to cut waiting lines by half within six months and normalize processing timelines by the end of 2026, according to the agency's president, Leandro Safatle. Initial results show significant reductions in several areas of regulatory review. Anvisa reports a 60% decrease in analysis time for clinical trial authorizations and in the backlog of radiopharmaceutical registration requests, while the pending stock of post-registration changes for medical and orthopedic devices has fallen by about 50%. The agency also indicates that the number of completed reviews reached record levels in the first two months of 2026. The strategy combines operational measures and structural reforms, including process reorganization, reliance on international regulatory assessments, stronger internal task forces and investments in digital tools and artificial intelligence to improve regulatory efficiency and predictability. [Read more.](#)

## **BRAZIL REGULATOR CONSIDERS PILOT PROGRAM TO ACCELERATE REVIEW OF SYNTHETIC MEDICINES**

A director of Brazil's National Health Surveillance Agency (Anvisa) has proposed creating a pilot program to speed up the regulatory review of synthetic medicines, aiming to reduce the backlog of pending applications. In an interview, director Daniela Marreco Cerqueira said the initiative would reinforce policies launched in 2025 to improve efficiency in the agency's drug evaluation process. The proposed pilot would test new procedures to streamline technical analysis and shorten review timelines for certain categories of synthetic drugs. According to Cerqueira, the initiative seeks to maintain regulatory rigor while improving predictability for pharmaceutical companies and addressing delays that affect market entry of new medicines in Brazil. The discussion occurs amid broader efforts within Anvisa to modernize regulatory processes and strengthen the agency's capacity to evaluate increasingly complex pharmaceutical technologies. [Read more.](#)

## **ANVISA TO DEBATE REGULATION OF MEDICINE SALES THROUGH ONLINE MARKETPLACES**

Brazil's National Health Surveillance Agency (Anvisa) plans to open internal discussions on the sale of medicines through third-party online marketplaces, according to the agency's president Leandro Safatle. The topic, along with the commercialization of private-label medicines, has been described by the regulator as a "very recent and emerging issue" within the agency's regulatory agenda. Safatle said Anvisa directors have already started evaluating the matter in weekly internal discussions and are considering the creation of dedicated working groups to study the regulatory implications. The debate reflects the growing relevance of digital commerce platforms in pharmaceutical distribution and the need to assess potential risks related to safety, traceability, and pharmaceutical oversight. The issue surfaced during the legislative debate over Bill 2158/2023, which authorizes pharmacies to operate inside supermarkets. While the final version addressed several sanitary concerns raised by Anvisa, discussions on online marketplace sales were left for a separate regulatory process within the agency. [Read more.](#)

## **BRAZIL ADVANCES LAW ALLOWING DRUGSTORES INSIDE SUPERMARKETS**

Brazil's Congress has approved legislation establishing rules for the operation of drugstores inside supermarkets, with the bill now awaiting presidential sanction. The measure, contained in Bill 2158/2023, authored by Senator Efraim Filho, authorizes supermarkets to host pharmacies or drugstores provided they operate in a physically separated and exclusive area dedicated to pharmaceutical services. Under the proposal, medicines cannot be displayed on supermarket shelves or sold in open areas. The pharmacy unit must follow the same sanitary and regulatory requirements applied to traditional pharmacies, including mandatory presence of a licensed pharmacist throughout operating hours, appropriate storage and traceability

conditions, and specific procedures for controlled medicines. Supporters argue the measure may expand access to medicines, particularly in smaller municipalities, while critics warn it could encourage self-medication and commercial pressure on drug sales. [Read more.](#)

### **BRAZIL CLINICAL TRIALS LAW FACES CHALLENGE IN SUPREME COURT**

A petition submitted to Brazil's Supreme Federal Court (STF) seeks to suspend the regulation of the country's new clinical trials law while the court analyzes its constitutionality. The request was filed by the Brazilian Society of Bioethics (SBB) and the National Confederation of Health Workers (CNTS), which argue that the Ministry of Health has advanced the implementation of the new regulatory framework even as a constitutional challenge against the legislation remains pending before the court, under the rapporteurship of Justice Cristiano Zanin. The dispute focuses on the governance model for ethical review of research involving human subjects, including the creation of the National Research Ethics Authority (INAEP). Critics claim the new structure began operating before its full institutional composition, potentially affecting research oversight. Stakeholders linked to the research ecosystem warn that suspending the framework could interrupt ethical approvals for new studies and create uncertainty for clinical trials conducted in Brazil. [Read more.](#)

### **ANVISA APPROVES NEW HEMOPHILIA DRUG TO REDUCE BLEEDING EPISODES**

Brazil's National Health Surveillance Agency (Anvisa) has approved the registration of Qfitlia (fitusiran sodium), a new therapy indicated for patients with hemophilia A or B, with or without inhibitors to clotting factors VIII or IX. The drug can be used both for prophylaxis and for reducing the frequency of bleeding episodes, one of the main complications associated with the rare genetic disorder. Developed by Sanofi, the treatment is indicated for adults and adolescents aged 12 and older and works by lowering levels of antithrombin, a protein that slows blood clotting, thereby helping restore the balance of the coagulation system. Brazil has more than 14,000 diagnosed hemophilia patients, and the approval adds a new therapeutic option to the country's treatment landscape. [Read more.](#)

### **BRAZIL STUDY HIGHLIGHTS POLICY GAP IN MENOPAUSE CARE AND DISPROPORTIONATE IMPACT ON BLACK WOMEN**

A recent study has drawn attention to the lack of structured public policies addressing menopause in Brazil, warning that the condition remains overlooked within the public health system despite affecting millions of women. Researchers argue that menopause should be treated as a relevant public health issue, given its potential impacts on physical health, mental well-being, and quality of life. The analysis also finds that the absence of targeted policies disproportionately affects Black women and those in vulnerable socioeconomic conditions. According to experts, structural inequalities in access to healthcare, information and specialized services tend to intensify menopause symptoms and delay diagnosis and treatment among these populations. Researchers and health specialists call for the development of dedicated public health strategies, including national data collection on menopause prevalence, training of healthcare professionals and expanded access to care within Brazil's Unified Health System (SUS). The study has fueled debate in Brazil's health community about the need to integrate menopause into broader women's health policies. [Read more.](#)

### **BRAZIL PROPOSES ICD CODE FOR FEMINICIDE AND LAUNCHES WOMEN'S HEALTH PACKAGE**

Brazil's Ministry of Health has proposed that the World Health Organization (WHO) create a specific code for femicide in the International Classification of Diseases (ICD-11), aiming to improve the identification and monitoring of gender-related killings of women in health information systems. Currently, these deaths are recorded under broader categories such as assault, limiting the ability to track the epidemiology of gender-based violence and design targeted public policies. The proposal was announced alongside a broader package of measures focused on women's health in the public health system (SUS). The initiatives include national health service mobilizations, expanded access to contraceptive methods, psychological tele-

care for victims of domestic violence, vaccination campaigns, and investments in maternal care infrastructure. Health authorities say the measures aim to strengthen prevention and assistance policies ahead of International Women's Day. [Read more.](#)

### **BRAZIL STUDY SHOWS RARE DISEASE PATIENTS WAIT 5.4 YEARS FOR DIAGNOSIS**

A study with more than 12,500 patients in Brazil shows that people with rare diseases wait an average of 5.4 years to receive a definitive diagnosis, highlighting persistent gaps in early detection and specialized care. The research, published in the Orphanet Journal of Rare Diseases, analyzed data from 34 public healthcare services, and represents one of the most comprehensive national assessments on the topic. The analysis found that 63.2% of patients had a confirmed diagnosis, while 19.5% were still under diagnostic investigation and 17.3% remained without a defined diagnosis. Researchers identified 1,778 different rare disease codes in the dataset, with conditions such as phenylketonuria, cystic fibrosis, acromegaly, osteogenesis imperfecta and muscular dystrophy among the most frequent. Rare diseases affect an estimated 13 to 15 million Brazilians, and more than 70% have a genetic origin. To help shorten diagnostic delays, Brazil's Ministry of Health recently announced the introduction of whole exome sequencing (WES) in the public health system, a genetic test that could reduce the diagnostic process from several years to around six months in many cases. [Read more.](#)

### **BRAZIL'S EMS PURCHASES SANOFI'S MEDLEY IN DEAL WORTH OVER \$500 MILLION**

Brazilian pharmaceutical company EMS announced on Friday the purchase of Medley, a unit of French drugmaker Sanofi (SASY.PA), opens new tab, according to a joint statement. The statement did not disclose the value of the deal, but Marcus Sanchez, vice president of EMS in Brazil, told reporters it was more than \$500 million. The transaction is still subject to approval by Brazil's antitrust watchdog, Cade, but EMS expects the green light by the end of the year. According to Sanchez, the group's market share in generic medicines will reach around 30% after the transaction is approved, which would not lead to market concentration. The executive said no plant closures were expected because of the deal. On the contrary, it would lead to new investments and possibly a new plant. During the regulatory approval period prior to closing the transaction, Medley will continue to be managed by Sanofi, ensuring continuity of operations, the companies said. [Read more.](#)

#### **MORE HIGHLIGHTS**

[Anvisa to host workshop on pricing methodologies for innovative health technologies](#)

[Brazil participates in PIC/S consultation on Good Manufacturing Practices updates](#)

[Brazil launches national system to improve traceability of medical devices](#)

[Brazil bill expanding immunotherapy access for cancer returns to Senate plenary](#)

[Brazil dengue vaccine shows five-year protection in new study](#)

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