

WEEKLY REPORT

06/15/2024



PROTECTION IN DRUG TRIALS COULD DELAY GENERICS, DEBATERS SAY

The delay in the development of generic medicines may be one of the consequences of the secrecy of laboratory tests on human medicines. The risks and benefits of Anvisa's protection in the pharmaceutical segment were presented to the Science and Technology Commission (CCT) by sector experts in recent weeks. Currently, the rule only applies to the use of veterinary medicines and pesticides, among other similar items. The so-called regulatory protection of the test dossier (PRDT) protects new products from competition for a set period. When the manufacturer sends clinical information to Anvisa to register the product, it is also used by the agency to compare with versions from other companies and thus also authorize the generic product. But, according to Law 10,603, of 2002, which does not apply in the case of medicines, when the results of the tests involve "considerable effort" and "have commercial value while not disclosed", the information becomes confidential and creates barriers for the registration of generics. But in the opinion of the president of the Brazilian Intellectual Property Association (ABPI), Gabriel Leonardos, protecting new products would encourage investment in pharmaceutical innovation. He defended confidentiality regarding clinical tests for five to ten years, the same as the law stipulates for veterinary products and pesticides. This was the last of three public hearings on the subject. [Read more.](#)

REPRESENTATIVE PRESENTS NEW VERSION FOR BILL ABOUT WOMEN'S CARE AND AWARENESS ABOUT MENOPAUSE AND CLIMACTERIC

Representative Socorro Neri (PP-AC) presented at the Commission for the Defense of Women's Rights (CMULHER), a replacement for Bill 5602/2019, which creates the Program for Attention to Women in Menopause and Menopause and establishes the Day National Menopause Awareness. Authored by former deputy Bia Cavassa, the matter is being processed alongside bills 4574/2021, by former deputy Marília Arraes; 4950/2023, authored by Lêda Borges (PSDB-GO); and 1330/2023, authored by deputy Silvyne Alves (União-GO), for addressing related topics. The proposal aims to ensure that patients have access to diagnostic tests and, at the same time, seeks to raise awareness about the importance of adopting healthy habits to prevent common diseases during menopause and menopause. Furthermore, the substitute aims to ensure the continuous training of health professionals, access to hormone replacement and other recommended therapies, monitoring by a multidisciplinary team, including psychological support, and the regular review of clinical protocols and therapeutic guidelines, incorporating new technologies as necessary. [Read more.](#)

PUBLIC HEARING DEBATES THE DIFFICULTIES FACED BY PEOPLE WITH POMPE SYNDROME

On Tuesday (11), the Committee for the Defense of the Rights of People with Disabilities held a public hearing where the difficulties faced by people with Pompe syndrome were discussed. The debate was requested and chaired by representative Sargento Portugal (Podemos-RJ). Nathan Monsores, coordinator in the Ministry of Health, said the organization of services for the population with Pompe disease is not limited to medication alone. In the current global scenario, there are two technologies (proteins) being dispensed, and the therapy chosen by pharmaceutical industries to treat the disease is enzyme replacement therapy. The coordinator also highlighted that new diagnostic technologies related to the National Neonatal Screening Program will be added, such as mass spectrometry, used in metabolic diseases, molecular technologies and, in the future, genetic tests available throughout the network. [Read more.](#)

DRUG WORTH R\$6.2 MILLION DID NOT REACH THE SUS EVEN AFTER INCORPORATION

Despite the announcement of the inclusion of the drug Zolgensma in the SUS (Unified Health System) in December 2022, the treatment remains unavailable to patients with Spinal Muscular Atrophy Type 1 and their families. According to Novartis Brasil, manufacturer of the therapy, four meetings have been held with the Ministry of Health since the positive recommendation for incorporation, with the submission of two draft proposals. [Read more.](#)

ONLY 48% OF BRAZILIANS HAVE EVER HEARD OF NEONATAL SCREENING

This month is marked by the June Lilac movement, an awareness campaign about the importance of neonatal screening for the health of newborns. Although the heel prick test plays a fundamental role in the early identification of medical conditions that can affect the development and quality of life of babies, its importance is still little known by the general population. According to a survey carried out by the Ipsos Institute, at the request of the Swiss pharmaceutical company Novartis, only 48% of Brazilians have heard of neonatal screening and 60% knew how to correctly define what the heel prick test is for. [Read more.](#)

LAWSUITS ON THE HEALTH SECTOR GREW BY 21.3% IN THE LAST TWO YEARS

Judicial authorities gathered at the opening of the 1st Health Law Day, this Thursday (13), expressed their concern about the growth of the judicialization of health in Brazil. The vice-president of the Superior Court of Justice (STJ) and the Federal Justice Council (CJF), minister Og Fernandes, when leading the opening session, stated that the theme of the event "permeates judicialization at a worrying level and deserves appropriate treatment, which takes public health policy into account, without losing sight of its recipient". The national inspector of justice, minister Luis Felipe Salomão, highlighted the urgency of expanding the discussion on the judicialization of health in its different contexts: "Data from the National Council of Justice (CNJ) indicate that, between 2022 and 2023, the number of lawsuits involving the health sector grew by 21.3%. This alarming figure reflects not only on judicial provision, but also on public budgets", he said. [Read more.](#)

PROGRAM AIMS TO PROVIDE SPECIALIZED CARE IN THE SUS

The Ministry of Health detailed this Wednesday (12) how the More Access to Specialists Program will work, which aims to expand and qualify access to specialized health care. The program will have an investment of R\$1 billion, in 2024, to increase the availability of consultations, exams and other diagnostic and therapeutic procedures, reducing queues and waiting times. The program was launched in April, but today six ordinances were published detailing the planned actions. So far, 1,237 municipalities have signed up to the program, in addition to 10 states: Ceará, Amazonas, Santa Catarina, Roraima, Paraná, Pernambuco, Piauí, Paraíba, Goiás and Bahia. According to the Minister of Health, Nisia Trindade, the idea is that patients have a single queue, a single appointment, and a guaranteed return to the family health unit to monitor the case. [Read more.](#)

CONSUMER PROTECTION ENTITIES ASK FOR PARTICIPATION IN AGREEMENT BETWEEN ARTHUR LIRA AND HEALTH INSURANCE PLANS

Idec (Institute for Consumer Protection) sent this Monday (10) a letter to the president of the Chamber of Deputies, deputy Arthur Lira (PP-AL), questioning the fact that the agreement between him and the health operators, to suspend the unilateral terminations of collective contracts do not count on the participation of consumer protection entities and civil society. When she announced the verbal agreement, on the 28th, Lira signaled that she would hear from consumer protection entities in the following days, but, so far, this has not happened. The cancellations affected children with autism, rare diseases, cerebral palsy, as well as patients with cancer and other serious illnesses and resulted in an increase in complaints to the ANS (National Supplementary Health Agency), federal government channels and health care entities. Consumer defense. [Read more.](#)

AFTER 2 YEARS OF LOSSES, HEALTH INSURANCE PLANS HAVE AN OPERATING PROFIT IN THE 1ST QUARTER

After two years with negative results in the first quarter, health plan operators recorded an operating profit of R\$1.8 billion, between January and March 2024. As a result, the sector reversed a loss of R\$1.6 billion calculated a year earlier, according to data from the National Supplementary Health Agency (ANS). [Read more](#).

MORE HIGHLIGHTS

[Approved bill that makes the examination to identify rare diseases in newborns mandatory in the SUS and in the private network](#)

[Representative presents favorable opinion to the bill that establishes the Support Program for Donation Campaigns for the Acquisition of High-Cost Medicines](#)

[Ministry of Health will provide information on the regulation of the National Cancer Prevention and Control Policy in the SUS](#)

[Limiting correction of Health and Education floors faces resistance from the government and the PT](#)

BRAZIL NEWS

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