

# WEEKLY REPORT



**03/21/2026**

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## **BRAZIL'S CMED DEBATES NEW PRICING MODELS FOR ADVANCED THERAPIES**

The Drug Market Regulation Chamber (CMED) is advancing discussions on new pricing methodologies for advanced therapies, as current regulations fail to adequately address these high-cost and complex treatments. During a recent workshop, regulators highlighted that such products are currently treated as “omitted cases,” leading to slower, less transparent decisions and increased regulatory uncertainty. Authorities signal a shift away from traditional external reference pricing, which is seen as insufficient for these therapies, and are evaluating alternative models such as value-based pricing, performance-based payments, installment schemes, and risk-sharing agreements. A specific resolution is under development and expected to go to public consultation in the coming months, aiming to improve predictability while balancing innovation, access, and system sustainability. [Read more.](#)

## **CMED FINES DRUG DISTRIBUTORS AND DEFENDS STRICTER REGULATION**

The Drug Market Regulation Chamber (CMED) imposes more than BRL 13.5 million in fines on pharmaceutical distributors for offering medicines above regulated price ceilings, reinforcing its stance on stricter market oversight. Sanctioned companies include Imediata Distribuidora de Produtos para a Saúde, Fabmed Distribuidora Hospitalar, Panorama Comércio de Produtos Médicos e Farmacêuticos, and Realmed Distribuidora, all penalized for exceeding the Price Factory (PF) and Maximum Price to Government (PMVG) limits. Regulators argue that pricing violations constitute abusive practices regardless of procurement outcomes and must be rigorously addressed to ensure fair access to medicines. The cases are part of a broader set of 54 administrative proceedings reviewed by CMED, highlighting ongoing tensions between regulatory enforcement and market dynamics in Brazil’s pharmaceutical sector. [Read more.](#)

## **BRAZIL'S HEALTH SECTOR RAISES CONCERNS OVER SINGLE HTA AGENCY BILL**

Nineteen healthcare and pharmaceutical industry associations issue a joint manifesto opposing the fast-track processing of Bill 4,741/2024, which proposes the creation of a single Health Technology Assessment (HTA) agency in Brazil. The proposal, authored by Congressman Dr. Luizinho, seeks to expand the role of the National Supplementary Health Agency (ANS) to centralize decisions on the incorporation, exclusion, and revision of health technologies across the system. Stakeholders warn that the initiative may create regulatory overlaps, increase bureaucracy, and generate legal uncertainty by redistributing responsibilities currently held by established bodies such as the National Commission for Health Technology Incorporation (CONITEC). They also caution that merging HTA processes between the public and private sectors—currently structured differently—could affect access to innovation and disrupt the balance between sustainability and coverage, calling for broader technical debate before advancing the bill. [Read more.](#)

## **BRAZIL'S GOVERNMENT APPEALS RULING LIMITING BUDGET FREEZES FOR REGULATORY AGENCIES**

The federal government appeals a decision by the Federal Court of Accounts (TCU) that restricts the ability to freeze (contingency) budget resources allocated to regulatory agencies, arguing that the measure undermines fiscal management and reduces flexibility in meeting budget targets. The appeal, led by the Ministry of Planning and the Presidential Chief of Staff’s Office, seeks to reverse a ruling that could limit the Executive’s discretion in allocating resources under

fiscal constraints. Government officials argue that budget requests from agencies often exceed available resources and must be balanced against broader fiscal priorities, emphasizing that contingency mechanisms are essential to comply with fiscal rules and manage trade-offs across public policies. Analysts warn that the TCU's position could set a precedent affecting other government bodies, while the case now returns for further technical review before a final decision by the court. [Read more.](#)

### **BRAZIL'S ANVISA DETAILS CHALLENGES FOR AI IMPLEMENTATION**

The National Health Surveillance Agency (ANVISA) is advancing the adoption of artificial intelligence but faces structural and regulatory barriers, including restrictions on the use of international commercial systems that store sensitive data abroad and the need for stronger coordination across public sector institutions. The agency is testing platforms and chatbots to support regulatory decision-making and sanitary monitoring, while also investing in internal capacity building, having trained over 100 specialists in data science and AI since 2023. ANVISA's implementation roadmap includes five pillars, such as developing data-driven platforms, improving interoperability with national health databases, and enhancing analytical maturity to support evidence-based regulation. [Read more.](#)

### **ANVISA EXPANDS BACKLOG REDUCTION PROJECT FOR BIOLOGICS**

The National Health Surveillance Agency (ANVISA) expands its backlog reduction initiative for biologic products to include post-registration petitions related to safety and efficacy, broadening the scope of its optimized review framework. The measure builds on recent regulatory changes aimed at accelerating technical assessments while maintaining quality and safety standards. The initiative introduces a dedicated optimized review queue and applies criteria established under Collegiate Board Resolution (RDC) 997/2025 and Normative Instruction 289/2024, including the grouping of similar dossiers and enhanced interaction with companies to streamline evaluations. ANVISA states that the expansion improves transparency, predictability, and efficiency in regulatory processes, reinforcing efforts to reduce backlogs and speed up access to biologic therapies in Brazil. [Read more.](#)

### **ANVISA UPDATES STATUS OF SEMAGLUTIDE REGISTRATION REQUESTS**

The National Health Surveillance Agency (ANVISA) reports that it has received at least 14 registration requests for medicines containing semaglutide, reflecting strong industry interest following the expiration of the molecule's patent in March 2026. The agency notes that these applications are at different stages of review and are subject to standard regulatory requirements for quality, safety, and efficacy. ANVISA emphasizes that none of the products under analysis are classified as generics, given the specific regulatory pathway for biologic products, and approvals will depend on rigorous technical evaluation. The agency also highlights that prioritization measures have been adopted to accelerate the review of high-demand therapies, although timelines remain uncertain and contingent on the submission of complete data by applicants. [Read more.](#)

### **BRAZIL SEEN AS PRIORITY MARKET FOR NOVO NORDISK'S ORAL WEGOVY**

Novo Nordisk identifies Brazil as a priority market for the launch of its oral version of Wegovy, a semaglutide-based treatment for obesity, as the company seeks to expand its footprint in one of the world's fastest-growing weight management markets. The tablet formulation, already submitted to the National Health Surveillance Agency (ANVISA), is expected to broaden access by offering a more convenient alternative to injectable therapies. The move comes amid strong demand for GLP-1 drugs in Brazil, where the segment already generates billions in annual sales and continues to expand rapidly. The oral version may also enhance market penetration due to easier administration and potentially lower costs compared to injectables, reinforcing Brazil's strategic role in Novo Nordisk's global growth strategy. [Read more.](#)

**BRAZIL'S OZEMPIC GENERICS EXPECTED TO MOVE BILLIONS IN 2026**

The expiration of the semaglutide patent in Brazil in March 2026 is set to trigger a multibillion-real market for generic versions of Novo Nordisk's blockbuster drug Ozempic, with several pharmaceutical companies already preparing to launch competing products and expanding supply in a high-demand segment. The National Health Surveillance Agency (ANVISA) is currently reviewing multiple applications, as companies anticipate rapid market entry following patent expiry. While increased competition is expected to reduce prices, analysts indicate that declines may be more moderate than typical generics due to complex manufacturing requirements and supply constraints for injectable delivery systems, even as demand for obesity and diabetes treatments continues to surge in Brazil. [Read more.](#)

**BRAZIL'S OZEMPIC PATENT EXPIRY OPENS PATH FOR COMPETITION AND EXPANDED ACCESS**

The expiration of the semaglutide patent in Brazil on March 20, 2026, marks the end of Novo Nordisk's market exclusivity and paves the way for new competitors to launch alternative versions of the compound used in Ozempic and similar drugs. The shift is expected to reshape a market currently estimated at BRL 6–6.5 billion annually, with potential to grow significantly as access expands. The National Health Surveillance Agency (ANVISA) has already received multiple applications for semaglutide-based products, signaling strong industry interest. Increased competition is expected to drive price reductions—potentially between 15% and 60%—although the extent will depend on regulatory approvals, manufacturing capacity, and pricing rules set by the Drug Market Regulation Chamber (CMED). Experts highlight that broader availability may improve patient access, including potential expansion within the Unified Health System (SUS). [Read more.](#)

**BRAZIL'S INPI PRESIDENT BLAMES USERS FOR PATENT DELAYS**

The president of the National Institute of Industrial Property (INPI) states that part of the delays in patent examination in Brazil is attributable to applicants themselves, citing incomplete submissions, procedural errors, and repeated requests that slow down the analysis process. The remarks were made during a public event, amid ongoing debate over backlog reduction and efficiency in the country's patent system. The statement adds to broader discussions on structural bottlenecks at INPI, including resource constraints and growing demand, while policymakers and industry continue to push for legislative and administrative measures to accelerate patent processing and improve legal certainty for innovation in Brazil. [Read more.](#)

**BRAZIL'S SENATE COMMITTEE ADVANCES BILL TO SPEED UP PATENT EXAMINATION**

The Senate's Economic Affairs Committee (CAE) approves a bill aimed at reducing patent examination timelines and modernizing procedures at the National Institute of Industrial Property (INPI), as part of broader efforts to tackle backlog and improve efficiency in Brazil's innovation system. The proposal (PL 4,972/2019), sponsored by Senator Confúcio Moura and reported by Senator Renan Calheiros, now moves to the Science and Technology Committee for further analysis. The bill introduces significant procedural changes, including reducing the confidentiality period for patent applications from 18 to 12 months, shortening the deadline to request examination from 36 to 18 months, and cutting response times to INPI requirements to 30 days. It also mandates that INPI reinvest its revenues into its own operations, aiming to enhance capacity and reduce delays in patent processing. [Read more.](#)

**BRAZIL'S LAWMAKERS DEBATE STRICTER PENALTIES AS PIRACY SEEN AS PUBLIC HEALTH RISK**

Industry representatives and policymakers warn that piracy and counterfeiting should be treated as a public health issue, citing risks associated with falsified medicines, beverages, and agricultural inputs during a public hearing at the Chamber of Deputies. Stakeholders call for the approval of bills to increase criminal penalties and fines, arguing that counterfeit products pose direct threats to consumer safety and undermine regulatory oversight. Participants highlight that piracy generates an estimated BRL 470 billion in annual losses and affects

multiple sectors, while exposing consumers to unsafe products such as fake cancer drugs and adulterated goods. Lawmakers and experts advocate a systemic response, including stricter enforcement, regulation of e-commerce platforms, and enhanced public-private cooperation to combat organized illicit trade. [Read more.](#)

### **BRAZIL'S HEALTH INSURERS POST RECORD PROFITS, BUT SMALLER OPERATORS STRUGGLE**

Brazil's private health insurance sector records a historic net profit of BRL 24.4 billion in 2025, driven by premium increases above medical cost growth and strong financial returns in a high-interest environment. The results, released by the National Supplementary Health Agency (ANS), highlight improved margins and reduced claims ratios across the industry. Despite the overall positive performance, smaller operators face significant financial pressure, with around 45% reporting losses, reflecting structural disparities in the sector. Large insurers concentrate most of the profits, while rising costs, judicialization, and operational challenges continue to weigh on medium and small companies, raising concerns about long-term market sustainability and competition. [Read more.](#)

### **BRAZIL'S HEMOBRÁS EXPANDS INVESTMENTS TO STRENGTHEN DOMESTIC PRODUCTION OF HEMODERIVATIVES**

The Brazilian Company of Hemoderivatives and Biotechnology (Hemobrás) is advancing new investments and international partnerships to expand domestic production of blood-derived medicines, amid renewed debate over plasma regulation and the role of the state in the sector. A recent agreement with China's Tiantan includes technology transfer and aims to increase Brazil's industrial capacity in hemoderivatives. Public investments are also reinforcing infrastructure and supply capacity, including BRL 116 million allocated through the Growth Acceleration Program (PAC) to modernize plasma storage and distribution. Despite more than BRL 3 billion invested in recent years and the inauguration of new production facilities, Hemobrás still depends on international partners for key stages of production, raising concerns about efficiency and the pace of achieving full national autonomy. [Read more.](#)

### **BRAZIL'S PALLIATIVE CARE SERVICES EXPAND, BUT GAPS IN QUALITY PERSIST**

Brazil records an 88.8% increase in palliative care programs between 2022 and 2025, rising from 234 to 423 services, according to the new National Atlas of Palliative Care 2025. Despite the expansion, the study highlights persistent regional inequalities and limited coverage, with the Southeast concentrating 40% of services, while the North accounts for just 3%. The report also raises concerns about quality and access, noting that around 65% of services do not meet minimum recommended standards and that overall availability remains below international benchmarks. Current coverage levels fall far short of global recommendations of at least two services per 100,000 inhabitants, underscoring structural gaps and the need for stronger federal coordination to scale and standardize palliative care within Brazil's health system. [Read more.](#)

### **ONLY 13% OF BRAZILIAN HOSPITALS FORMALLY ADOPT AI TOOLS, STUDY FINDS**

Only 13% of hospitals in Brazil have officially integrated artificial intelligence into their operations, according to a survey by Opinion Box in partnership with Rivio, highlighting the early stage of digital transformation in the country's healthcare system. Despite limited formal adoption, around 80% of healthcare professionals express interest in using AI solutions. The study shows that most AI use remains informal and fragmented, often limited to chat-based tools and specific tasks rather than full system integration. Key barriers include lack of organizational culture, limited knowledge and training, and implementation costs, while experts point to strong potential for automation in administrative workflows and patient care optimization. [Read more.](#)

## **BRAZILIAN STUDY HIGHLIGHTS KEY FACTORS IMPACTING DOCTORS' QUALITY OF LIFE**

A new survey on Brazilian physicians' well-being identifies excessive workload, long working hours, and lack of work-life balance as the main factors negatively affecting quality of life, according to findings presented in a recent study. The results also point to emotional exhaustion and stress as central issues across different specialties and regions. The study indicates that organizational factors—such as poor working conditions, administrative burden, and limited institutional support—play a significant role, while income and professional recognition are less decisive than expected. Experts emphasize the need for structural changes in healthcare systems and workplace environments to improve physicians' well-being and ensure sustainable care delivery. [Read more.](#)

### **MORE HIGHLIGHTS**

[Brazil's ANVISA launches dedicated Solicita profile for fee payments](#)

[Brazil's Senate advances expansion of prostate cancer prevention program](#)

[Brazil's lawmakers call for adjustments and more funding in specialist care program](#)

[Brazil's lawmakers debate multidisciplinary care model for autism policy](#)

[Brazil's UFRJ to launch rare diseases precision health center](#)

### **BRAZIL NEWS**

[Brazil central bank kicks off easing with cautious 25-bp cut after oil shock](#)

[Brazil finance minister Haddad to run for Sao Paulo governor](#)

[Brazilian fuel distributor group warns government of supply risks](#)

[Brazilian regulator tells Petrobras to supply fuel from canceled auctions](#)

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[Brazil's Lula pitches Petrobras-Pemex partnership, signals plan to buy back refinery](#)

[US in talks with Brazil on critical minerals, US diplomat says at signing of Goias state deal](#)

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