

# WEEKLY REPORT



09/13/2025

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## **BRAZILIAN COURT SUSPENDS PATENT EXTENSION FOR NOVO NORDISK'S WEIGHT-LOSS PEN**

A federal appellate judge has suspended the extension of Novo Nordisk's patent for liraglutide, the active ingredient in Victoza and Saxenda. The ruling overturns a lower court decision that had granted the company an additional eight years of exclusivity due to delays at Brazil's patent office (INPI). The court found that maintaining the extension would restrict competition, prevent the entry of generics, and perpetuate higher prices, with potential negative impacts on the public health system (SUS). The decision follows an appeal by EMS, a domestic pharmaceutical company that recently launched synthetic versions of liraglutide. [Read more.](#)

## **COURT OFFICIAL SAYS NO CONFLICT OF INTEREST IN LIRAGLUTIDE PATENT CASE**

A federal appellate judge affirmed there was no conflict of interest in his decision to suspend the patent extension for liraglutide (Victoza and Saxenda). The judge refuted claims suggesting bias or personal ties to pharmaceutical companies, stating that the ruling was independent and grounded purely in legal and technical considerations. The decision overturns an earlier extension meant to compensate for delays at the National Industrial Property Institute (INPI). The judge emphasized that his judgment was based solely on principles of fair competition and protection of public health, given the consequences of extended exclusivity for the SUS. [Read more.](#)

## **NEW ANVISA LEADERSHIP SWORN IN WITH FOCUS ON AUTONOMY AND FASTER REVIEWS**

The National Health Surveillance Agency (Anvisa) held a swearing-in ceremony on Wednesday (10) for its new leadership team. President Leandro Safatle pledged to accelerate regulatory reviews using digital tools and AI, while maintaining the agency's autonomy and credibility. Director Daniela Marreco emphasized the need to shorten approval times and modernize regulation, while Tiago Campos highlighted Anvisa's role in defending the SUS and ensuring evidence-based decisions. Health Minister Alexandre Padilha praised the agency's resilience during the pandemic and announced the incorporation of a new RSV vaccine into the SUS. [Read more.](#)

## **NEW DRAFT PROPOSES CLINICAL PROTOCOL FOR CLIMACTERIC THERAPIES IN BRAZIL'S SUS**

Congresswoman Rogéria Santos (Republicanos-BA) presented a new substitute to Bill 876/2025, which addresses the provision of therapies for climacteric care in the Unified Health System (SUS). Originally authored by Congresswoman Ana Paula Lima (PT-SC), the bill proposed the incorporation of hormonal treatments for menopause and climacteric symptoms, with medical prescription and in line with Law 8.080/1990. The first substitute introduced by the rapporteur allowed SUS to offer different therapeutic approaches, including hormonal treatments, subject to clinical guidelines and individualized patient evaluation. It also provided for the creation of clinical protocols or equivalent documents to guide care and ensure the rational use of medicines. The latest version under discussion establishes the mandatory preparation of a Clinical Protocol and Therapeutic Guideline (PCDT) specifically for climacteric care. While the PCDT is not yet implemented, the bill guarantees transitional access to hormonal

therapies, provided with medical prescription and in accordance with Law 8.080/1990. [Read more.](#)

## **JUDICIALIZATION OF HEALTH REMAINS HIGH IN BRAZIL, GOVERNMENT SEEKS SOLUTIONS**

Health-related judicial actions continue to climb in Brazil, with over 383,000 new cases filed by July 2025 (more than 60,000 alone in July) according to the National Council of Justice (CNJ). Such lawsuits account for about 33% of Brazil's medication spending, amounting to approximately R\$3.2 billion in 2024 by the Ministry of Health. Despite stricter criteria defined by the Supreme Federal Court (STF) in October (requiring that medications be incorporated by Conitec and backed by scientific evidence) measurable reductions in litigation have not yet materialized. Both executive and judicial branches are advocating reforms to tackle excessive judicialization. Proposed measures include better alignment among drug registration, pricing, and incorporation processes, as well as mechanisms to curb abusive litigation—when legal action is used as a commercial strategy to introduce ultra-high-cost drugs into the system. [Read more.](#)

## **HEALTH MINISTER CITES JUDICIALIZATION AS SUS'S MAIN CHALLENGE**

In a hearing at the National Congress, Health Minister Alexandre Padilha warned that judicialization has become the main driver of financial pressure on Brazil's health system, especially with high-cost drugs. Expenses rose from R\$1.5 billion in 2022 to R\$2.7 billion in 2024, and R\$1.9 billion has already been spent in 2025. Padilha highlighted that lawsuits for drugs costing up to R\$17 million per dose divert resources from broader policies and compromise equity in the SUS. He presented measures such as risk-sharing agreements, strengthened coordination with the judiciary, and programs to expand specialized care and patient transport. Despite budget growth to R\$248 billion, Padilha noted that Brazil still invests proportionally less in public health than OECD countries. [Read more.](#)

## **CNJ COUNCILOR SAYS JUDICIALIZATION SIGNALS A FAILING HEALTH SYSTEM IN BRAZIL**

A judicialization of health in Brazil reflects systemic dysfunction, says Daiane de Lira, councilor at the National Council of Justice (CNJ), in a new Futuro Talks episode. She highlights that, although judicial claims for health rights are backed by the Constitution, their overuse threatens the sustainability of the public health system. Scientific evidence now forms the backbone of such cases, with NatJus supporting judges technically, and a recent STF decision providing greater legal clarity for claims involving non-incorporated SUS medications. [Read more.](#)

## **BRAZIL'S FORUM ON RARE AND NEGLECTED DISEASES HIGHLIGHTS URGENCY OF ACCESS TO DIAGNOSIS AND TREATMENT**

The Brazilian Forum on Rare and Neglected Diseases, promoted by the Parliamentary Front to Support the ITEC Raras Institute, brought together legislators, experts, patients, and civil society to discuss the challenges in guaranteeing timely access to diagnosis and innovative therapies. Lawmakers emphasized recent advances such as the Clinical Research Law (Law 14.874/2024) and the expansion of patient representation in Conitec (Law 15.120/2025) but pointed out persistent barriers including delays in technology incorporation, shortage of geneticists, and reliance on litigation. Ongoing bills such as PL 2583/2020, which establishes the National Health Strategy, and PL 1033/2024, aimed at strengthening medical genetics training, were highlighted as key to advancing the agenda. Patient testimonies revealed diagnostic delays of years and dependence on judicialization to obtain drugs already approved by Anvisa, underscoring systemic failures and regional inequalities. Experts reinforced that late access worsens health outcomes and increases costs for the SUS, calling for specific clinical protocols, early diagnosis, and greater professional training. [Read more.](#)

## **BRAZIL APPROVES NEW PDPS TO EXPAND PRODUCTION OF STRATEGIC MEDICINES AND VACCINES**

The Ministry of Health signed two new technology transfer agreements under the Productive Development Partnerships (PDPs): one for a Respiratory Syncytial Virus (RSV) vaccine with Instituto Butantan and Pfizer, and another for the biologic natalizumab, used in multiple sclerosis, with Sandoz and Butantan. The RSV vaccine's first 1.8 million doses are expected by year-end, and SUS distribution will begin in late November, potentially preventing around 28,000 hospitalizations annually and benefiting approximately 2 million babies. The natalizumab agreement aims to foster competition and reduce reliance on a single supplier. In addition, the Ministry's Science, Technology, Innovation and CEIS Secretariat released preliminary results from the latest PDP cycle: 12 projects approved and 36 rejected. Among the approved are nine cancer treatments and three new vaccines—including rabies, varicella, and the mRNA COVID-19 vaccine mRNS-1273 developed by Moderna and produced by Butantan. [Read more.](#)

### **BRAZILIAN EXPERIMENTAL POLILAMININA SHOWS PROMISE IN REVERSING SPINAL CORD INJURY**

Researchers at UFRJ (Federal University of Rio de Janeiro), in partnership with pharmaceutical company Cristália, presented a new experimental drug, polilaminina, in São Paulo. Derived from a placenta-extracted protein called laminina, it has shown potential to regenerate spinal cord tissue and restore partial or complete mobility in preliminary trials. In early human studies involving approximately 10 patients with severe spinal injuries, including cases of tetraplegia and paraplegia, polilaminina was administered directly into the spinal cord shortly after injury, followed by physiotherapy. Notably, one patient regained full mobility and returned to normal daily life. Researchers emphasize stronger results occur when treatment begins soon after trauma, though improvements were also observed in older injuries. The team now awaits authorization from Anvisa to begin broader regulated clinical trials (Phase 1), which will involve additional patients and aim to validate safety and efficacy. [Read more.](#)

### **BRAZILIAN STUDY REVEALS WHY SOME BREAST CANCER TYPES DO NOT RESPOND TO TREATMENTS**

A recent Brazilian study explains that certain types of breast cancer fail to respond to standard treatments due to the unique biology of aggressive tumor subtypes, including triple-negative and hormone-receptor negative variations. Researchers identified that these tumors lack hormone or HER2 receptors, making traditional hormone therapies ineffective. Investigators also noted that resistance may be fostered by genetic and micro-environmental factors, such as altered immune profiles and cell signaling pathways. The findings reinforce the need for targeted therapies and biomarker-driven approaches. [Read more.](#)

### **MORE HIGHLIGHTS**

[State Legislative Assembly in Amazonas is analyzing a bill to reinstate men undergoing prostate cancer treatment at work.](#)

[Congresswoman Rosângela Moro presents a separate vote on the import of unregistered medicines](#)

[Congress honors spinal muscular atrophy awareness month](#)

**BRAZIL NEWS**

[Brazil's Bolsonaro sentenced to 27 years after landmark coup plot conviction](#)

[What next for Brazil's Bolsonaro after 27-year sentence for coup plot?](#)

[Eduardo Bolsonaro says US sanctions on Brazil officials likely after his father's conviction](#)

[Rubio vows US response following conviction of Brazil's Bolsonaro](#)

[As trial of Brazil's Bolsonaro winds up, likely heir to right-wing coalition emerges](#)

[Brazil's Lula calls for tighter trade ties for BRICS as tariffs bite](#)

[China clears imports of Brazil sorghum, official says, in blow to US](#)

[Brazil's central bank to keep rates unchanged at 15% on September 17](#)

[Brazil consumer prices forecast to have dropped 0.15% in August vs July: Reuters poll](#)

[Embraer eyes 100 commercial jet deliveries per year in 2028, CEO says](#)

[Deere & Co Brazil sales could fall amid global trade tensions, executive says](#)

[Brazil animal feed output to drop after bird flu outbreak](#)

[Brazil to propose new forum to address climate and trade complaints, sources say](#)

[Brazil links last unconnected state to its national electric grid](#)