

# WEEKLY REPORT

07/20/2024



## **HEALTH INDUSTRIAL ECONOMIC COMPLEX WORKSHOP PRESENTS GUIDANCE FOR PREPARING AND SUBMITTING PROJECT PROPOSALS FOR THE PDIL AND PDP PROGRAMS**

A workshop at the Health Industrial Economic Complex of the Ministry of Health was held this Thursday (18), in which information was presented for the preparation and submission of project proposals for the Partnerships for Productive Development (PDP) programs and the Program of Local Development and Innovation (PDIL) for the development of the Health Economic-Industrial Complex. The programs were established through ordinances 4472/2024 and 4473/2024. The Partnerships for Productive Development (PDP) program seeks to encourage cooperation with private, public, and scientific entities for projects focused on the development, transfer and absorption of technologies that benefit the SUS. The Local Development and Innovation Program foresees strategic health alliances with public institutions, private non-profit entities, and startups. At the opening of the event, Leandro Pinheiro Safatle, director of the Department of the Industrial Complex and Innovation in Health, contextualized the published regulations aimed at reconstructing the CEIS structure, highlighting the creation of the department of the Economic-Industrial Complex of Health and Innovation for the SUS on January 1, 2023 and the executive group, for government coordination and formulation of measures to strengthen production and innovation to serve the SUS, made up of 20 public bodies, 11 ministries and 9 government bodies. He highlighted that the policies were made in a well-connected way, thinking about platform logic to serve the SUS. [Read more.](#)

## **STUDY INVESTIGATES POLITICS AND GOVERNANCE IN TECHNOLOGY TRANSFER**

Medicines production and technology transfer in low- and middle-income countries are crucial to ensuring affordable medicines and strengthening technological capacity. Therefore, the local manufacturing of innovative pharmaceutical products is an important goal for health and industrial policies, especially in Latin America. However, there is a gap in knowledge about the policy and governance that makes these arrangements viable, especially when there is no consent from the company holding the patent. Brazil is historically known for promoting policies that encourage the production of generics and the development of the local pharmaceutical industry. For 20 years, the country has promoted public-private technology transfer initiatives, called "partnerships for productive development" (PDPs). Researchers Helena Achcar and Elize Massard da Fonseca, from the São Paulo School of Business Administration (FGV EAESP), analyze this context under study, in which they discuss politics and governance in the local production of Sofosbuvir, an innovative drug for treating Hepatitis C. [Read more.](#)

## **BNDES SUPPORT FOR THE PHARMACEUTICAL INDUSTRY IN 2024 REACHES A RECORD VALUE OF R\$2 BILLION**

Credit approvals from the National Bank for Economic and Social Development (BNDES) for the Brazilian pharminochemical and pharmaceutical industries until mid-July 2024 reached a record. The value reached R\$2 billion and is the highest recorded since 1995. [Read more.](#)

## **HEALTH ENTITIES COMPLAIN ABOUT ANVISA'S DELAY IN APPROVING MEDICINES**

Eleven entities in the health sector, including Grupo FarmaBrasil, Abifina and Sindusfarma, sent a letter to Anvisa's board of directors to complain about the decrease in the pace of approval of medicines in the body, amidst the movement to stop regulatory agencies, reported Veja

magazine. The associations and unions also asked for a meeting with Anvisa management, to find ways to minimize impacts and maintain the availability of products for the Brazilian population. In the document, the signatories pointed out that the National Union of Employees of National Regulatory Agencies, which has led the strike movements, found that there was a 15-day delay in approving 30% of import consents. Previously the deadline was one day. According to the entities, seven major areas of the agency are no longer scheduling hearings, and there has been a decrease in the frequency of publications, from weekly to fortnightly or monthly. And delays in cargo releases at ports, airports, borders, and customs areas are already starting to harm medicine production planning. [Read more.](#)

### **ANVISA WILL REVIEW RULES FOR ADVANCED THERAPY TRIALS**

With the sanction of Law 14,874/2024, which regulates the conduct of clinical trials with human beings and establishes the National System of Ethics in Research with Human Beings, the National Health Surveillance Agency (Anvisa) intends to update the standards relating to the trials for advanced therapies. "We will begin the review immediately after this approval [sanction]. The agency will comply with the laws, this is its role, and the same is already being done for medicines in general", stated Fabrício Carneiro, manager of Biological Products, Blood, Tissues, Cells, Organs and Advanced Therapy Products at Anvisa, in a seminar on rare diseases held in the House of Representatives before the presidential sanction. [Read more.](#)

### **ANVISA PROVIDES A TOOL FOR UPDATING PROVISIONAL DRUG PRICES**

The Executive Secretariat of the Medicines Market Regulation Chamber (SCMED) informs that the tool for updating provisional medicine prices is available in the Medicines Market Monitoring System (Sammed), web module. This is a specific tool for fulfilling obligations relating to medicines provisionally priced by CMED. The evolution of the system is part of Anvisa's Digital Transformation Plan, which prioritized, between 2023 and 2024, several corrective and evolutionary actions in Sammed. These actions have provided improvements in analysis time and traceability of medication pricing processes. [Read more.](#)

### **SENACON STRENGTHENS STRATEGIES TO COMBAT PIRACY AND SMUGGLING IN HEALTHCARE, WITH PARTICIPATION IN AN INTERNATIONAL EVENT**

The fight against piracy and smuggling crimes in the health sector and in the digital environment was the theme of a series of meetings that took place in Buenos Aires, Argentina, and which included the participation of the Ministry of Justice and Public Security (MJSP), through the National Consumer Secretariat (Senacon). Organized by the regional office of the International Criminal Police Organization (Interpol) and the IP KEY project, the European Union's intellectual property institute, the event brings together police officers, intelligence agents, customs inspectors, and other professionals from several South American countries. For the executive secretary of the National Council to Combat Piracy and Crimes against Intellectual Property (CNCP), Andrey Correa, "the collaboration between the various professionals and the exchange of experiences during the event promise to strengthen the fight against these crimes and protect the health of South American citizens", he highlighted. [Read more.](#)

### **NEW VERSION FOR BILL ON RARE DISEASES AIMS TO ESTABLISH NATIONAL ATTENTION POLICY**

Representative Daniel Agrobom (PL-GO) presented, at the Committee for the Defense of the Rights of People with Disabilities, a new version of Bill 4691/2019, which intends to make the notification of rare diseases mandatory. The new text establishes that, among the principles of public health actions and services and the contracted or agreed private services that make up the SUS, will be actions aimed at promoting, protecting, and recovering mental health, individual and collective, for people with illnesses rare species and their caregivers. The proposal will also define the national management of the SUS, the competence to formulate, finance, evaluate, and participate in the execution of public health actions and services to assist people with rare diseases. In the absence of a clinical protocol or therapeutic guideline,

dispensing will be carried out in the case of rare diseases, based on the recommendations of medical associations of specialists in the disease or health problem for which the medication was prescribed, regardless of the patient's medication list. The text also explains that in the evaluation for the incorporation of medicines intended for the treatment of rare diseases, the cost-effectiveness assessment will be waived, when there is no other medicine for comparison that can be used in the same situation. [Read more](#).

### **COOPERATION AGREEMENT BETWEEN ABRAMED AND THE MINISTRY OF HEALTH IS BEING FORMALIZED AND SHOULD BE DETAILED AT THE END OF AUGUST**

The technical cooperation agreement between the Ministry of Health and the Brazilian Association of Diagnostic Medicine (Abramed) with the aim of standardizing exam data and, consequently, facilitating the transit of information in the SUS is in the process of being formalized and should be detailed at the end of August. The information was confirmed by Abramed to Futuro da Saúde. The entity's expectation is that more details will be released at an event that will be held by Abramed on August 29 in São Paulo, SP. The agreement was mentioned by the secretary of information and digital health, Ana Estela Haddad, in a press conference at the Ministry of Health on Tuesday, 16th. The partnership involves the direct transmission to the government of information on compulsory notification tests conducted by the laboratories, through the National Health Data Network (RNDS). [Read more](#).

#### **MORE HIGHLIGHTS**

[Ministry of Health provides information cancer treatment in Brazil](#)

[Law establishes September 17th as Muscular Dystrophy Awareness Day](#)

[Bill establishing State Fabry Disease Awareness Day is forwarded for analysis to the Constitution Committee](#)

[Representative requests urgency regime for the bill that defines the prioritization of processes involving neonatal screening](#)

#### **BRAZIL NEWS**

[Lula condemns attack on Donald Trump: "unacceptable"](#)

[Brazil's Lula questions need for spending cuts, hints at missing fiscal target](#)

[Brazil freezes \\$2.7 billion from 2024 budget after market turmoil](#)

[Brazil holds 2024 GDP projection at +2.5%, raises inflation forecasts](#)

[Brazil government pushes central bank to handle rural insurance, say sources](#)

[Brazil secures deal for G20 consensus documents ahead of Rio meetings, official says](#)

[Brazil air traffic control not affected by global outage, but some flights delayed](#)

[Meta decides to suspend its generative AI tools in Brazil](#)