WEEKLY REPORT

08/22/2026

INTERFARMA PRESENTS 10 HEALTH PRIORITIES FOR THE NEXT GOVERNMENT

The Brazilian Association of Research-Based Pharmaceutical Industries (Interfarma) has presented its 2026 Letter to Presidential Candidates, outlining 10 priorities for the next government to expand access to healthcare, strengthen innovation and create a more predictable and competitive environment for the pharmaceutical sector. The proposals are organized around four pillars: access to healthcare, innovation and development, institutional environment, and social responsibility and integrity. Among the priorities are strengthening legal certainty and regulatory impact assessments, consolidating clinical research as a national priority, approving Patent Term Adjustment (PTA), creating regulatory data protection for innovative medicines, reducing the National Institute of Industrial Property (INPI) patent backlog, and ensuring greater financial and technical autonomy for the Brazilian Health Regulatory Agency (Anvisa) and the National Supplementary Health Agency (ANS). Interfarma also calls for reducing Anvisa's registration backlog and shortening the time between the incorporation of technologies into the SUS and effective patient access. The association also proposes modernizing the National Committee for Health Technology Incorporation (Conitec), including greater use of real-world evidence and closer integration between health technology assessment, price negotiation and availability. It further calls for stronger action against counterfeit and illegal medicines. According to Interfarma, Brazil could reach the world's 10th position in clinical research, potentially generating R$2.1 billion annually in direct investment and benefits for 286,000 patients. Read more.

PHARMACEUTICAL SECTOR OPPOSES PROPOSED PATENT EXTENSIONS

Pharmaceutical industry groups are opposing a proposal in the House of Representatives that could extend drug patent terms by up to five years to compensate for delays at Brazil's National Institute of Industrial Property (INPI). Around 20 industry associations, including Grupo FarmaBrasil, Abifina and Alanac, argue that the measure could delay the entry of generics and biosimilars, reduce competition and increase medicine costs. The proposal, introduced by Representative Adriana Ventura (Novo-SP), has also raised concerns because it could conflict with a recent Supreme Court (STF) decision establishing fixed patent terms. Industry groups are calling for a broader assessment of the potential impact on competition, access to medicines and public spending before any changes to patent legislation are approved. Read more.

PHARMACEUTICAL INDUSTRY CALLS FOR GREATER REGULATORY COOPERATION TO EXPAND MARKET ACCESS

The National Confederation of Industry (CNI) and FarmaBrasil have launched the International Regulatory Cooperation Map for the Pharmaceutical Industry, a guide aimed at identifying priority markets and reducing regulatory barriers to Brazilian medicine exports. The initiative comes as Brazil faces a significant trade deficit in pharmaceuticals, having imported more than US$12 billion in products and exported less than US$1 billion in 2024. The document calls for greater international recognition of certificates and inspections conducted by the Brazilian Health Regulatory Agency (Anvisa), which could reduce duplicated inspections of Brazilian manufacturing facilities and lower the costs and time required to access foreign markets. The industry argues that stronger regulatory cooperation and reliance mechanisms could improve Brazil's competitiveness and expand the international presence of its pharmaceutical sector. Read more.

BRAZIL TARGETS 70% DOMESTIC PRODUCTION OF MEDICINES FOR SUS

Brazil aims to increase the share of medicines, active pharmaceutical ingredients (APIs) and vaccines produced domestically for the Unified Health System (SUS) from around 50% today to 70% by 2033, according to Vice President and Minister of Development, Industry, Foreign Trade and Services Geraldo Alckmin. The target is part of the government's industrial policy and seeks to reduce Brazil's dependence on imported health products. Alckmin said the health sector represents Brazil's second-largest trade deficit and highlighted efforts to strengthen domestic production following supply vulnerabilities exposed during the Covid-19 pandemic. The government's strategy also covers vaccines, medical devices and other health technologies, with investments and financing intended to expand the country's industrial and technological capacity. Read more.

SUS DRUG PRICE NEGOTIATION COMMITTEE EXPECTED TO BEGIN WORK IN 2026

Brazil's Ministry of Health expects the new Committee for Price Negotiation and Economic Conditions of Health Technologies to begin operating later this year. Created by a July ordinance, the permanent technical body will negotiate prices and commercial conditions for medicines and other health technologies being considered for incorporation into the Unified Health System (SUS), as well as products already purchased by the Ministry. The committee will be particularly relevant for high-cost technologies, products with a single supplier or limited competition, and cases in which prices increase significantly after incorporation. The National Committee for Health Technology Incorporation (Conitec) may refer technologies under evaluation to the committee, while the Ministry's technical areas can request negotiations for products already incorporated. According to Science, Technology and Innovation Secretary Fernanda de Negri, the government expects to leverage the SUS's purchasing power to secure significant discounts, potentially exceeding 50% for new or recently incorporated medicines. The initiative also creates a framework for confidential discounts and is intended to free resources for the incorporation of additional high-cost treatments. Read more.

AF-ONCO TO BEGIN ONCOLOGY DRUG SUPPLY IN OCTOBER

Brazil's Ministry of Health expects to begin supplying the first oncology medicines under the Oncology Pharmaceutical Assistance Component (AF-Onco) in October, with the rollout occurring gradually depending on manufacturers' production capacity. According to Nélio Cezar de Aquino, director of the Department of Pharmaceutical Assistance and Strategic Supplies (DAF), the Ministry is negotiating with manufacturers and expects some of the 23 medicines included in the program to reach patients in October, while the full implementation will depend on supply and production timelines. The AF-Onco implementation also includes Brazil's first national procurement negotiation for very high-cost oncology therapies aimed at relatively small patient populations. Cancer centers will identify eligible patients, with information consolidated by states and submitted to the Ministry of Health, which will negotiate the national volume. The strategy is intended to leverage aggregated demand to reduce prices and avoid separate negotiations by individual oncology centers. The Ministry is also implementing drug dilution centers to reduce waste and improve the use of multi-dose oncology medicines, alongside new information systems to monitor the policy's impact. Aquino said the government is also discussing broader changes to pharmaceutical assistance, including models for rare diseases and advanced therapies, although it is too early to determine whether a new component similar to AF-Onco will be created. Read more.

CONITEC OPENS CONSULTATIONS ON NEW ONCOLOGY TREATMENT PROTOCOLS

Brazil's National Committee for Health Technology Incorporation (Conitec) has opened public consultations on 12 Clinical Protocols and Therapeutic Guidelines (PCDTs) for cancer treatment within the Unified Health System (SUS). The protocols cover breast, prostate, thyroid, stomach, ovarian, kidney and skin cancers, as well as multiple myeloma, Hodgkin and follicular lymphomas, esophageal cancer and head and neck cancer. The updates are intended to align clinical guidelines with the latest scientific evidence and treatments and technologies

incorporated into the SUS following Conitec assessments. Contributions can be submitted until September 8, 2026, providing an opportunity for patients, healthcare professionals, industry and other stakeholders to contribute to the proposed guidelines. Read more.

BRAZIL CONSIDERS NEW FINANCING MODEL FOR SPECIALIZED HEALTHCARE

Brazil's Ministry of Health is discussing a major revision of how specialized and hospital care is financed through the Unified Health System (SUS), with the goal of moving away from a model based primarily on payment for individual procedures and successive financial incentives. A working group is studying alternatives that could provide greater predictability for hospitals and reduce recurring financial deficits. One proposal is to strengthen the ApuraSUS cost-management system, which collects data on healthcare providers' costs and production, and use it as a basis for a new model of hospital budgeting. Under the approach being considered, funding would consider the costs, complexity and characteristics of each facility rather than simply the volume of services delivered. The Ministry is also reviewing the policy for hospitals that provide 100% of their services to the SUS. Created in 2013, the program currently provides an additional 20% of the annual contracted amount for medium-complexity procedures to eligible nonprofit hospitals. The government believes the current incentives are outdated and is considering changes to encourage hospitals that currently dedicate 80% or 90% of their capacity to the public system to move toward exclusive SUS provision. Read more.

ANVISA OPENS CONSULTATION ON UPDATE TO BIOLOGICAL PRODUCTS REGULATION

The Brazilian Health Regulatory Agency (Anvisa) is seeking technical contributions to support the revision of RDC 55/2010, which establishes the rules for the registration of new biological products and other biological products. Contributions will be accepted until September 17. The review is being led by Anvisa's General Management of Biological Products, Radiopharmaceuticals, Blood, Tissues, Cells, Organs and Advanced Therapy Products (GGBIO) and aims to update the regulatory framework based on the Agency's regulatory experience since 2010, scientific and technological advances, and developments in national and international regulatory standards. Anvisa is inviting companies, industry associations, scientific organizations and other stakeholders to submit technical input. The contributions will help assess the feasibility of proposed requirements and anticipate potential regulatory impacts. The initiative is a preliminary stage to gather technical evidence and does not replace the formal regulatory procedures required for the revision of the regulation. Read more.

ANVISA PREPARES NEW MODEL TO ACCELERATE CLINICAL TRIALS

The Brazilian Health Regulatory Agency (Anvisa) is preparing a new scientific advisory program to support and accelerate clinical research in Brazil. The initiative will provide early regulatory guidance to innovative clinical research projects, allowing developers to engage with the Agency's technical teams during the development process and before formal submissions. The public call is expected to be published in the coming months. According to Anvisa Director Daniela Marreco, the model is intended to allow the Agency to assess projects and discuss regulatory requirements with sponsors in advance, potentially shortening approval timelines. Early engagement could also accelerate registration and post-registration procedures, as Anvisa's technical teams would already be familiar with the development process and evidence generated. The initiative is inspired by the European Medicines Agency's (EMA) PRIME program, which provides early and enhanced support for the development of medicines addressing unmet medical needs. Anvisa's move comes alongside recent changes to Brazil's clinical research framework, including the implementation of continuous submission procedures for clinical trial documentation under RDC 945/2024. Read more.

INAEP EXPANDS NATIONAL RESEARCH ETHICS COMMITTEE

Brazil's National Research Ethics Authority (Inaep), linked to the Ministry of Health, has completed the formation of its new 30-member scientific committee, with 15 full members and 15 alternates representing all regions of the country. The body, established in 2024 under the

National System of Ethics in Research with Human Beings (Sinep), is responsible for defining and guiding ethical standards for research involving human subjects. The new composition seeks to strengthen regional, academic and professional diversity in research ethics. The Ministry of Health said that more than 59,000 studies involving human beings were approved between November 2025 and July 2026, while Brazil currently has 915 accredited Research Ethics Committees. Read more.

ANVISA AND PARAGUAY STRENGTHEN COOPERATION AGAINST ILLEGAL PRODUCTS

The Brazilian Health Regulatory Agency (Anvisa) and Paraguay's National Directorate of Health Surveillance (Dinavisa) have signed a five-year cooperation agreement to strengthen the exchange of regulatory information and joint action against counterfeit, smuggled and irregular products. The agreement covers medicines, pharmaceutical ingredients, biological products, medical devices, cosmetics, food and tobacco products, and includes information sharing on laboratory testing, inspections, manufacturing practices, clinical trials, sanitary alerts and seizures. The agreement comes amid increased circulation in Brazil of medicines from Paraguay without Anvisa authorization, including products marketed as tirzepatide alternatives. Anvisa President Leandro Safatle emphasized that the partnership does not create an exception for Paraguayan medicines: products must still meet Brazilian regulatory requirements and respect patent protections. The agreement also introduces regulatory reliance mechanisms, allowing one authority to consider technical assessments conducted by the other and potentially streamline regulatory processes. Read more.

PARAGUAYAN MANUFACTURER PLANS ANVISA REGISTRATION FOR TIRZEPATIDE

Paraguayan pharmaceutical company Lasca, manufacturer of Gluconex, a tirzepatide-based weight-loss medicine, is preparing to seek sanitary registration from the Brazilian Health Regulatory Agency (Anvisa). The company is evaluating whether to wait for Eli Lilly's patent on tirzepatide in Brazil to expire in 2036 or pursue a compulsory license. Anvisa said it has not yet received an application and that its sanitary assessment is independent of patent issues. Gluconex is currently not authorized for sale in Brazil and has been subject to restrictions by Anvisa. The product has gained attention because of its lower price in Paraguay, contributing to irregular imports into Brazil. The development could open a new regulatory and intellectual property debate over access to tirzepatide in the Brazilian market. Read more.

ANVISA APPROVES TWO NEW SEMAGLUTIDE PENS FOR DIABETES

The Brazilian Health Regulatory Agency (Anvisa) has approved two new injectable GLP-1 medicines containing synthetic semaglutide for the treatment of adults with inadequately controlled type 2 diabetes. The products were registered by EMS, as a generic medicine without a brand name, and Germed, which will market the similar product as Semaclique. Both are interchangeable with the reference medicine Ozivy. The weekly injectable pens may be used alone when metformin is inappropriate or alongside other diabetes medicines. The approvals expand the number of semaglutide options available in Brazil, while GLP-1 medicines remain subject to a two-copy prescription requirement. Read more.

OBESITY EXPERT CALLS FOR TALKS TO LOWER PRICES OF WEIGHT-LOSS DRUGS

Bruno Halpern, president of the World Obesity Federation, says Brazil needs an urgent dialogue among the pharmaceutical industry, Ministry of Health, Anvisa and the National Committee for Health Technology Incorporation (Conitec) to expand access to GLP-1 weight-loss medicines. He argues that negotiations with manufacturers should explore ways to reduce prices, particularly as demand grows and obesity treatment remains largely inaccessible through the Unified Health System (SUS). Halpern also warns that expanding access to medicines alone will not be enough, stressing the need for trained physicians, long-term patient monitoring and nutritional and psychological support. He opposes the use of unregistered products imported from Paraguay, arguing that Brazil should pursue regulated alternatives and broader public policies for obesity treatment. Read more.

EUROFARMA CUTS PRICES OF SEMAGLUTIDE PENS BY UP TO 39%

Eurofarma has reduced the prices of its Poviztra semaglutide pens by up to 39% for the 1.7 mg and 2.4 mg presentations, which now cost R$829 and R$1,169, respectively, under the company's EuroCuida patient support program. The reductions are aimed at facilitating treatment continuity for patients with obesity and overweight associated with comorbidities. The move comes amid growing competition in Brazil following the expiration of semaglutide's patent in March 2026. Anvisa has already approved five new semaglutide pens and the country's first generic version, with additional approvals expected by the end of the year. The increased competition is also occurring alongside growing demand for lower-cost, unauthorized versions imported from Paraguay. Read more.

ANVISA BEGINS REGULATION OF MEDICATION SALES THROUGH DIGITAL PLATFORMS

The Brazilian Health Regulatory Agency (Anvisa) has unanimously approved the opening of an administrative process to regulate the use of digital channels and e-commerce platforms by pharmacies and drugstores for the logistics and delivery of medicines. The initiative follows the enactment of Law No. 15,357/2026, which authorized licensed pharmacies and drugstores to contract digital platforms for medication delivery. The regulatory process comes shortly after Anvisa revoked restrictions that had prevented platforms such as iFood, Rappi, Mercado Livre, Americanas and Shopee from advertising and commercializing medicines. Until new rules are established, remote sales remain subject to RDC 44/2009, including restrictions on the online sale of controlled medicines and requirements related to the identification of the responsible pharmacy, access to a pharmacist and adequate transportation and storage conditions. Anvisa Director Daniel Pereira said the new framework could expand access and improve convenience and efficiency, while highlighting the sanitary risks associated with the digital commercialization of medicines. Agency President Leandro Safatle emphasized that pharmacies must continue to be treated as healthcare establishments rather than conventional retailers, making it necessary to clearly define the responsibilities of pharmacies and digital platforms. The Agency plans to hold a public consultation, although there is no deadline for the publication of the final regulation. Read more.

CONSUMERS IDENTIFY COUNTERFEITING AS MAIN RISK IN ONLINE MEDICINE PURCHASES

A survey by Instituto QualiBest, commissioned by the Brazilian Association of Pharmacy Networks (Abrafarma), found that 69% of consumers consider counterfeit medicines the main risk when purchasing medicines online. Concerns also include expired products (59%) and medicines without registration with the Brazilian Health Regulatory Agency (Anvisa) (54%). The findings come as Anvisa moves to regulate medicine sales through apps and marketplaces. Some 85% of respondents believe digital platforms should be held responsible for counterfeit or irregular medicines, while 82% support restricting online sales to authorized pharmacies. Read more.

STF SCHEDULES NEW HEARING ON ANVISA ADVERTISING RULES

Supreme Court (STF) Justice Cristiano Zanin has scheduled a new conciliation hearing for December 1 to discuss Anvisa rules governing the advertising of medicines and food products. The case, ADI 7788, challenges RDC 96/2008 and RDC 24/2010, which establish requirements and restrictions for the promotion of medicines and certain foods. The hearing will continue negotiations among the parties over the scope and legal basis of Anvisa's regulatory powers. The dispute involves the balance between the Agency's authority to establish sanitary requirements, commercial communication and public health protection. Read more.

ANS PRESIDENT ADVOCATES PERSON-CENTERED CARE AND VALUE-BASED HEALTHCARE

National Supplementary Health Agency (ANS) President Wadih Damous defended the transition toward person-centered care and value-based healthcare models during the V Health Forum,

held in Brasília. Speaking to representatives from government, industry and academia, Damous argued that the sustainability of Brazil's private health insurance sector should be linked not only to financial balance but also to timely access, quality of care and better health outcomes for patients. According to the ANS president, the agency's 2026–2028 Regulatory Agenda prioritizes placing patients at the center of healthcare delivery, encouraging a shift away from a system primarily focused on procedures toward one based on care coordination, primary care, prevention and measurable clinical outcomes. Damous also highlighted the agency's efforts to promote value-based payment models, in which reimbursement is linked to health outcomes, quality indicators and patient experience rather than the volume of services provided. The discussion also addressed the role of innovation in healthcare transformation. Damous pointed to the potential of artificial intelligence, telehealth and data interoperability tools to improve care delivery, while emphasizing the importance of transparency, patient safety, data protection and evidence-based regulation. Read more.

BRAZIL RAISES FUNDING FOR PHILANTHROPIC HOSPITALS

Brazil's Ministry of Health will increase by 40% the federal resources allocated to Santa Casas and philanthropic hospitals, bringing the sector's annual budget to R$1.4 billion. The measure, announced by Health Minister Alexandre Padilha during the 34th National Congress of Santa Casas and Philanthropic Hospitals in Brasília, responds to a longstanding demand from the sector and aims to expand access to consultations, surgeries and diagnostic procedures through the Unified Health System (SUS). The institutions play a significant role in specialized care within the public health system. According to Ministry of Health data, Santa Casas and philanthropic hospitals performed more than 5 million elective surgeries through the SUS in 2025, a 52% increase compared with 2022, while accounting for 60% of high-complexity oncology services in the public network. The additional funding is also aligned with the government's efforts to reduce waiting lists for specialized procedures, a key objective of the Agora Tem Especialistas program. Read more.

STJ RESTORES RESTRICTIONS ON LOW-PERFORMING MEDICAL SCHOOLS

Brazil's Superior Court of Justice (STJ) has suspended a lower court injunction and restored measures imposed by the Ministry of Education (MEC) on 107 higher education institutions with poor results in the 2025 National Medical Education Assessment (Enamed). The measures include suspending new Fies and Prouni places, reducing authorized vacancies and restricting new admissions and entrance exams. The decision reinforces the MEC's authority to supervise medical education and comes amid the government's efforts to use the Enamed as a tool to assess both student proficiency and the quality of medical programs. The ministry said the measures aim to improve training standards and ensure the quality of future physicians. Read more.

ANA ESTELA HADDAD LEAVES DIGITAL HEALTH SECRETARIAT

Ana Estela Haddad has left the position of Secretary of Information and Digital Health (SEIDIGI) at Brazil's Ministry of Health to join President Luiz Inácio Lula da Silva's reelection campaign in São Paulo. She had led the Secretariat since its creation in 2023, overseeing initiatives including the Meu SUS Digital, the National Health Data Network (RNDS) and the expansion of telehealth. Maria Aparecida Cina da Silva, previously SEIDIGI's deputy secretary, has taken over the position. The change comes as the Ministry advances the National Information and Digital Health Policy and plans further expansion of the RNDS and the use of artificial intelligence in healthcare. Read more.

DATA AND INFRASTRUCTURE GAPS HINDER AI EXPANSION IN HEALTHCARE

Healthcare organizations face significant barriers to scaling artificial intelligence (AI), particularly gaps in data access, governance and infrastructure performance, according to the Data Readiness Index 2026, a survey by data and AI platform Cloudera. While 87% of healthcare professionals surveyed say they know where their data is located, many organizations still struggle to integrate, govern and operationalize reliable data at scale. The

survey found that 28% of healthcare organizations report infrastructure performance as a consistent obstacle to operational initiatives. The growing use of clinical, operational and patient-generated data is increasing the need for systems capable of applying AI across distributed environments while maintaining security, governance and regulatory compliance. Read more.

MORE HIGHLIGHTS

Senate Debate Highlights Gaps in Rare Lung Disease Care

Brazilian Women Recognize Breast Cancer Recurrence Risk but Lack Awareness

Hepatitis D and E Remain Underdiagnosed in Brazil

Tafenoquine Contributes to Decline in Malaria Cases in Brazil

Brazil to Build World's First Tilapia Skin Factory for Burn Treatment

BRAZIL NEWS

Lula retains lead over Flavio Bolsonaro ahead of Brazil election, Datafolha shows

Brazil's Bolsonaro campaign adds Sachsida, market figures to policy team

Amazon oil find gives Brazil's Lula reelection campaign a boost, but returns are far from certain

Brazil to keep fiscal framework, spending restraint under new Lula term, minister says

Trump told Lula that officials should meet soon to discuss tariffs, Brazil says

Brazil launches AI supercomputer push, splits projects between Chinese, US firms