

# WEEKLY REPORT



**05/16/2026**

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## **BRAZIL HEARING EXPOSES DIVISIONS OVER PHARMACEUTICAL PRICING RULES**

A public hearing held by the Health Committee of the House of Representatives highlighted divisions between pharmaceutical companies, consumer advocates and government officials over Brazil's drug pricing framework and upcoming regulatory changes at the Drug Market Regulation Chamber (CMED). One of the main topics discussed during the hearing was CMED Resolution No. 3/2025, whose implementation was postponed following concerns raised by the pharmaceutical industry. Civil society representatives criticized the current pricing model, arguing that CMED-authorized price caps remain above real market prices and may affect access to drugs. Consumer advocates also questioned drugstore discount programs linked to taxpayer identification numbers under Brazil's General Data Protection Law (LGPD). Meanwhile, Interfarma defended the current framework, stating that Brazil already applies one of the world's lowest international reference price systems and that taxes can account for up to 45% of medicine prices. The association also warned that the new resolution could affect regulatory predictability, innovation, and the entry of new therapies into the Brazilian market. CMED representatives said the new regulation seeks to balance affordability, innovation, and sustainability, including expanding the number of reference countries used in price-setting from nine to 14 and creating mechanisms for extraordinary price revisions. [Read more.](#)

## **FORMER HEALTH MINISTRY SECRETARY CALLS FOR BROADER DEBATE ON UNIFIED HTA AGENCY IN BRAZIL**

The creation of a unified national agency for health technology assessment and incorporation decisions requires broader debate, according to an interview with former secretary in the Ministry of Health, Denizar Vianna, published by Futuro da Saúde. The proposal would centralize evaluations currently divided between the Unified Health System (SUS), through Conitec, and the supplementary healthcare sector, potentially creating a single framework for assessing medicines, devices, and innovative therapies across public and private healthcare systems. According to Denizar Vianna, a unified model could reduce duplication of analyses, improve regulatory predictability, and accelerate patient access to new technologies. Supporters of the idea argue that greater coordination between public and private sectors could strengthen evidence-based decision-making and increase efficiency in healthcare spending. However, the debate also raises concerns over governance, funding structures and the balance between cost-effectiveness criteria and access to innovation in Brazil's highly fragmented healthcare system. [Read more.](#)

## **BRAZIL COURT DENIES ACCESS TO RARE DISEASE DRUG OUTSIDE APPROVED AGE RANGE**

A court in the state of São Paulo denied a request for the public provision of the high-cost drug Elevidys (delandistrogene moxeparvovec) for a child with Duchenne muscular dystrophy whose age falls outside the range approved in the medicine's regulatory authorization. The decision reinforced the understanding that treatments authorized by the Brazilian Health Regulatory Agency – Anvisa and incorporated into Brazil's public healthcare system must follow technical and scientific criteria established in regulatory approvals and clinical protocols. According to the ruling, the absence of evidence demonstrating safety and efficacy for patients outside the approved age group weighed against granting the request. The case reignites debate in Brazil

over judicialization of healthcare and access to high-cost therapies, particularly for rare diseases and pediatric patients. Specialists argue that courts increasingly face complex decisions involving off-label treatments, budgetary constraints, and regulatory standards, while patient groups continue to advocate for broader access in situations where therapeutic alternatives are limited. [Read more.](#)

### **BRAZIL EXPANDS STRATEGY TO STRENGTHEN CLINICAL RESEARCH CENTERS AND ATTRACT COMPLEX TRIALS**

Brazil's Ministry of Health is advancing a strategy to strengthen the country's clinical research infrastructure through the National Clinical Research Program (PPClin), aiming to qualify research centers, decentralize studies and expand the country's ability to conduct more complex clinical trials, including phase 1 studies. According to officials interviewed by Futuro da Saúde, the initiative seeks to map the technical capacity and infrastructure of Brazilian research centers to create qualification criteria and improve visibility for international and multicenter studies. The program is part of broader government efforts to position Brazil as a strategic global hub for health research and innovation. The program includes investments in research infrastructure, regulatory modernization, digital systems and professional training, alongside closer coordination between the Ministry of Health, the Brazilian Health Regulatory Agency (Anvisa) and university hospitals. The federal government has already announced R\$ 120 million in initial funding for the initiative, which also aims to reduce regional inequalities in access to clinical research and innovative therapies. Industry representatives and specialists argue that the initiative could improve regulatory predictability and attract more pharmaceutical investment to Brazil, although challenges remain regarding governance, workforce qualification, and long-term execution capacity. [Read more.](#)

### **BRAZIL EXPANDS ETHICS COMMITTEE NETWORK FOR HIGH-RISK CLINICAL RESEARCH**

Brazil's Ministry of Health published a new resolution aimed at expanding the network of Research Ethics Committees (CEPs) authorized to review high-risk clinical studies involving human subjects. The measure seeks to increase the capacity and agility of Brazil's ethical review system amid growing demand for authorization of complex clinical trials, particularly in areas such as advanced therapies, oncology, and rare diseases. According to the ministry, the initiative is part of broader efforts to modernize the national clinical research environment and strengthen Brazil's position in global pharmaceutical development. The resolution establishes criteria for accreditation and operation of committees qualified to evaluate studies classified as high risk, including projects involving innovative technologies and greater ethical complexity. Health authorities argue that expanding the number of specialized ethics committees may help reduce bottlenecks in the approval process while maintaining participant safety and regulatory oversight. The debate over clinical research governance has intensified in Brazil as the country seeks to attract more international studies and accelerate access to innovative therapies. [Read more.](#)

### **BRAZIL ANNOUNCES ONCOLOGY TREATMENT EXPANSION IN SUS**

President Luiz Inácio Lula da Silva announced a R\$ 2.2 billion package to expand access to cancer treatment through Brazil's Unified Health System (SUS), described by the federal government as the largest oncology treatment expansion ever implemented in the public healthcare network. The announcement was made during an event at the Hospital de Amor and includes the incorporation and financing of 23 high-cost oncology medicines covering 18 different types of cancer, including breast, lung, ovarian and leukemia treatments. According to the Ministry of Health, the initiative is expected to benefit approximately 112,000 patients and unlock therapies that had already been incorporated into SUS but remained pending implementation for up to 12 years. The package also includes permanent financing for robotic surgery in prostate cancer treatment, expansion of breast reconstruction procedures and investments in radiotherapy infrastructure. Federal officials said the measure aims to guarantee full public-sector demand for oncology medicines while strengthening Brazil's clinical research

and high-complexity treatment capacity. Specialists note that the initiative reflects increasing political and financial pressure to expand access to innovative cancer therapies within SUS amid rising oncology demand and growing incorporation costs. [Read more.](#)

### **BRAZIL'S PUBLIC HEALTH SYSTEM TO OFFER GENETIC TEST FOR HEREDITARY BREAST CANCER MUTATIONS**

Brazil's Unified Health System (SUS) will begin offering genetic testing for breast cancer patients to identify hereditary mutations in the BRCA1 and BRCA2 genes, following the incorporation of the technology by the Ministry of Health. The measure was published in the Official Gazette and establishes that the public health system must make the test available within 180 days. The exam uses next-generation sequencing (NGS) technology and is expected to help guide treatment decisions, identify patients eligible for targeted therapies such as PARP inhibitors and improve prevention strategies for families at increased genetic risk. Specialists said the decision represents an important step toward expanding precision medicine in Brazil's public healthcare system, as genetic testing for hereditary cancer risk remains concentrated in the private sector and can cost thousands of reais. Experts also noted that broader implementation may still face structural challenges, including limited availability of genetic counseling services and specialized professionals within SUS. According to the National Cancer Institute (INCA), breast cancer remains one of the most common cancers among Brazilian women, with approximately 70,000 new cases diagnosed annually. [Read more.](#)

### **BRAZIL'S INCORPORATION OF GENETIC BREAST CANCER TESTING INTO SUS HIGHLIGHTS IMPLEMENTATION CHALLENGES**

The incorporation of genetic testing for BRCA1 and BRCA2 mutations into Brazil's Unified Health System (SUS) represents an important step toward expanding precision medicine and hereditary cancer prevention in the country, according to experts interviewed by Futuro da Saúde. The Ministry of Health recently approved the use of next-generation sequencing (NGS) testing for women diagnosed with breast cancer, with implementation expected within 180 days. Specialists say the measure may improve access to targeted therapies, preventive strategies, and earlier identification of high-risk families. Experts, however, warn that the success of the initiative will depend on the creation of structured care pathways within SUS, including expansion of genetic counseling services, professional training and integration between oncology and primary care networks. According to the report, specialists also stress the need for broader public policies to support long-term follow-up and preventive care for patients and relatives identified as carriers of hereditary cancer mutations. [Read more.](#)

### **CONITEC RECOMMENDS INCORPORATION OF MULTIPLE MYELOMA THERAPY INTO BRAZIL'S PUBLIC HEALTH SYSTEM**

Brazil's National Committee for Health Technology Incorporation (Conitec) recommended the incorporation of a new treatment for multiple myeloma into the Unified Health System (SUS), according to JOTA. The decision represents another step in expanding access to innovative oncology therapies within Brazil's public healthcare system and follows Conitec's evaluation of clinical evidence, cost-effectiveness, and budget impact. The recommendation will now move forward in the formal incorporation process coordinated by the Ministry of Health. The incorporation debate highlights increasing pressure on SUS to expand access to high-cost cancer therapies amid growing demand for precision medicine and hematologic oncology treatments. Specialists say the decision may improve therapeutic options for patients with relapsed or refractory multiple myeloma, although implementation challenges remain related to funding, treatment infrastructure, and regional access disparities across the public healthcare network. [Read more.](#)

### **BRAZIL'S OTC MEDICINES LOSE MARKET SHARE AMID CHANGING CONSUMER BEHAVIOR**

Sales growth of over-the-counter medicines (OTC) in Brazil has slowed relative to the broader pharmaceutical retail market, according to data from Close-Up International highlighted by

Panorama Farmacêutico. OTC products accounted for 13.9% of total pharmacy revenue in the 12 months through February 2026, the lowest share since 2022, despite continued nominal growth in sales. Analysts attribute the slowdown to changing consumer behavior, warmer winters that reduced demand for cold and flu treatments, limited product innovation, and lower investment in in-store activation by pharmaceutical companies. Industry specialists also pointed to the growing popularity of GLP-1 drugs as a potential factor affecting demand for some OTC categories, particularly digestive health products. Experts interviewed by the publication argued that pharmacies may need to revise pricing strategies, strengthen pharmacist engagement with consumers and focus on higher value-added products to sustain profitability in the category. [Read more.](#)

### **ANVISA INTENSIFIES CRACKDOWN ON ILLEGAL WEIGHT-LOSS PENS FROM PARAGUAY**

The Brazilian Health Surveillance Agency (Anvisa) has intensified enforcement actions against illegal weight-loss injectable drugs entering Brazil from Paraguay, amid growing concerns over counterfeit and unauthorized GLP-1 products. According to Folha de S.Paulo, the agency recently prohibited the commercialization and importation of another tirzepatide-based brand that was preparing to enter the Brazilian market without regulatory approval. Anvisa has repeatedly warned that no weight-loss injectables imported from Paraguay are currently authorized for sale in Brazil. The crackdown comes amid booming demand for obesity treatments such as tirzepatide and semaglutide, which has fueled parallel markets, social media advertising, and irregular imports. Regulators and specialists warn that unauthorized products may pose serious health risks due to uncertain origin, inadequate storage conditions, and lack of quality control. Anvisa has also expanded discussions on tighter oversight of compounded GLP-1 medicines and imported active pharmaceutical ingredients as part of broader efforts to strengthen regulatory control over the fast-growing obesity drug market. [Read more.](#)

### **WEIGHT-LOSS INJECTABLE BOOM RESHAPES BRAZIL'S FOOD AND CONSUMER MARKETS**

Sales of weight-loss injectable drugs in Brazil grew 88% over the past year, intensifying the impact of GLP-1 medicines on the country's food and consumer goods sectors, according to data highlighted by SEGS. The rapid expansion of obesity treatments such as semaglutide and tirzepatide has begun to alter eating habits, reduce consumption of high-calorie products and reshape demand patterns across segments including snacks, soft drinks, and processed foods. Analysts say the trend mirrors changes already observed in the United States and Europe as GLP-1 therapies become more widely used. Industry experts believe the growing adoption of obesity drugs may create long-term pressure on food manufacturers, restaurants, and beverage companies, while opening opportunities for healthier product portfolios and personalized nutrition strategies. The phenomenon has also increased attention from pharmaceutical companies, retailers, and investors, amid expectations that the obesity treatment market will continue expanding rapidly in Brazil despite high prices and regulatory debates surrounding access and distribution. [Read more.](#)

### **COLLECTIVE HEALTH PLANS IN BRAZIL POST AVERAGE 9.9% PREMIUM INCREASE, ANS DATA SHOW**

Collective health insurance plans in Brazil recorded an average premium increase of 9.9% over the past 12 months, according to data from the National Supplementary Health Agency – ANS highlighted by O Globo. The adjustment reflects continued financial pressure on the supplementary healthcare sector driven by higher healthcare utilization, incorporation of new medical technologies and rising hospital and service costs. Collective plans account for the majority of private health insurance contracts in Brazil and, unlike individual plans, are not subject to a predefined annual adjustment ceiling established by ANS. Consumer advocates continue to criticize the sector's pricing dynamics, arguing that repeated increases have made private health insurance less affordable for families and small businesses. Health insurers, however, maintain that premium adjustments are necessary to preserve the economic

sustainability of the system amid rising medical inflation and demographic changes, including population aging and increased demand for healthcare services. [Read more.](#)

### **BRAZIL EXPANDS ICU CAPACITY, BUT ACCESS REMAINS FAR HIGHER IN PRIVATE HEALTHCARE THAN IN SUS**

Brazil has significantly expanded its intensive care unit (ICU) capacity in recent years, but access to beds in the private healthcare system remains higher than in the Unified Health System (SUS), according to a report by Folha de S.Paulo. Data analyzed by the newspaper indicate that patients covered by private health insurance are approximately five times more likely to secure an ICU bed compared with users who depend exclusively on the public healthcare network. Specialists attribute the disparity to regional inequalities, chronic underfunding, and differences in infrastructure distribution between public and private sectors. Health policy experts warn that the imbalance highlights persistent structural inequalities in Brazil's healthcare system despite investments made during and after the Covid-19 pandemic. Researchers argue that unequal ICU access continues to affect outcomes for severe cases, particularly in poorer regions and municipalities with limited hospital infrastructure. The debate also reinforces broader discussions on healthcare financing, hospital capacity planning, and the long-term sustainability of critical care services within SUS. [Read more.](#)

### **ANS RESUMES DEBATE ON COPAYMENT LIMITS IN HEALTH PLANS**

Brazil's National Supplementary Health Agency (ANS) has resumed discussions on regulating copayment and deductible mechanisms in private health insurance plans, eight years after a previous rule allowing copayments of up to 40% was revoked following criticism from consumer groups and a suspension by the Supreme Federal Court (STF). The agency says the goal is to establish clearer parameters to prevent abusive charges and define limits for the use of copayment models in the supplementary health sector. According to ANS, approximately 96% of health insurers in Brazil currently adopt some form of copayment arrangement. Consumer protection entities argue that excessively high copayment rates may discourage access to healthcare and create financial barriers for patients, especially in high-complexity treatments. Preliminary discussions within the agency include caps around 30% per procedure and annual spending limits linked to monthly premiums, with exemptions for oncology treatment, chronic therapies, and preventive exams. Health insurers, however, defend copayment as a mechanism to reduce unnecessary healthcare utilization and contain rising medical costs amid growing financial pressure on the supplementary healthcare sector. [Read more.](#)

### **OLDER ADULTS EXPECTED TO ACCOUNT FOR HALF OF BRAZIL'S HEALTHCARE SPENDING BY 2044**

People over the age of 50 are expected to represent approximately half of all healthcare consumption in Brazil by 2044, according to projections highlighted by Agência Brasil. The estimates reflect Brazil's accelerated demographic transition and population aging, which are expected to significantly increase demand for healthcare services, medicines, long-term care, and chronic disease management over the coming decades. Specialists warn that the trend will place growing pressure on both the Unified Health System (SUS) and the private healthcare sector. Experts interviewed by the agency said the aging population will require broader investments in prevention, primary care, digital health, and integrated care models focused on chronic conditions such as cancer, cardiovascular diseases, and neurodegenerative disorders. The projections also reinforce debates over healthcare financing, workforce shortages, and the sustainability of Brazil's health systems amid rising longevity and changing epidemiological patterns. [Read more.](#)

### **BRAZIL FACES GROWING PRESSURE TO INCREASE OVERSIGHT OF HEALTHCARE BUDGET AMENDMENTS**

Brazil's Supreme Federal Court (STF) and the Ministry of Health are intensifying efforts to strengthen oversight and traceability of congressional budget amendments allocated to healthcare, amid concerns over transparency, planning and efficiency in the use of public

resources within the Unified Health System (SUS). According to experts interviewed by Futuro da Saúde, the growing dependence of municipalities on politically allocated funds has increased pressure for stricter technical criteria and monitoring mechanisms. Congressional budget amendments directed to healthcare reached R\$ 21.4 billion in 2026 and now represent a significant share of discretionary spending within the Ministry of Health. Specialists argue that although recent judicial decisions and new federal rules represent progress, current controls remain insufficient given the scale of the resources involved. The debate also includes concerns about regional inequalities, fragmentation of healthcare planning and the growing role of congressional budget amendments in financing essential healthcare services. [Read more.](#)

## **BRAZIL ADVANCES INTEROPERABILITY AGENDA FOR NATIONAL DIGITAL HEALTH SYSTEM**

Brazil is accelerating efforts to expand interoperability across its healthcare system as part of a broader national digital health strategy, according to an interview with Ana Estela Haddad, Secretary of Information and Digital Health at the Ministry of Health, published by Futuro da Saúde. The initiative seeks to integrate clinical, administrative, and epidemiological data across public and private healthcare networks, enabling greater continuity of care, expansion of digital services and improved management of healthcare information within the Unified Health System (SUS). According to Haddad, interoperability is considered a strategic pillar for strengthening Brazil's digital health infrastructure and supporting initiatives such as the National Health Data Network (RNDS), telehealth services, and electronic health records integration. Specialists say broader connectivity between healthcare databases may improve efficiency, reduce duplication of exams and support population health management, although challenges remain related to cybersecurity, governance standards, infrastructure disparities, and data protection compliance under Brazil's General Data Protection Law (LGPD). [Read more.](#)

## **AI ADOPTION EXPANDS ACROSS BRAZIL'S HEALTHCARE SECTOR, SURVEY SHOWS**

Nearly 20% of healthcare facilities in Brazil already use artificial intelligence tools in clinical or administrative activities, according to a new survey highlighted by O Globo. The study indicates that AI adoption has accelerated in hospitals, clinics, and diagnostic centers, particularly in areas such as imaging analysis, clinical decision support, patient triage, and operational management. Specialists interviewed by the newspaper said the technology has the potential to improve efficiency, reduce diagnostic errors and optimize resource allocation across both public and private healthcare systems. Despite growing adoption, experts also warned about challenges involving regulation, data protection, professional training, and ethical oversight. According to the report, healthcare institutions remain cautious about fully replacing human decision-making processes, particularly in high-risk clinical settings. [Read more.](#)

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