# WEEKLY REPORT



08/30/2025

#### BRAZIL APPOINTS NEW DIRECTORS FOR ANVISA, ANS, AND 10 OTHER REGULATORY AGENCIES

President Luiz Inácio Lula da Silva signed the appointment of new directors for regulatory agencies on August 28, following Senate approval. At Anvisa, Leandro Pinheiro Safatle was named director-president, while Daniela Marreco Cerqueira and Thiago Lopes Cardoso Campos were appointed as directors. At ANS, Wadih Damous was named director-president, alongside Lenise Secchin as director. In total, 24 directors were appointed across 12 agencies. In his speech, Lula highlighted that agency directors have the responsibility of making decisions on issues that often neither the Senate president nor the president of the Republic directly follow, emphasizing the weight of their roles. Read more.

#### BRAZIL TO REVIEW CMED RULES AFTER LEGAL CHALLENGE OVER DRUG PRICING PENALTIES

The Drug Market Regulation Chamber (CMED), linked to Anvisa, will review its rules after distributors challenged fines imposed for offering medications above price caps in public bids. Distributors argue that CMED's rules are unclear and penalties unlawful. The agency committed to revising and clarifying the regulation to improve transparency and legal certainty. Industry representatives highlighted the need for a more predictable environment, as disputes over price regulations can affect access to medicines and the sustainability of the supply chain. Read more.

Relações Governai

# SUPREME COURT ORDERS MEASURES TO ENFORCE RULINGS ON MEDICATION ACQUISITION

The Supreme Federal Court (STF) mandated actions to ensure compliance with rulings on the supply of medicines by SUS. The decision responds to repeated failures by public administration and courts. Among the measures, the Drug Market Regulation Chamber (CMED) must update or issue a new regulation within 60 days requiring adherence to the Maximum Government Sale Price (PMVG). Ministers also stressed the importance of coordination between federal entities to avoid delays that compromise patient access to essential therapies. Read more.

### BRAZIL'S SUPREME COURT RULING ON OFF-LIST SUS MEDICATIONS APPLIES TO PENDING CASES

The Supreme Federal Court (STF) ruled that its precedent on the supply of medications not incorporated into SUS applies immediately to all ongoing lawsuits. The decision reaffirms the role of Conitec and the Ministry of Health in defining SUS coverage, while also clarifying that judicial rulings must respect established timelines and budgetary processes to avoid destabilizing the public health system. Read more.

# BRAZIL APPROVES UNPRECEDENTED CERTIFICATION TO IMPROVE CANCER CARE IN SUPPLEMENTARY HEALTH

The National Supplementary Health Agency (ANS) unanimously approved the inclusion of oncology-focused proposals from the OncoRede Manual into its Certification Program of Good Practices in Healthcare. The measure follows Public Consultation No. 144/2024, held between December 2024 and January 2025, which received more than 63,000 contributions — the largest volume in the agency's history. The new certification recognizes health insurance

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providers that adopt qualified practices for cancer care, such as multidisciplinary monitoring, faster access to treatment, and patient navigation programs. ANS stated that the goal is to improve clinical outcomes and the overall patient experience in oncology. Read more.

# BRAZIL'S SUPREME COURT DEBATES ADVERTISING OF MEDICINES AND UNHEALTHY FOODS

The Supreme Federal Court (STF) began deliberations on restrictions related to the advertising of medicines and unhealthy foods. The case addresses the scope of regulation by health authorities and the balance between consumer protection and commercial freedom. Ministers highlighted the need to safeguard vulnerable populations — particularly children — from marketing practices that could encourage the consumption of unhealthy products, while ensuring freedom of enterprise in regulated markets. Read more.

### COMMITTEE PASSES BILL ESTABLISHING NATIONAL POLICY FOR WOMEN'S HEALTH CARE DURING MENOPAUSE

The Women's Rights Defense Committee (CMULHER) approved, this Wednesday (27), Congresswoman Daniela do Waguinho's (UNIÃO-RJ) amendment to Bill 4504/2024, which establishes the National Policy for Comprehensive Health Care and Quality of Life for Women During Climacteric and Menopause. The bill is being processed as an annex to Bill 4941/2024, authored by Congressman Capitão Augusto (PL-SP), which also addresses the creation of a national policy focused on the topic. The approved amendment integrates both bills and reinforces principles such as humanized care within the Unified Health System (SUS), awareness campaigns, the appreciation of scientific research, combating discrimination, and coordination between different public policy sectors. Furthermore, it establishes National Climacteric and Menopause Awareness Week, to be held annually in the second week of October, with information activities, debates, and educational campaigns. Read more.

# HOUSE'S COMMITTEE APPROVES LIST OF PARTICIPANTS FOR HEARING TO DISCUSS MENOPAUSE

The Health Committee of the Chamber of Deputies approved, this Wednesday (27), Request 205/2025, authored by Representative Romero Rodrigues (PODE-PB), which amends Request 134/2025, also authored by him, to expand the list of guests for the public hearing that will discuss the "National Policy for Comprehensive Health Care and Quality of Life for Women in Menopause: Challenges and Pathways to Implementation." According to the congressman, the hearing will aim to discuss the implementation of this policy, establishing concrete guidelines, promoting consultation with experts and affected women, and encouraging coordination between the government and civil society. Read more.

# BRAZIL'S SENATE COMMITTEE APPROVES INCLUSION OF IMMUNOTHERAPY IN CANCER TREATMENT PROTOCOLS

The Senate's Social Affairs Committee (CAS) unanimously approved a bill requiring the inclusion of immunotherapy in clinical protocols for cancer treatment in Brazil. The initiative aims to expand patient access to innovative therapies within the SUS and aligns with international practices in oncology care. The proposal will now proceed to further legislative review. Read more.

#### FEDERAL SENATE LAUNCHES SUBCOMMITTEE TO DEBATE CANCER PREVENTION AND TREATMENT

The Senate's Social Affairs Committee (CAS) established a Temporary Subcommittee on Cancer Prevention and Treatment, which will operate for 180 days. The subcommittee will prepare legislative proposals and organize public hearings to address prevention, early diagnosis, and patient access to therapies, aiming to strengthen national cancer control policies. Read more.

# BRAZIL DEBATES NATIONAL HEALTH STRATEGY TO REDUCE DEPENDENCE ON IMPORTS

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Bill 2,583/2020, already approved in the House of Representatives and now under Senate review, seeks to establish a National Health Strategy to reduce Brazil's reliance on imports of medicines, vaccines, devices, and other critical supplies. The proposal integrates mechanisms such as Productive Development Partnerships (PDPs), Local Innovation Programs (PDILs), and Technological Orders (ETECs). It also connects with broader initiatives like the Health Economic-Industrial Complex (CEIS) and the Nova Indústria Brasil (NIB). Industry leaders compare the bill's potential impact to that of the generics law and the creation of Anvisa. Read more.

#### **BRAZIL'S PHARMACEUTICAL INDUSTRY TO PRODUCE 9 IN 10 DRUGS BY 2030**

Brazilian manufacturers sold 5.7 billion drug units in the first half of 2025, a 5% increase compared to 2024, according to data from the Latin American Pharmaceutical Industry Association (Alanac). The sector's target is to supply 90% of all medicines consumed in Brazil by 2030, strengthening local production capacity and reducing dependence on imports. Alanac highlighted that investments in industrial capacity, regulatory streamlining, and public-private partnerships are critical to achieving this goal. Read more.

### BRAZIL'S FIOCRUZ TO PRODUCE SPINAL MUSCULAR ATROPHY DRUG NUSINERSENA DOMESTICALLY

The Oswaldo Cruz Foundation (Fiocruz), in partnership with Hypera Pharma and Aurisco Pharmaceutical, will begin domestic production of nusinersena, a therapy for spinal muscular atrophy (SMA). This initiative makes Brazil the first Latin American country capable of manufacturing oligonucleotides, a key technology for advanced therapies. The Ministry of Health stated that local production will improve access, reduce dependency on imports, and strengthen the country's biotechnological sovereignty. Read more.

# BRAZIL'S PROGRAM TO EXTEND SPECIALIZED HEALTHCARE STALLS AFTER LAUNCH WITH LULA

The Ministry of Health's initiative to allow SUS patients to be treated in private hospitals, launched on August 14 in Recife with President Lula present, has yet to move beyond its initial stage. Eight patients were treated during the launch event, but no new procedures have been carried out since then. The ministry stated that the expansion will occur "as more private agents complete their enrollment," but did not provide a timeline for when treatments in private hospitals will become routine. The initiative is seen as a flagship project for Lula's third term in health policy, but its implementation remains uncertain. The program, Agora Tem Especialistas, aims to trade R\$1.3 billion in annual debts owed by private health operators for specialized care delivered to SUS patients. Read more.

### MINISTRY OF HEALTH SELECTS 501 SPECIALIST DOCTORS FOR UNDERSERVED REGIONS UNDER NEW SUS PROGRAM

The Ministry of Health announced the selection of 501 doctors to work in 212 municipalities across all states and the Federal District, prioritizing regions with shortages of specialists. According to the ministry, 67% of the selected professionals will be assigned to inland municipalities, with coverage in specialties such as general surgery, gynecology, anesthesiology, and otolaryngology. The initiative seeks to strengthen specialized care access within SUS and reduce regional disparities. Read more.

### BRAZIL REASSESSES MEDICAL SPECIALIST TRAINING AMID ALARMING SHORTAGE IN SUS

Brazil faces a shortage of nearly 30,000 medical specialists in the Unified Health System (SUS), with significant regional disparities. The Ministry of Health announced measures to expand training programs and create incentives to address the deficit, especially in underserved areas. Read more.

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### BRAZIL'S MEDICAL COUNCIL LAUNCHES AI TOOL TO DETECT FAKE SPECIALISTS ON SOCIAL MEDIA

The Federal Council of Medicine (CFM) announced the launch of an artificial intelligence tool to actively detect false specialists on social media platforms such as Instagram and Facebook. The system, expected to go live in September, will compare claimed titles with CFM's database, identifying not only professionals who lack certification but also those misrepresenting their specialty. The initiative responds to a surge of unqualified individuals presenting themselves as experts online. Read more.

#### **MORE HIGHLIGHTS**

Representative requests information on care for women during menopause and climacteric in Paraná

<u>Congressman proposes ICMS exemption for medicines for rare diseases and cancer</u> in Minas Gerais

Brazil considers banning manipulated Mounjaro (tirzepatide) amid Ozempic restrictions

Brazil averages 149 days to diagnose lymphoma, new survey finds

Brazil public overwhelmingly supports proficiency exam for new doctors, Datafolha shows

#### **BRAZIL NEWS**

Brazil carries out raids in crackdown on organized crime in the fuel sector

Brazil central bank chief flags still sluggish convergence of inflation expectations

Brazil creates fewer formal jobs than expected in July

Brazil's Bolsonaro and his coalition adrift as trial verdict nears, allies say

Brazil might challenge tariffs in US courts, finance minister says

Brazil's Lula in "no rush" to retaliate against US tariffs

Brazil starts formal process to assess US tariff retaliation

Tariffs on Brazil will reshape global beef trade flows, analysts say

Brazil readies updated sector trade deals with México

<u>Brazil approves temporary antidumping measures against Canadian, US</u> polvethylene resins

China looks to strengthen coordination with Brazil, work with BRICS

Brazil judge grants injunction against soy moratorium suspension

Brazil launching data center incentives next month to woo big tech, sources say