WEEKLY REPORT

06/01/2024

SANCTIONED, WITH VETOES, THE LAW ABOUT CLINICAL TRIALS IN BRAZIL

Law No. 14,874, of May 28, 2024, was sanctioned, with vetoes, by the President of the Republic with new rules for the clinical trials and for the National System of Ethics in Research with Human Beings. The regulations, published in the Official Gazette of the Union this Wednesday (29), originated from Bill 6007/2023, sponsored by former senators Ana Amélia, Waldemir Moka and Walter Pinheiro. The Law establishes ethical and scientific requirements in research, instances of ethical review, protection of volunteers, and responsibility of researchers and sponsors. Furthermore, it creates rules for the manufacture, use, import and export of goods or products for this type of research. Rules are also set for the storage and use of data and human biological material. Read more.

PARTIAL VETO ON CLINICAL TRIALS BILL SUSPENDS POSSIBLE INTERRUPTION OF POST-STUDY SUPPLY AFTER 5 YEARS OF COMMERCIAL AVAILABILITY

The article that defined that the free supply of the experimental drug in the post-study supply program could be interrupted, upon submission of justification to the CEP, for consideration, within a period of 5 years, counting from the commercial availability of the experimental medicine in the country, was vetoed. Country. In justification of the veto, it was informed that "currently, all participants are guaranteed, at the end of the study, by the sponsor, free and indefinite access to prophylactic, diagnostic and therapeutic methods that have proven to be effective". Furthermore, it was reported that "the interruption of the supply of the medicine in the post-study period violates the rights of research participants and compromises the eventual development of ethical research based on principles of dignity, beneficence and justice". Therefore, it was argued that "the experimental medicine must continue to be supplied to research participants, regardless of its commercial availability by the private sector." Another vetoed device was the one that intended to guarantee communication to the Public Ministry about the participation of a member of an indigenous group in research. Read more.

HEALTHCARE OPERATORS SUSPEND TERMINATION OF PLANS

After the threat of an investigative parliamentary committee (CPI) in the Lower House, healthcare plan operators promised on Tuesday (28) to suspend the unilateral termination of contracts for individuals undergoing continued treatment for serious illnesses and autism spectrum disorder (ASD). They also promised not to carry out new exclusions of users from group health insurance plans and those aimed at small and medium-sized enterprises until the conclusion of the debate on the bill establishing new rules for the sector. The agreement was negotiated in a meeting attended by Lower House Speaker Arthur Lira and congressmen Duarte Júnior, the bill rapporteur, and Mário Heringer, who is a physician, with trade associations representing the sector. At the meeting, healthcare operator Amil informed that 35,000 users will not have their contracts terminated. Unimed's number ranges between 20,000 and 40,000. A new meeting is expected for next week with the Brazilian Federal Council of Medicine and consumer protection agencies to discuss the bill. Read more.

ANVISA APPROVES NEW REGULATION FOR REGISTRATION OF BIOSIMILAR DRUGS

Anvisa approved, at the Collegiate Board meeting this Monday (27/5), the new regulation for the registration of biosimilar drugs. The objective of the new standard is to simplify the development process of these products, based on the safe relaxation of requirements. The regulation will make it possible to waive some specific steps and studies, when technically

feasible, thus promoting a transparent and predictable regulatory environment for the sector. The points and requirements for proving comparability between products were exhaustively discussed during the regulatory process. One of the novelties of the new regulation is the possibility of using a comparator reference medicine acquired in international territory in a situation of unavailability and if the necessary technical requirements have been proven. Read more.

MINISTRY OF HEALTH PROVIDES INFORMATION ON THE INCREASE IN THE PRICE OF DRUGS

The Ministry of Health responded to request 790/2024, which requested information from the Ministry of Health about the increase in medicines authorized by Resolution 1/2024. In response, the Ministry of Health claimed that the economic regulation of the Brazilian pharmaceutical market is based on a price ceiling model, as established by Law 10,742/2003. In this model, specific criteria are defined for setting and adjusting the maximum sales prices for medicines. He explained that CMED is responsible for establishing these maximum prices, both the Factory Price (PF) and the Maximum Consumer Price (PMC) and the Maximum Sales Price. Furthermore, it informed that retail units must keep medicine price lists updated, which cannot exceed the prices published by CMED on the Anvisa Portal. Read more.

NÍSIA TRINDADE MAKES HER TENTH DISMISSAL FROM STRATEGIC POSITIONS IN HEALTH SINCE THE BEGINNING OF THE YEAR

After being the target of pressure and facing wear and tear in the management of federal hospitals, the Minister of Health, Nísia Trindade, yesterday dismissed the general coordinator of Hospital Governance in Rio de Janeiro, Carlos Ney Pinho Ribeiro. The decision was published in the Official Gazette and adds to at least nine other changes in strategic positions in the Health department since the beginning of the year. Read more.

AT WHO, BRAZIL DEFENDS GLOBAL TECHNOLOGY TRANSFER TO FACE PANDEMICS

During the official opening of the 77th World Health Assembly, Secretary Carlos Gadelha, Brazilian representative on the agenda, argued that "the main challenge now is the agreement on the pandemic, a critical decision for human society". The agenda deals with new rules for responding to pandemics at a global level, such as the transfer of technologies to expand access to healthcare. "Will we rebuild the global health order after millions of deaths or will we wait for the next pandemic to cry again?", questioned, in his speech, Gadelha, who is Secretary of Science, Technology and Innovation and the Health Economic-Industrial Complex , of the Ministry of Health. Read more.

MORE HIGHLIGHTS

Favorable opinion presented to the bill about composition criteria and transparency to Conitec

Anvisa releases annual clinical trial report

Waterborne illnesses now threaten flood-ravaged southern Brazil

Dengue cases in Americas surpass last year's record high, WHO says

BRAZIL NEWS