WEEKLY REPORT

12/21/2024

CONSULTORES
Relações Governamentais

THE LONGEST-SERVING HEALTH MINISTER OF HEALTH IN THE LAST 10 YEARS, NÍSIA TRINDADE REACHES THE HALFWAY POINT OF LULA'S GOVERNMENT

Minister Nísia Trindade is close to completing two years as head of Health. Despite pressures and crises involving the ministry, Nísia is the name that has had the most stability in the last 10 years, reaching, this Thursday, 18,717 days in government. The last minister who remained in office for the longest time was Alexandre Padilha, current Minister of Institutional Relations, with just over 3 years as Minister of Health during the Dilma government. Protected by President Lula, Nísia was summoned on seven occasions to provide clarifications in hearings in the Chamber of Deputies. The relationship with Congress was marked by tensions, with disputes over nominations and parliamentary amendments. However, she survived and continued to lead the country's health sector. In 2024, programs such as SUS Digital and Mais Acesso a Especialistas were announced and showed potential to resolve access issues to the Unified Health System (SUS) beyond primary care. However, specialists and the health sector expect to monitor the implementation of these actions. In the area of supplementary healthcare, the Ministry's approach was viewed positively by the sector, both in relation to judicialization and data interoperability, but the sector is still waiting for practical results. On the other hand, the lack of discussions with the ministry about the country's proposal to adopt a single, independent agency for health technology assessment is criticized. Within the scope of the Health Economic-Industrial Complex, the publication of the regulatory frameworks on Partnerships for Productive Development (PDP) and the Local Development and Innovation Program (PDIL) were celebrated. The Ministry has already received proposals from industry, but the year ends without announcing which projects were selected. Sources interviewed by Futuro da Saúde indicate that in addition to resuming programs and restructuring public health in the first two years, the Ministry needs to advance on policies that have already been initiated, as the Lula government is halfway through its term. The third year will be decisive in demonstrating the path that the country should follow. Read more.

LIST OF MEDICATIONS RETURNS TO TAX REFORM

The controversial list of medications that determines which ones will have reduced taxation was returned to the text of the tax reform approved by the Chamber of Deputies yesterday, the 17th. The information is from UOL and CNN. Now, the content will no longer return to the Senate, which has already participated in the review process, and will go to President Luiz Inácio Lula da Silva for approval. The executive branch will have two weeks to approve the proposal. Read more.

CLINICAL TRIALS IN BRAZIL FACES BUREAUCRACY AND LOSES GROUND ON THE GLOBAL STAGE

With one of the largest and most mixed populations in the world, renowned research institutions in the health area, hospitals that are among the best in global rankings and large pharmaceutical laboratories, Brazil would be fully capable of assuming a prominent role in clinical research for new drugs. But that is not what has been happening in recent years. In 2023, according to research by the Association of the Pharmaceutical Research Industry (Interfarma), the country ranked 19th among the nations that participate most in clinical trials, taking part in only 1.6% of the studies initiated in the period. China, first on the list, was involved in 38% of the research, followed by the United States (27%). According to the entity's

calculations, Brazil could reach tenth place, a position that would be consistent with its magnitude in this area. Read more.

GOVERNMENT NOMINATES WADIH DAMOUS FOR ANS AND LEANDRO SAFATLE FOR ANVISA

Health regulatory agencies have already been nominated by the Lula government to fill their main management positions. Among the nominations are Wadih Damous to take over as director of the National Supplementary Health Agency (ANS) and Leandro Safatle for the National Health Surveillance Agency (Anvisa). The nominations for the new directorships of ANS and Anvisa were published in the Official Gazette of the Union on Monday, the 16th, and must be approved in a hearing in the Federal Senate. In addition to these directorships, the order also includes nominations for Daniela Marreco Cerqueira and Diogo Penha Soares to take over the second and third directorships of Anvisa. Except for Diogo, these names were being considered by the sector behind the scenes, as anticipated in an article by Futuro da Saúde. Current head of the National Consumer Secretariat (Senacon), Wadih Nemer Damous Filho was chosen to take the position of CEO of ANS in place of Paulo Rebello, who will leave the position on December 21. Damous was president of the Brazilian Bar Association in Rio de Janeiro and a federal deputy affiliated with the Workers' Party (PT). Leandro Pinheiro Safatle was appointed to serve as CEO of Anvisa, replacing Antônio Barra Torres, whose term also ends on December 21. Safatle is Deputy Secretary of the Secretariat of Science, Technology and Innovation and of the Health Economic-Industrial Complex. He was also executive secretary of the Chamber for the Regulation of the Medication Market (CMED) between 2014 and 2019. Read more.

LULA SENDS 17 NOMINATIONS FOR REGULATORY AGENCIES TO THE SENATE AT ONCE

President Luiz Inácio Lula da Silva has submitted 17 nominations to the Senate for management positions in regulatory agencies. The list of names was published in an extra edition of the Official Gazette of the Union (DOU) this Monday, the 16th. All names will be subject to hearing with senators. As Estadão/Broadcast showed, the vacancy of seats in regulatory agencies caused internal disputes in the government of President Luiz Inácio Lula da Silva and among senators supporting the government in Congress. Read more.

DISMISSAL OF CIVIL SERVANT CONSIDERED FOR DEPUTY DIRECTOR INCREASES TENSION AT ANVISA

The National Union of Employees of National Regulatory Agencies (Sinagências) has released a new statement criticizing the way the National Health Surveillance Agency (Anvisa) is conducting the process of appointing the agency's deputy director. The statement, released on Monday (12/16), classifies the filling of the vacant directorship as a "coup". The trigger was the dismissal of employee Fabrício Oliveira, who was tipped to be the new deputy director. Employees maintain that Oliveira would be the next name on the list of replacements, according to the rules defined by the agency law. Since 2023, with the departure of director Alex Machado, the temporary occupation of the position has occurred as expected: lists are prepared, with the indication of older employees in positions held at the agency. Read more.

ANS PROPOSES NEW RULES FOR READJUSTING HEALTH PLANS AND CO-PARTICIPATION LIMITS

The ANS (National Supplementary Health Agency) presented this Monday (16) the preliminary results of studies to reformulate the rules for adjustments and charges in health plans. The proposal includes changes in the definition of adjustments for collective plans, limits for co-participation, rules for contract termination and the technical review for individual plans. See the main changes under discussion. According to the agency, the detailed proposal will be presented in a public hearing in January 2025 and, if approved, will come into effect in January 2026. Read more.

THE EXPIRATION OF BILLION-DOLLAR PATENTS IS ALREADY MOBILIZING THE PHARMACEUTICAL INDUSTRY IN THE COUNTRY

While large global pharmaceutical companies are increasingly resorting to the courts to extend the patent terms of best-selling drugs, such as Ozempic, the biosimilar and generic industry established in Brazil continues to invest in increasing production capacity and research to capture at least a portion of the billion-dollar market that is opening up. Read more.

117 DRUG PATENTS WILL EXPIRE BY 2028

With the expiration of some drug patents, the pharmaceutical market is likely to undergo major change by 2028. This is because, during this period, 117 drugs will lose exclusivity, according to Abifina. The information is from Valor Econômico. The number alone is already striking. But when the combined sales are analyzed, the impact becomes even more evident. The drugs in question total a market worth between US$5 billion and US$6 billion (R$31 billion and R$37.2 billion), according to the consulting firm Alvarez & Marsal. On the one hand, international pharmaceutical companies are trying to find loopholes to maintain the exclusivity of their drugs for longer. On the other, Brazilian laboratories are waiting for the opportunity to grab a slice of the billion-dollar blockbuster market. Read more.

PHARMACEUTICAL INDUSTRY STILL RELIES ON IMPORTS OF APIS

A survey recently released by the Ministry of Health revealed that the Brazilian pharmaceutical industry is still highly dependent on imports of APIs (Active Pharmaceutical Ingredients), with 90% of these products being of foreign origin. The scarcity of materials of national origin is due to the complexity of developing each ingredient, which involves a long process of research and study, starting on a small scale, with chemical reactions that produce a few grams of the active pharmaceutical ingredient. Read more.

ORDINANCE PUBLISHED ESTABLISHING RULES FOR INTERFEDERATIVE REIMBURSEMENT OF AMOUNTS SPENT ON MEDICINES IN COMPLIANCE WITH COURT ORDERS

The Ministry of Health published, in the Official Gazette of the Union on Friday (20), the Ordinance that establishes the rules for interfederative reimbursement of financial amounts resulting from court orders related to the supply of medicines. The measure defines the procedures for federative entities (States, Municipalities and the Federal District) that provide medicines determined by court order to request reimbursement from the Union. Read more.

JUSTICE ORDERS THE UNION TO PAY R$17 MILLION IN MEDICINE FOR PATIENTS WITH INJUNCTIONS THAT HAD BEEN SUSPENDED UNTIL THEN

Minister Gilmar Mendes, of the STF (Supreme Federal Court), lifted this Thursday (19) the suspension of decisions for the purchase of the high-cost drug Elevidys for children aged 4 to 7 diagnosed with Duchenne muscular dystrophy. Thus, if patients meet the requirements defined by Anvisa (National Health Surveillance Agency), the Union must pay for the treatment. The drug has an average cost of R$17 million and is not yet available in the SUS (Unified Health System). Earlier this month, Anvisa granted registration for Elevidys. It is the first gene therapy drug approved in Brazil to treat ambulatory children (who can still walk) aged 4 to 7 with Duchenne. The rapporteur set a 90-day deadline for the Union to complete the administrative procedures to comply with the injunctions that had been suspended until then. He also submitted the decision for analysis by the collegiate. The referendum is scheduled for the virtual plenary session from February 14 to 21, 2025. Read more.

BILL AIMS TO CREATE A POLICY OF CARE AND AWARENESS WEEK FOR WOMEN IN CLIMACTERIC AND MENOPAUSE

Representative Captain Augusto (PL-SP) presented Bill 4941/2024, which establishes the National Policy of Awareness and Comprehensive Health Care for Women in Climacteric and Menopause. According to the bill, the policy will aim to guarantee free access to hormonal and non-hormonal medications, provided by the Executive Branch in public and private health units

affiliated with the SUS. It also seeks to ensure that diagnostic exams are carried out, offer specialized psychological and multidisciplinary monitoring to women from the time of diagnosis, and provide continuous and personalized treatment. Read more.

RESOLUTION INCLUDES REPRESENTATION FROM THE PHARMACEUTICAL INDUSTRY, MEDICAL DEVICES, AND DIAGNOSTIC MEDICINE IN THE COMPOSITION OF CAMSS

The Ministry of Health published in the Official Gazette of the Union on Thursday (19), the Normative Resolution that amends Normative Resolution No. 482, of March 16, 2022, which establishes the Internal Regulations of the Supplementary Health Chamber (CAMSS), to include new representatives. Thus, representatives from the following segments will be included in the composition of CAMSS: the pharmaceutical industry; the medical equipment industry; and diagnostic medicine. Read more.

CREATION OF THE PARLIAMENTARY FRONT FOR THE PHARMACEUTICAL INDUSTRY IS APPROVED

At a meeting of the Steering Committee of the Federal Senate, held this Tuesday (17), Resolution Project 69/2023 was approved, which creates the Parliamentary Front for the Development of the Pharmaceutical Industry and Production of Active Pharmaceutical Ingredients in Brazil. The creation of the front is an initiative of Senator Astronaut Marcos Pontes (PL-SP) and aims to create an environment conducive to the discussion and implementation of measures that seek to reduce external dependence, promoting the country's autonomy and productive capacity. Read more.

MORE HIGHLIGHTS

Ministry of Health launches vaccine distribution dashboard

Anvisa approves new rules for regulating medicines

SCMED launches panel to consult drug price requests

New CNS advisors are sworn in in Brasília

Bill aims to ensure adequate treatment for patients with rare diseases

Brazil records lowest AIDS mortality in a decade, says Ministry of Health

BRAZIL NEWS

Brazil's Lula leaves hospital, speaks publicly for first time since surgeries

Case against Brazil coup plotters could end decades of impunity

Brazil Congress votes on fiscal package; changes could limit impact

Brazil lawmakers pass key regulations to enact tax reform

Delay to EU deforestation law confirmed after countries approve

Can the bioeconomy help save the Amazon from deforestation?

Forensic technology aids Brazil's crackdown on illicit Amazon gold trade