WEEKLY REPORT

06/21/2025

BRAZILIAN CONGRESS OVERRIDES PRESIDENTIAL VETOES AND FINALIZES LEGAL FRAMEWORK FOR CLINICAL TRIALS

The Brazilian National Congress concluded, on Tuesday (18), the legislative process for Law No. 14,874/2024, which establishes a comprehensive legal framework for clinical trials in Brazil. The law originated from Senate Bill No. 200/2015, sponsored by former Senators Ana Amélia, Waldemir Moka, and Walter Pinheiro. Ana Amélia is currently part of the senior advisory team at NK Consultores. After more than a decade of debate, the legislation was finalized with the overriding of two presidential vetoes, fully restoring the original provisions approved by Congress. The new law is expected to enhance Brazil's competitiveness as a destination for clinical trials, improve legal certainty for sponsors, and strengthen protections for participants. Key changes following Tuesday's vote: - Post-trial access: Clinical trial sponsors must provide free access to the investigational drug for up to five years after it becomes commercially available in Brazil. This provision, previously vetoed in favor of indefinite supply, was reinstated to provide legal clarity while ensuring participant support. - Protection of Indigenous participants: Clinical trials involving Indigenous individuals must be reported to the Public Prosecutor's Office, ensuring additional oversight and safeguarding the rights of vulnerable populations. Read more.

CONGRESS APPROVES RESOLUTION ALLOWING USE OF AMENDMENTS TO PAY HEALTH SALARIES

The National Congress approved, this Tuesday (17/6), the draft resolution (PRN 3/25) that allows the use of parliamentary amendments from committees and benches to pay salaries of active health professionals. The use of individual amendments for this purpose remains prohibited. The text also allows for changes to the amendment schedule, provided that it is voted on by the committees when formally requested by the parliamentarian who suggested the original amendment. The bill will be sent for enactment by the Board of Directors of the National Congress and will have the force of law. Read more.

CONGRESSWOMAN PROPOSES THAT BILLS ON THE INCLUSION OF TREATMENTS IN CONITEC BE REJECTED

Representative Adriana Ventura (Novo-SP) sponsored, in the Health Committee of the House of Representatives, Request 157/2025, proposing the approval of a summary recommendation on Bills that aim to incorporate medications into the SUS without the analysis of Conitec be rejected. According to the parliamentarian, these proposals ignore the work of Conitec, the technical body responsible for evaluating, based on scientific and economic evidence, the introduction of new technologies into the SUS. For Adriana Ventura, such bills violate constitutional principles such as efficiency, economy, reasonableness, proportionality, legitimacy, and the supremacy of the public interest. Read more.

ELEVIDYS HAS ITS EFFECTIVENESS QUESTIONED AND OPINION AGAINST ITS USE IN THE SUS

Treatment aimed at children with Duchenne muscular dystrophy and costing R$14.6 million, Elevidys (delandistrogen moxeparvoveque) received an initial negative opinion from Conitec (National Commission for the Incorporation of Technologies into the Unified Health System) in the process that evaluates the supply of the drug in the public network. The agency's medicines

committee considered that "there are uncertainties regarding the efficacy of this therapy, in addition to it presenting a safety profile that indicates a potential risk of serious adverse events, such as myositis (inflammation of the muscles) and liver damage". The opposing opinion was assessed in April by Conitec and sent for public consultation, which ends on June 25, a stage that precedes the body's final decision. While the debate on offering Elevidys in the SUS is open, the medicine has been delivered by the Ministry of Health to patients who obtain favorable decisions in court. The federal government estimates that it will spend around R$1 billion to comply with the court orders, a figure that includes more than R$120 million in treatments already provided to ten patients. Read more.

ANVISA CLARIFIES THE SITUATION OF ELEVIDYS IN BRAZIL

The National Health Surveillance Agency (Anvisa) issued a clarification on the status of the drug Elevidys, the commercial name for the delandistrogen moxeparvovequel, indicated for the treatment of Duchenne muscular dystrophy (DMD), in Brazil. The drug was suspended in the United States for patients who can no longer walk after the deaths of two teenagers. The measure in the American country was announced by Sarepta, the biotechnology company that developed the medicine, and by Roche, which markets the medicine in Brazil and the rest of the world, and was taken after the young people, aged 16 and 15, developed acute liver failure and died in March and June. Anvisa, however, reinforced that the approval of the drug in Brazil was only for children aged 4 to 7 who are able to walk without assistance. Therefore, the public for whom use was suspended in the US, where the deaths were recorded, could no longer access the drug in the country. Read more.

COMMITTEE DEBATES THE IMPORTANCE OF MUCOPOLYSACCHARIDOSIS AWARENESS DAY

On Tuesday (17), the Committee for the Defense of the Rights of Persons with Disabilities met to discuss Mucopolysaccharidosis Awareness Day. Initially, Congressman Duarte Jr. (PSB-MA), who chairs the committee, mentioned the importance of giving visibility to little-known topics, such as rare diseases, through requests on commemorative dates. He reinforced that early diagnosis is essential to ensure more quality and time of life for patients. Read more.

16 MILLION CASES: RESEARCH CREATES A NEW MAP OF RARE DISEASES IN BRAZIL

In 2020, the National Network for Rare Diseases (RARAS) was created. This epidemiological survey was funded by the National Council for Scientific and Technological Development (CNPq), and brings together university hospitals, neonatal screening services and referral centers, all linked to the Unified Health System (SUS). The results reveal crucial aspects of who Brazil's "rare" patients are. The median age of participants was 15 years, with a slight female majority (50.5%). Approximately 47% self-identified as a mixed race. Most patients (63.2%) already had a confirmed diagnosis, with the most common conditions being phenylketonuria, cystic fibrosis, and acromegaly. Among the most common symptoms reported were global developmental delay and seizures. The so-called "diagnostic odyssey" — the average time between the onset of symptoms and confirmation of diagnosis — was 5.4 years, with wide variation. This highlights the great challenge faced by patients and families in the search for answers, in addition to the difficulties faced by health professionals in recognizing these conditions. Read more.

BRAZILIANS WAIT FIVE YEARS FOR ACCESS TO INNOVATIVE THERAPIES

Brazil has one of the most efficient regulatory systems in Latin America. However, the gap between the approval of innovative medicines and their actual availability to patients remains significant. This was one of the main conclusions of the ACESSO Brasil 2025 event, organized by FIFARMA and Interfarma, where the results of the FIFARMA Patient WAIT Indicator 2025 study, developed by IQVIA, were presented. "Brazil has made significant progress in the regulatory process, but there is an urgent need to translate this progress into real availability for patients. This study shows that while many medicines are approved, they are not reaching

those who need them most in time," explained André Ballalai, Associate Director at IQVIA and co-author of the study. Read more.

BREAST CANCER MEDICATIONS INCORPORATED INTO THE SUS IN 2021 STILL DO NOT REACH PATIENTS

Six months after the publication of the new PCDT (Clinical Protocol and Therapeutic Guidelines) for breast cancer by the Ministry of Health , the medications recommended in the document — which could help patients prolong survival and postpone chemotherapy, in addition to reducing hospitalizations— are still not available in the SUS (Unified Health System). Published in December 2024 after a delay of two years and six months, the new PCDT brings updates on the management of the disease in the country, such as the availability of cyclin inhibitors (abemaciclib, palbociclib and ribociclib succinate), incorporated by Conitec (National Commission for Incorporation of Technologies into the SUS) in December 2021. Read more.

REVENUE OF LARGE PHARMACEUTICAL CHAINS GROWS 14.2% IN 2024

Large pharmaceutical retail chains had revenue of R$103.14 billion last year, an increase of 14.2% compared to 2023. The number of associated units grew 8.17%, totaling 11,244 stores in December. The data, released by the Brazilian Association of Pharmacy and Drugstore Chains (Abrafarma), reinforced the resilient performance of Brazilian pharmaceutical retail, although they indicate a slowdown compared to the 17% growth in the previous period. Read more.

MORE HIGHLIGHTS

Congress overturns veto and resumes lifetime pension for children with microcephaly

Voting on the PEC on the supervision of Regulatory Agencies postponed

New draft for bill to create the National Registry of Trials on Experimental Drugs for the Treatment of Cancer

Substitute bill to create the National Cancer Research Program presented

BRAZIL NEWS

Brazil central bank raises rates, sees 'very prolonged' pause

States and cities now drive 80% of public investment in Brazil

Congress preserves opaque budget practices under new resolution

Government moves to secure control of INSS fraud probe

Lula signals possible 2026 run, takes aim at right-wing governors

Bolsonaro was main beneficiary in illegal surveillance scheme, Brazil police allege

Brazil to push for corporate, local government climate targets at COP30

Brazil's soy farmers raze Amazon rainforest despite deforestation pact

WOAH considers Brazil bird flu outbreak on commercial farm resolved

China floods Brazil with cheap EVs triggering backlash