WEEKLY REPORT

07/26/2025

MINISTRY OF HEALTH WILL SEND CLINICAL TRIALS REGULATION TO THE EXECUTIVE OFFICE OF BRAZILIAN GOVERNMENT

The Ministry of Health plans to publish regulations for the Clinical Research Law by September. Fernanda de Negri, Secretary of Science, Technology, and Innovation and the Health Industrial Economic Complex (SECTICS), told JOTA that the text has been finalized, is now undergoing review by legal counsel, and should be sent to the Chief of Staff's Office in the coming days. In this exclusive interview, Negri previews the most important aspects of the regulation, eagerly awaited by both the manufacturing sector and the scientific community. Among the highlights are the adoption of risk classification for analyzing applications, how the National Research Ethics Committee should operate, and how the registration system will work. Read more.

PATENT SUSPENSION COULD HAVE A DOMINO EFFECT AND DRIVE AWAY INVESTMENT

The suspension of intellectual property rights in the pharmaceutical industry could create a negative "domino effect" beyond Brazil and the United States, according to industry experts. While there is consensus that the measure is exceptional and unlikely at this time, sources point out that patents are a pillar for investment in research and development. When contacted by Valor, pharmaceutical companies Pfizer, Novo Nordisk, Eli Lilly, Bayer, and EMS stated that they would not comment on the matter and that they are monitoring the positions of their industry entities. The Ministry of Development, Industry, Trade, and Services (MDIC) stated that "any proposed exceptional and provisional measures" will be submitted to the Interministerial Committee for Negotiation and Economic and Trade Countermeasures, which "may consult the private sector and other federal agencies before deliberating." Read more.

MINISTRY OF HEALTH PREPARES PILOT FOR RADICAL DRUG INNOVATION

The Ministry of Health, in partnership with the Ministry of Science, Technology, and Innovation (MCTI) and the National Center for Research in Energy and Materials (CNPEM), is preparing to launch a pilot program for radical innovation in pharmaceuticals. In an exclusive interview with JOTA, Fernanda de Negri, Secretary of Science, Technology, Innovation, and the Health Industrial Economic Complex, stated that the initiative will begin by coordinating existing instruments in the country to boost the activity. Read more.

NEW RULES REQUIRE HEALTH PLANS TO RESPOND TO REQUESTS WITHIN 10 DAYS, BUT EXPERTS POINT OUT GAPS

Starting this month, health plan providers have a maximum time limit to respond to service requests and can no longer leave consumers unanswered. The change is a result of a new regulation from the National Supplementary Health Agency (ANS), which also requires 24-hour online support and a mandatory written response to coverage denials. Normative Resolution No. 623/2024, from ANS, determines that all operators must provide a conclusive response to requests for medical care , respecting the following deadlines: Immediately, in cases of urgency or emergency; Within 10 business days, for more complex procedures and elective hospitalizations; Within 5 business days, for other cases. Read more.

ANVISA SUSPENDS ELEVIDYS, DRUG FOR DUCHENNE MUSCULAR DYSTROPHY THAT COSTS ALMOST R$20 MILLION PER DOSE

The National Health Surveillance Agency (Anvisa) has temporarily suspended the marketing, distribution, manufacturing, import, advertising, and use of the drug Elevidys (delandistrogeno moxeparvoveque), indicated for the treatment of Duchenne muscular dystrophy (DMD), in Brazil. According to the agency, the measure was taken as a precaution after three deaths associated with the therapy were reported in the United States during clinical trials. The suspension was published in the Official Gazette of the Union this Thursday. Read more.

HPV PREVENTION AND CARE POLICY APPROVED

The Official Gazette of the Union this Wednesday (23) brings the sanction of Law 15.174, which creates the National Policy to Combat Human Papillomavirus (HPV) Infection. The text establishes a set of public health measures aimed at the prevention, detection and treatment of HPV, a virus that affects the skin and mucous membranes and of which there are more than 200 types. The rule comes into effect in October, 90 days after publication. Law 15.174 establishes guidelines that include information campaigns, expanded access to care, and strengthened reporting and scientific research. President Luiz Inácio Lula da Silva vetoed a section that required serological testing to diagnose HPV. He argued that the test is not indicated for this purpose and, therefore, "is not part of the HPV diagnostic protocol." Read more.

MORE HIGHLIGHTS

Public hearing to discuss the situation of regulatory agencies in the House of Representatives has been rescheduled

Ministry of Health may provide information on the implementation of the National Neonatal Screening Program in the SUS

Law defines fibromyalgia as a disability nationwide from 2026

Brazilians have difficulty controlling diabetes and hypertension even when treated, study shows

BRAZIL NEWS

Brazil's top court rules out Bolsonaro arrest, for now

Trump tariffs wreaking havoc in Brazil's citrus belt

Brazil VP hails 'good' and 'fruitful' conversation with Lutnick on tariffs

Brazil scrambles as U.S. tariff deadline looms, talks stall

US lovers of Amazon berry açaí to feel tariff pinch

Trump tariffs weigh on Brazil chemical exporters, spark order cancellations

Brazil inflation hits 5.3%, central bank set to hold rates next week

Brazil eases 2025 spending curbs needed to comply with fiscal rules

Brazil economy on track despite U.S. tariffs, but inflation risk up - Reuters poll

Brazil's biggest conilon coffee cooperative to launch cocoa pilot project in Bahia state