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08/02/2025

LULA REQUESTS DIAGNOSIS ON IMPORTED DRUGS FROM THE US AFTER TRUMP'S TARIFF HIKE

President Lula (PT) asked his team for a diagnosis of the pharmaceutical industry, one day after the President of the United States, Donald Trump, signed a decree that implements an additional tariff of 40% on products imported from Brazil, increasing the value of the surcharge to 50%. In a meeting with ministers this Thursday (31), Lula asked for information about medicines imported from the USA and the inputs needed for their manufacture. According to participants, the president requested data on different sectors of the economy, including energy, to evaluate measures that may be taken in response to the sanctions announced by the US government. Regarding medicines, the president is seeking information on the possibility of purchasing items produced in other countries, even if patented in the US. Lula also wants data on Brazil's drug production capacity. Although the Reciprocity Law provides for the possibility of manufacturing imported medicines in the event of a threat to the Brazilian economy, the possibility of resorting to the rule for breaking patents is not on the table. Read more.

US ACCUSES BRAZIL OF INTENTIONALLY DELAYING PATENT REVIEW

The efficiency of Brazilian agencies responsible for analyzing drug patents has always been criticized. The problem now is that the United States is claiming this delay is intentional. The issue was raised amid the trade war between the countries, which intensified after Donald Trump imposed 50% tariffs on Brazilian products, and took a new step after the formal opening of an investigation by the Office of the United States Trade Representative (USTR). The lawsuit, based on Section 301 of the Trade Act, targets alleged unfair trade practices by the Brazilian government, such as the chronic delay in granting pharmaceutical patents, and could result in unilateral retaliatory measures against the country. The accusation is seen as a response to the hypothesis of breaking drug patents in Brazil, discussed as a counterpoint to taxation, but already denied by the Brazilian government. "Breaking patents may expand immediate access to medicines, but it undermines legal certainty and directly affects companies' confidence in continuing to invest in research in Brazil. The patent system exists to provide predictability and returns on high-risk, long-term investments," explains Leonardo Almeida, partner at Avance Propriedade Intelectual. Read more.

BRAZIL'S EMS TO SELL INJECTOR PENS TO TREAT OBESITY

Brazilian pharmaceutical company EMS on Friday said that local pharmacies will start selling its injector pens aimed at treating diabetes and obesity from August 4. The pens, made in Brazil, uses liraglutide as an active ingredient, like Saxenda, from Novo Nordisk (NOVOb.CO), which has demonstrated consistent benefits in controlling blood glucose and weight, EMS said. Saxenda is part of the same class of medication as Nordisk's popular Ozempic. Read more.

ORDINANCE PUBLISHED EXPANDING THE SCOPE OF THE NATIONAL DRUG POLICY AND UPDATING RULES ON HEALTHCARE PATENTS

The Ministry of Health published, in the Official Gazette of the Union this Monday (28), the Ordinance amending Chapters III and V-A of Annex XXVII of the GM/MS Consolidation Ordinance No. 2, of September 28, 2017, which establishes the National Drug Policy (PNM). Initially, the text amends Chapter III, which addressed pharmaceutical products or processes

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considered of interest to drug or pharmaceutical assistance policies for prior approval review by Anvisa. The new provision broadens the scope, now including medical devices and the purpose of requesting priority processing and submitting information for the technical review of patent applications. Also in this chapter, the ordinance defines as being of interest to the policies on medicines, pharmaceutical care, or medical devices within the SUS (Brazilian Unified Health System), for the purposes of issuing a public advisory opinion to the National Institute of Industrial Property (INPI), any technology subject to legal action seeking access to a medicine or medical device, provided there is a request from the Ministry of Health to Anvisa. The text also addresses the Health Innovation Patent Application Evaluation Group (GAPIS), which must follow the PNM guidelines and the standards applicable to medical devices. The group will be coordinated by a representative from the Secretariat of Science, Technology, and Innovation and the Health Economic-Industrial Complex of the Ministry of Health. Read more.

SENATE COMMITTEE TO BEGIN REVIEWING NOMINATIONS FOR ANVISA AND ANS

The Social Affairs Committee (CAS) is expected to receive reports on the appointment of directors for Anvisa and the National Supplementary Health Agency (ANS) on Wednesday (6) at 10:30 am. The documents present the professional backgrounds of those nominated by the Executive Branch. The committee must grant a collective review—more time for senators to analyze the names—according to Senate rules. The hearings are scheduled to take place the following week. The candidate for ANS CEO is the current National Consumer Affairs Secretary, Wadih Nemer Damous Filho. A former representative, Damous will serve until 2029 if appointed. Senator Sérgio Petecão (PSD-AC) has not yet released his report, which will be read at the meeting. Of the five directorships at Anvisa, senators are evaluating candidates for three of them: - the position of CEO until 2029, which has been nominated former Deputy Secretary of Science and Technology of the Ministry of Health, Leandro Pinheiro Safatle. - board until 2029, nominated Daniela Marreco Cerqueira, who already works at Anvisa as executive secretary of the Chamber for the Regulation of the Medicine Market; - board until 2030, to which Thiago Lopes Cardoso Campos, legal coordinator of the Brazilian Hospital Services Company (MSF 35/2025), was appointed. Read more.

PUBLIC CONSULTATION PUBLISHED ON THE MAIN DIFFICULTIES AND CHALLENGES FACED IN STRENGTHENING CLINICAL RESEARCH IN BRAZIL

The Ministry of Health published, in the Official Gazette of the Union this Friday (1st), a public consultation aimed at gathering feedback from civil society regarding the main difficulties and challenges faced in strengthening the clinical research environment in Brazil. The consultation aims to identify the current situation and the main challenges, considering the capacity of clinical research centers and other relevant information. The information collected will assist in the formulation of public policies that strengthen the clinical research ecosystem, promote technological innovation, and expand public access to new treatments. The contributions, suggestions, and proposals will be systematized by the Department of Science and Technology (Decit/SECTICS/MS), which will prepare a Final Report and submit it to the Secretariat of Science, Technology, and Innovation and the Health Economic and Industrial Complex (SECTICS/MS) for deliberation. Read more.

ANS APPROVES CERTIFICATION TO QUALIFY ONCOLOGY CARE IN SUPPLEMENTARY HEALTHCARE

The National Supplementary Healthcare Agency (ANS) unanimously approved, this Monday (28), the inclusion of the proposals from the Manual of Certification of Good Practices in Oncology Care – OncoRede in the Certification Program of Good Practices in Healthcare for health insurance providers. The decision, which amends Normative Resolution No. 506/2022, was made during the 10th Extraordinary Meeting of the Board of Directors, following a public consultation process that mobilized the sector. Public Consultation No. 144/2024, held between December 2024 and January 2025, received more than 63,000 contributions, the largest volume in the agency's history. The new version of the standard establishes technical criteria to recognize providers that invest in more qualified practices in the care of cancer patients. To

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this end, ANS created a specific certification for oncology care. The model emphasizes initiatives such as continuous monitoring by multidisciplinary teams, faster access to treatment, and the implementation of patient navigation programs, strategies to improve clinical outcomes and healthcare experience. Read more.

SUS PATIENTS WILL BE ABLE TO RECEIVE HEALTH INSURANCE COVERAGE STARTING THIS MONTH

Starting this month, some patients in the Unified Health System (SUS) will be able to receive free care from private health plans under the Ministry of Health's "Agora Tem Especialistas" program. The measure, announced last Monday, will allow providers to exchange debts with the government for the provision of services to public health system users. According to the ministry, the notice outlining the rules for voluntary membership of health plans in the program will be published next Monday, the 4th. A week later, on the 11th, the registration system for health providers will be open. The ministry will then assess whether the plan meets the necessary criteria. If approved, the services will be offered to the SUS (Unified Health System). Read more.

MINISTER OF HEALTH ANNOUNCES NEW INVESTMENTS IN TECHNOLOGICAL INNOVATION IN THE SUS

Health Minister Alexandre Padilha (PT-SP) announced this Friday (July 25) the creation of the country's first RNA Competence Center, focusing on messenger RNA (mRNA). The project is part of a package of investments in innovation in the Unified Health System (SUS), in partnership with the Pan American Health Organization (PAHO) and the Brazilian Company for Industrial Research and Innovation (Embrapii). Read more.

60% OF HEALTH CENTERS NEED RENOVATIONS AND ONLY 9% PERFORM ELECTROCARDIOGRAMS, SAYS UBS CENSUS

Six out of ten Brazilian Basic Health Units (UBS)—the gateways to Unified Health System (SUS) services —need renovations to their physical infrastructure. This information comes from the National Census of UBS, conducted by the Ministry of Health. Of the approximately 45,000 primary health care (PHC) establishments that participated in the survey, just over 27,000 (60.1%) reported that they need structural improvements. Among the main repairs identified, 3,473 need repairs to the walls; 2,271, to the ceiling; 1,974 have problems with the plumbing installations and 2,495, with the electrical installations. Read more.

MORE HIGHLIGHTS

Congresswoman proposes suspension of patents on drugs for HIV/AIDS and other serious diseases in retaliation against the US

<u>Cancer research products may be exempt from Import Tax</u>

Late diagnosis compromises head and neck cancer treatment

BRAZIL NEWS

Trump says Brazil's Lula can call him anytime

Lula's approval rises amid tariff dispute with Trump, poll shows

Brazil's Justice Moraes ignores US sanctions, says he will continue doing his job

Brazilian banks scramble to understand scope of US sanctions on STF justice

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Brazilian companies react to Trump's tariffs with relief and doubt

Brazil sees 35.9% of exports to US facing steeper tariff, pushes reversal for coffee

<u>Trump's 50% Brazil coffee tariff expected to rejig trade, send more beans to China</u>

Trump tariffs spark 'deep concern' among Brazil chemical firms

More tariffs on Brazil would mean steeper slowdown in activity, says IMF

Brazil tightens credit fund rules to limit bank risk-taking

Brazil pauses rate hikes, signals prolonged hold, eyeing US tariffs

Brazil brings forward disassembled electric vehicles import tax hike

