WEEKLY REPORT

CONSULTORES
Relações Governamentais

08/29/2026

WHO IS SHAPING THE HEALTH PLANS OF BRAZIL'S PRESIDENTIAL CANDIDATES

The health proposals of Brazil's main presidential candidates are being developed by a group of former health ministers, lawmakers and public health professionals with different backgrounds in healthcare management and policymaking. For Luiz Inácio Lula da Silva, current Health Minister Alexandre Padilha is coordinating the health proposals. Flávio Bolsonaro's plan is being coordinated and validated by former Representative Eduardo Cury and Senator Rogério Marinho, with former Health Minister Marcelo Queiroga also participating in its development. Ronaldo Caiado's health program was developed with the technical participation of former Health Minister Luiz Henrique Mandetta, while Representative Adriana Ventura is responsible for coordinating the health proposals in Romeu Zema's government plan. Renan Santos' proposals were developed by a group of health researchers, with Representative Kim Kataguiri coordinating the broader government plan. The profiles of those responsible for the plans offer indications of the approaches candidates may adopt on health policy. Padilha brings experience in federal health management and programs such as Mais Médicos and Farmácia Popular; Cury and Marinho combine legislative and executive experience, including discussions on private health insurance; Mandetta has a background in primary care, healthcare financing and pandemic management; and Ventura has focused on digital health, telehealth, data integration and artificial intelligence. The different backgrounds point to distinct priorities in areas such as SUS financing, private-sector participation, healthcare management, digital transformation and access to health services. Read more.

FLÁVIO BOLSONARO NAMES CLAUDIO LOTTENBERG AS HEALTH MINISTER IN POTENTIAL GOVERNMENT

Presidential candidate Flávio Bolsonaro has announced that physician and healthcare executive Claudio Lottenberg will serve as Minister of Health if he is elected in October. The announcement was made during a presidential candidate debate on TV Globo, with Lottenberg having accepted the invitation. He is the first ministerial appointment publicly announced by Flávio for a potential administration. Lottenberg is an ophthalmologist who served as president of the Hospital Israelita Albert Einstein and currently chairs its deliberative board. He has also led the Instituto Coalizão Saúde and the Israelite Confederation of Brazil (CONIB) and served as São Paulo's municipal health secretary in 2005. Flávio has said that his choice reflects his intention to bring private-sector management practices, technology and artificial intelligence to the SUS, describing the goal as a more modern and efficient public health system. Read more.

FIOCRUZ PRESENTS HEALTH PRIORITIES TO CANDIDATES IN 2026 ELECTIONS

The Oswaldo Cruz Foundation (Fiocruz) has released an open letter to candidates running for office in Brazil's 2026 elections, outlining seven priorities for the country's health agenda. The document calls for strengthening the Unified Health System (SUS), valuing the health workforce, producing more science, vaccines, medicines and technologies in Brazil, reducing inequalities, preparing for climate-related health emergencies and future pandemics, combating misinformation and strengthening Brazil's role in international health cooperation. The document comes as candidates begin presenting their health proposals and highlights the need to address disparities in access to healthcare across regions, climate change, violence and misinformation. For the pharmaceutical and healthcare industries, Fiocruz's call for greater domestic production of medicines, vaccines and technologies reinforces the strategic

importance of Brazil's health economic-industrial complex and productive capacity as part of the political debate ahead of the elections. Read more.

ANVISA AND ROCHE CANCEL ELEVIDYS REGISTRATION

The Brazilian Health Regulatory Agency (Anvisa) and Roche have announced the cancellation, at the company's request, of the conditional registration of Elevidys (delandistrogene moxeparvovec), a gene therapy for Duchenne muscular dystrophy (DMD). The decision follows the agency's assessment that the available evidence was not sufficient to meet the regulatory requirements for maintaining the conditional registration. Elevidys was granted conditional approval in Brazil in December 2024 for ambulatory children aged 4 to 7 with DMD and specific clinical and laboratory criteria. The product's commercialization had already been suspended in Brazil in July 2025 as a precautionary measure following international safety concerns, including reports of acute liver failure and deaths in patients treated with the therapy. The cancellation does not end Roche's obligations to monitor Brazilian patients previously exposed to Elevidys and report relevant safety information to Anvisa. Roche said it will continue its clinical program and work to generate additional evidence, while Anvisa indicated that future submissions containing new evidence may receive priority review. Read more.

SENATE HEARING PRESSURES ANVISA AND MINISTRY OF HEALTH OVER ELEVIDYS ACCESS

Brazil's Senate Human Rights Committee (CDH) held a public hearing to discuss access to Elevidys, the gene therapy for Duchenne muscular dystrophy (DMD), following the cancellation of its registration in Brazil. Senators, patient families, medical experts, Anvisa, Roche and the Ministry of Health debated the regulatory decision and its impact on children eligible for the therapy, with lawmakers calling for greater transparency, faster access to innovative treatments for rare diseases and continued monitoring of patients who have already received the medicine. During the hearing, the Ministry of Health said it has asked Roche to include Brazilian patients who received Elevidys through court orders in an observational clinical study to generate real-world evidence on the therapy's safety and effectiveness. At the end of the session, Senator Damares Alves announced the creation of a congressional working group involving lawmakers, patient organizations, Anvisa and the Ministry of Health to seek alternatives for access to advanced therapies for rare diseases while new evidence on Elevidys is generated. Read more.

NATJUS RECOMMENDATIONS FOR TREATMENTS VARY ACROSS BRAZILIAN STATES

Recommendations issued by Brazil's Technical Health Support Centers (NatJus) in lawsuits involving medicines and treatments vary significantly across states, according to a study by the Institute for Health Policy Studies (IEPS). The analysis found differences in the frequency with which courts seek technical opinions, the types of treatments assessed and the recommendations issued, highlighting inconsistencies in the use of scientific evidence in health-related litigation. The findings underscore challenges in Brazil's efforts to make judicial decisions on healthcare more consistent and evidence-based. NatJus centers were created to provide technical support to judges, particularly in cases involving medicines and health technologies, but differences in their operation and recommendations may contribute to uneven outcomes across the country. The issue is especially relevant for access to high-cost medicines and technologies and for efforts to reduce healthcare judicialization. Read more.

STJ LIMITS RIGHT TO SUS-FUNDED TREATMENT ABROAD

Brazil's Superior Court of Justice (STJ) has ruled that the Unified Health System (SUS) is not required to fund medical treatment abroad simply because a foreign center offers better technology or higher success rates. In a unanimous decision, the Second Panel held that treatment outside Brazil may be ordered only in exceptional circumstances, when there is no effective therapeutic alternative available in the country, the treatment's efficacy and safety are scientifically demonstrated, it is clinically indispensable and the patient cannot afford it. The case involved an 11-year-old girl with short bowel syndrome whose family sought SUS

funding for an intestinal transplant and treatment at a hospital in the United States. The court found that Brazil has qualified centers capable of performing the procedure and that there was no evidence that the national alternatives were technically inadequate. The ruling reinforces the use of evidence-based medicine and technical opinions in health litigation and states that there is no subjective right to the best medical technology available worldwide. Read more.

PRIVATE HEALTH SECTOR SEEKS ROLE IN MEDICINE PRICE NEGOTIATIONS

Brazil's private health insurance sector is seeking to participate in government negotiations on medicine prices, arguing that agreements negotiated with pharmaceutical companies should also consider the private healthcare market. The proposal comes amid discussions over new mechanisms to reduce medicine costs and expand access, with the government exploring ways to leverage Brazil's purchasing power in negotiations. The sector argues that including private health plans could increase the scale of negotiations and generate broader savings for patients and the healthcare system. The debate also raises questions about the scope of government-led medicine purchasing and pricing policies, particularly as Brazil seeks to balance lower costs with incentives for pharmaceutical innovation and investment. Read more.

ANS HIGHLIGHTS INTEGRATION BETWEEN SUS AND PRIVATE HEALTHCARE

The National Supplementary Health Agency (ANS) highlighted the importance of greater integration between Brazil's Unified Health System (SUS) and the private healthcare sector during a seminar hosted by Fundação Getulio Vargas (FGV). Discussions focused on strengthening coordination between the two systems, with greater emphasis on patient-centered care, health outcomes and value-based healthcare. The event brought together representatives from government, healthcare providers, insurers and academia to discuss ways to improve coordination and efficiency across Brazil's healthcare system. The debate comes amid efforts to strengthen cooperation between public and private healthcare, including the exchange of information and more coordinated approaches to care, financing and the use of health technologies. Read more.

MINISTRY OF HEALTH REPORTS INCREASED TRANSPARENCY IN HEALTH-RELATED BUDGET AMENDMENTS

Brazil's Ministry of Health has told Supreme Court Justice Flávio Dino that it has increased transparency and oversight over congressional budget amendments allocated to the health sector. The ministry presented measures aimed at strengthening the tracking of funds and improving public access to information on the allocation and execution of resources transferred to states and municipalities. The measures are part of a broader effort to improve governance of parliamentary amendments following scrutiny by the Supreme Court over the transparency and traceability of public funds. For the health sector, the changes are particularly relevant given the significant volume of amendment resources directed to the Unified Health System (SUS) and the need to ensure that transfers are properly identified, monitored and linked to their intended purposes. Read more.

MINISTRY OF HEALTH HIGHLIGHTS MEASURES ON LITIGATION, CLIMATE CHANGE AND INNOVATION

Brazil's Ministry of Health has highlighted measures to address health-related litigation, climate change and technological innovation as priorities for strengthening the Unified Health System (SUS). The initiatives were presented during the 5th edition of the Conexão SUS event and include the expansion of the Technical Center for Health Technology Assessment (NATS) network, measures to improve the incorporation of health technologies and efforts to strengthen Brazil's capacity to respond to climate-related health emergencies. The Ministry also highlighted the expansion of the SUS Digital program and the use of artificial intelligence and other digital technologies to improve healthcare management and services. In the area of judicialization, the government is seeking to strengthen coordination between the Executive and Judiciary branches and expand the use of technical evidence in court decisions involving

healthcare. The measures are part of a broader strategy to increase efficiency, sustainability and innovation across the public health system. Read more.

MINISTRY OF HEALTH CREATES WORKING GROUP TO IMPROVE FARMÁCIA POPULAR

Brazil's Ministry of Health has established a working group to propose improvements to the Farmácia Popular program, which provides free or subsidized medicines and supplies through accredited private pharmacies. The group will review the program's operational rules, monitoring mechanisms, governance and financing, with the goal of expanding access and improving the efficiency and transparency of public resources. The initiative is part of the government's broader effort to strengthen pharmaceutical assistance within the Unified Health System (SUS). The working group will bring together representatives from different areas of the Ministry of Health and is expected to assess measures to improve management and monitoring of the program, which has become an important channel for access to medicines outside public health facilities. Read more.

ANVISA ESTABLISHES TECHNICAL CHAMBER ON HEALTH LAW

Brazil's Health Regulatory Agency (Anvisa) has established a Technical Chamber on Health Law to provide specialized legal support on issues related to health surveillance and regulation. The new body will bring together experts to discuss legal matters affecting the agency's activities and contribute to greater consistency in the interpretation and application of health regulations. The initiative is intended to strengthen the agency's legal and regulatory capacity by promoting dialogue between technical and legal areas and improving the quality of regulatory decisions. The chamber is also expected to support the development and interpretation of health surveillance rules amid increasingly complex legal and regulatory challenges facing Anvisa. Read more.

ABDI AND ANVISA ADVANCE DIGITAL TRANSFORMATION OF REGULATORY PROCESSES

The Brazilian Agency for Industrial Development (ABDI) and the Brazilian Health Regulatory Agency (Anvisa) have signed a Work Plan to advance the digital transformation of regulatory processes under the Destrava Brasil program. The initiative includes the use of artificial intelligence (AI), data intelligence and optical character recognition (OCR) to automate the extraction and analysis of regulatory information related to applications for the registration of synthetic medicines. A proof of concept demonstrated the potential of the technologies, with the expectation that AI could double the number of registration analyses performed by the agency. The initiative is intended to help Anvisa's technical staff automate repetitive tasks and dedicate more time to technical assessments, contributing to the reduction of regulatory backlogs. In the first half of 2026, Anvisa issued 209 registration decisions, including 56 for new or innovative medicines, while 270 registration processes were closed compared with 194 new applications. Despite the improvement, the agency still faces a significant backlog, with an estimated R$14 billion to R$18 billion associated with medicines, registrations or investments held up in regulatory processes. Read more.

ANVISA WARNS AGAINST USING SMARTWATCHES AND RINGS TO DIAGNOSE DISEASES

Brazil's Health Regulatory Agency (Anvisa) has warned consumers and healthcare professionals that smartwatches, smart rings and other wearable devices should not be used to diagnose diseases unless they have been specifically authorized for that purpose. The agency said some devices may collect health-related data such as heart rate, blood oxygen levels and sleep patterns, but the availability of this information does not mean the product is approved to provide a medical diagnosis. Anvisa also stressed that users should verify whether a wearable device has a valid registration or notification for its intended use before relying on its measurements for healthcare decisions. The warning comes amid the rapid expansion of consumer health technologies and reinforces the distinction between wellness features and

regulated medical devices, particularly as manufacturers increasingly incorporate health-monitoring and artificial intelligence capabilities into wearable products. Read more.

BRAZIL AND PARAGUAY STRENGTHEN COOPERATION AGAINST IRREGULAR MEDICINES

Brazil's National Health Surveillance Agency (Anvisa) and Paraguay's National Directorate of Health Surveillance (Dinavisa) have signed a new cooperation agreement to strengthen the monitoring and control of irregular medicines and other health products. The memorandum provides for the exchange of information, including confidential data and laboratory results, as well as joint efforts against counterfeiting, smuggling and the circulation of unauthorized products. The agreement comes amid a sharp increase in the illegal trade of GLP-1 weight-loss medicines, with more than 165,000 units seized in Brazil through June 2026. According to Anvisa Director-President Leandro Safatle, the agreement will improve coordination between the two countries and support enforcement actions, particularly along the border. However, he stressed that the cooperation does not create an exception for medicines authorized in Paraguay to enter Brazil. The agencies are also discussing greater regulatory convergence and reliance, although Safatle said the mechanism still requires further development given the different levels of regulatory maturity between the two authorities. Read more.

BRAZILIAN PEDIATRIC SOCIETY URGES CAUTION OVER WEIGHT-LOSS DRUGS FOR CHILDREN

The Brazilian Society of Pediatrics (SBP) has issued a technical note urging physicians to exercise caution when prescribing weight-loss drugs to children and adolescents. The document emphasizes that these medicines should only be used according to indications approved by the Brazilian Health Regulatory Agency (Anvisa), with physicians assessing the severity of obesity, previous treatments, associated conditions and the patient's ability to maintain treatment. Liraglutide is approved for obesity in patients aged 12 and older weighing more than 60 kg, while semaglutide has the same age and weight criteria; tirzepatide is approved for type 2 diabetes in patients aged 10 and older under specific conditions. The SBP also warned against the use of these medicines for aesthetic purposes and rejected products obtained outside authorized channels or without Anvisa registration. The society highlighted risks including hypoglycemia, pancreatitis, gallstones and gastrointestinal reactions, while stressing that obesity should be treated as a chronic disease rather than simply as a weight-loss issue. The guidance comes amid the rapid expansion of GLP-1 medicines in Brazil and growing demand for their use among younger patients. Read more.

INFORMAL MARKET ACCOUNTS FOR 54% OF GLP-1 CONSUMPTION IN BRAZIL

Brazil's informal market is estimated to account for 54% of the country's consumption of GLP-1 medicines, according to a survey by IQVIA presented during the 4th National Congress of Pharmacists. The estimate highlights the scale of unauthorized distribution of medicines used to treat diabetes and obesity, amid rapidly growing demand for products such as semaglutide and tirzepatide. The data reinforce concerns among regulators and the pharmaceutical sector about the circulation of GLP-1 products outside authorized channels, including imported and compounded medicines. Anvisa has recently intensified measures to combat irregular products and strengthen controls over these medicines, while also expanding cooperation with neighboring countries to address cross-border trade. The size of the informal market underscores the challenges of ensuring patient safety, product quality and appropriate medical use as demand for GLP-1 therapies continues to rise. Read more.

SEIZURES OF WEIGHT-LOSS PENS INCREASE MORE THAN 20-FOLD IN BRAZIL

Seizures of weight-loss pens by Brazil's Federal Revenue Service increased more than 20-fold in the first half of 2026 compared with the same period last year, reflecting the rapid expansion of the illegal market for GLP-1 medicines. The agency seized 113,000 pens between January and June, compared with 5,000 during the same period in 2025. Most of the products were intercepted in parcels and cargo originating in Paraguay and Argentina. The seizures come amid

growing demand for medicines such as semaglutide and tirzepatide, which has also prompted increased regulatory scrutiny. Anvisa and the Federal Revenue Service have intensified actions against irregular imports and unauthorized products, while authorities warn about risks related to counterfeit, improperly stored or unregistered medicines. The scale of the increase highlights the challenges facing Brazilian regulators in controlling the supply chain as the GLP-1 market expands rapidly. Read more.

SUS TO ADD THREE MEDICINES FOR LUNG CANCER TREATMENT

Brazil's Ministry of Health will gradually make three new medicines available through the Unified Health System (SUS) for the treatment of lung cancer starting in October. Brigatinib, gefitinib and durvalumab will be funded by the federal government under the implementation of the Oncology Pharmaceutical Assistance program, with approximately 1,900 patients expected to benefit. Some of the treatments had been awaiting incorporation into the public system for more than 12 years. Brigatinib and gefitinib are oral therapies targeting specific alterations in cancer cells, while durvalumab is an immunotherapy indicated for patients with stage III lung cancer who cannot undergo surgery. The Ministry said the rollout will depend on negotiations with suppliers and the operational characteristics of each technology. The move represents another step in the federal government's effort to expand access to oncology medicines and centralize federal financing for treatments within the new pharmaceutical assistance model. Read more.

LUNG CANCER GENERATES R$885 MILLION IN HOSPITAL COSTS OVER FIVE YEARS

Lung cancer generated approximately R$885 million in hospital care costs between 2021 and 2025, according to a study by DRG Brasil, from IAG Saúde Group. The analysis covered more than 50,000 hospitalizations, including 26,309 in which lung cancer was the main reason for admission and another 24,028 involving patients with the disease who were hospitalized for other reasons. The latter group had a higher average cost, at R$19,800 per hospitalization, compared with R$16,000 for admissions directly attributed to lung cancer. The study also found a hospital mortality rate of 20.8% in admissions directly attributed to lung cancer, rising to 37.9% among patients with metastatic disease. DataSUS records show 140,616 lung cancer hospitalizations in the SUS between 2021 and 2025, with a 25.1% mortality rate and an estimated R$2.25 billion in hospital care costs based on the average cost identified by DRG Brasil. The findings highlight the broader burden of the disease on the health system, including infections, respiratory complications, metastases and treatment-related conditions, reinforcing the importance of early diagnosis and integrated care. Read more.

SANOFI EXPANDS PARTNERSHIPS WITH BUTANTAN AND FIOCRUZ FOR VACCINE PRODUCTION

French pharmaceutical company Sanofi is expanding its partnerships with Brazil's Butantan Institute and Oswaldo Cruz Foundation (Fiocruz) to strengthen local vaccine production. The agreements are part of the company's strategy to expand technology transfer and manufacturing capacity in Brazil, supporting the country's efforts to increase domestic production of strategic health technologies and reduce dependence on imported products. The partnerships reinforce the growing role of technology transfer and local manufacturing in Brazil's health industrial policy. Cooperation with major public laboratories such as Butantan and Fiocruz also reflects the government's strategy of using the Unified Health System (SUS) as a driver for innovation, productive capacity and greater resilience in the national vaccine supply chain. Read more.

BRAZILIAN COMPANIES ACCOUNT FOR 79.2% OF PUBLIC MEDICINE PURCHASES

Brazilian pharmaceutical companies accounted for 79.2% of the units of medicines purchased by Brazilian states and municipalities in 2024, up from 69.1% in 2020, according to a study by the National Association of Pharmaceutical Laboratories (ALANAC). The analysis, based on data from the Ministry of Health's Health Price Database (BPS) and Anvisa's medicine registration records, highlights the growing role of domestic manufacturers in public procurement,

particularly in high-volume products such as generics and similar medicines. However, Brazilian companies accounted for only 12% of applications for new and innovative medicines and 15.2% of applications for biological products. These categories represented R$20.93 billion, or 81.7% of the total value of government-channel transactions in 2024, despite accounting for only 21.1% of units purchased. The figures highlight a key challenge for Brazil's pharmaceutical industrial policy: increasing domestic participation in innovation and higher-value medicines, as the government seeks to strengthen productive autonomy in the SUS. Read more.

DIABETES AND OBESITY MEDICINES DRIVE PHARMACY SALES

Medicines for diabetes and obesity continue to support growth in Brazil's retail pharmacy market, according to Safra. The analysis points to sustained demand for therapies used to treat these conditions, particularly amid the rapid expansion of the GLP-1 class, which includes semaglutide and tirzepatide. The performance of these medicines has become increasingly important for pharmaceutical retailers and manufacturers as demand for obesity treatments expands beyond traditional diabetes care. The trend also highlights the growing commercial relevance of GLP-1 therapies in Brazil and the impact of new indications and broader patient access on the pharmaceutical market. Read more.

MORE HIGHLIGHTS

Anvisa approves second generic semaglutide in injectable pen

Anvisa approves new medicine for lymphoma

Anvisa publishes guidance manuals for medical device registration

Brazil becomes first country to approve nipocalimab for autoimmune hemolytic anemia

Brazil to begin screening for type 5 diabetes

Medical device industry seeks to extend tax exemption

ANS highlights importance of combating fraud in medical devices

TCU launches pilot project to improve cervical cancer care in Brasília

BRAZIL NEWS

Lula, Flavio Bolsonaro neck and neck ahead of Brazil election, Nexus poll shows

Brazil vote offers opposing politics, similar fiscal outcomes

Brazil election rivals offer competing cures for high long-term interest rates

Brazil's Lula says public debt is not a concern in a potential new term

Brazil's Flavio Bolsonaro to introduce public debt ceiling if elected president, adviser says

Senator Flavio Bolsonaro vows to respect Brazil election outcome

Brazil weighs lending curbs as household debt stress mounts

Brazil creates fewer formal jobs than expected in July