WEEKLY REPORT

05/11/2024

DEADLINE FOR DECISION ABOUT THE BILL ON CLINICAL TRIALS IS MAY 28

The Federal Senate sent, this Wednesday (08), Bill 6007/2023, about clinical trials, to be analyzed by the Presidency. The President of the Republic has until 05/28/2024 to decide whether to fully approve the matter or apply vetoes. The bill proposes to guarantee rights to participants of the trials, as well as establish duties for researchers, sponsors and entities involved. Another key point is the 90-working day period given to the National Health Surveillance Agency (Anvisa) to analyze primary petitions for clinical trials with human beings, aiming at the health registration of the product under investigation. The legislation also ensures that, before the start of the clinical trial, the sponsor and the researcher must submit to the Research Ethics Committee (CEP) a post-study access plan, in which they must present and justify the need, or not, for provide the experimental medicine free of charge after the end of the clinical trial to participants who need it. Read more.

ANVISA WILL HOLD A PUBLIC CONSULTATION TO UPDATE CLINICAL TRIAL RULES

The National Health Surveillance Agency (Anvisa) will open a public consultation to debate the review of Collegiate Board Resolution (RDC) No. 9, of February 20, 2015, which provides for the regulations for carrying out clinical trials in Brazil. The review was motivated by the need for greater harmonization with international standards, in addition to providing a more favorable environment for clinical research in Brazil, but without affecting the safety of therapies. The director responsible for the matter, Meiruze Freitas, cited the recent approval in the National Congress of Bill No. 6007 of 2023, which updates the rules for studies with human beings in Brazil. "In this context, this review is necessary. We highlight that clinical development is fundamental for the country, and also goes hand in hand with strengthening the Health Industrial Complex", said Freitas. Read more.

BILL AIMS TO CHANGE THE REGULATION OF THE MEDICINES MARKET REGULATION CHAMBER

Representative Adriana Ventura (Novo-SP) sponsored Bill 1732/2024, aiming to change the regulation of the Chamber of Regulation of the Pharmaceutical Market Medicines - CMED. The matter proposes that the CMED Council of Ministers may authorize positive or negative price adjustments. It also seeks to determine that CMED will be able to establish factory prices for generic medicines at a different level from the reference medicine, which must be adjusted, for all existing or future registrations, whenever there is a positive or negative adjustment in the price of the reference medicine. The proposal aims to define CMED's obligation to adopt a periodic price review system, where the periodicity of reviews must be fixed in cycles not exceeding 5 years. Furthermore, the PL also adds to CMED's competencies the duty to monitor, in cooperation with the National Consumer Protection System and the Brazilian Competition Defense System, the occurrence of anti-competitive practices in the medicines market. Read more.

GOVERNMENT AND EXPERTS SUPPORT FUTURE LAW ON SINGLE ELECTRONIC MEDICAL RECORDS IN BRAZIL

Representatives of the federal government, states and municipalities and health experts expressed support and presented this Tuesday (7), in the Chamber of Deputies, specific suggestions for the idea of consolidating the rules of the single electronic medical record into federal law, gathering detailed information from health of users of the country's public and private systems. The measure is provided for in Bill 5875/13, from the Senate, and in 29 other annexes. The proposals are being analyzed by the Health Committee and have as rapporteur the deputy Adriana Ventura (Novo-SP), who proposed the debate in the collegiate. Read more.

REPRESENTATIVE PROPOSES WORKING GROUP ON NATIONAL STRATEGY FOR THE DEVELOPMENT OF THE HEALTH ECONOMIC-INDUSTRIAL COMPLEX

Representative Jandira Feghali (PCdoB-RJ) presented, to the Health Committee of the House of Representatives, request 125/2024, which proposes the creation of a Working Group to monitor the implementation of the National Strategy for the Development of the Economic-Industrial Complex of Health and the 'New Industry Brazil' policy, as well as the progress of the proposals contained in the report of the Health Economic-Industrial Complex Subcommittee. According to the parliamentarian, the subcommittee was installed by the collegiate in 2021, and she herself chaired it. Read more.

AT A MEETING OF THE HEALTH COMMITTEE, REPRESENTATIVES CRITICIZE THE INPI'S DELAY IN RELEASING DRUG PATENTS

At a meeting of the Health Committee of the House of Representatives held this Wednesday (08), representatives from Mozambique delegation discussed HIV and Acquired Immunodeficiency Syndrome (AIDS). During the meeting, representative Jandira Feghali (PCdoB-RJ) highlighted the pressing need for certain medicines for the diseases mentioned by SUS users, however, she emphasized the difficulties encountered at INPI in releasing the patents for these medicines, aiming for production by public laboratories. She reported that the matter was taken to the Ministry of Health and highlighted the importance of intervening in the distribution of innovative medicines. She proposed that the committee should promote a public hearing on HIV and AIDS, addressing the stages and challenges, to explore ways to contribute to the government in the evolution of this issue. Read more.

CONSUMERS DEFEND THE RETURN OF THE PRINTED LEAFLET ON ALL MEDICINES

Since 2022, thanks to a change in Law 11,903/09, the National Health Surveillance Agency (Anvisa) can determine that some medicines do not have a printed leaflet - only digital, readable by reading a QR code printed on the medicine's packaging. But a bill (PL 715/2024) that is being analyzed in the Chamber ends this permission that was given to Anvisa. The possible implications of this change were discussed by the Chamber's Health Committee in the presence of representatives from the Federal Pharmacy Council and other associations and federations in the sector. The representative of a movement called Exija a Bula, Alexandre Rolf de Moraes, expressed concern about the current legislation. “Whose mother and father here can access a digital leaflet? Which grandmother has the ability to open a device? The Demand the Bull movement is not against the digital medium. Our life, part of it, is digital. We have to maintain both means,” he stated. Read more.

RESEARCH AIMS TO DEEPEN KNOWLEDGE ABOUT SUS SPENDING ON MEDICINES

Investigating the expenditure of the Union, states and municipalities on medicines, in order to draw up a diagnosis of problems related to the financing of pharmaceutical assistance, is the objective of the research “Pharmaceutical Assistance in the SUS”, launched this Monday (06/05) by the Institute of Applied Economic Research (Ipea) in partnership with the National Council of Municipal Health Secretaries (Conasems) and the National Council of Health Secretaries (Conass). Read more.

LUNG CANCER TREATMENT IN THE SUS IS 10 YEARS OUT OF DATE

A new study conducted by the Oncoguia Institute compared the treatments offered in the SUS (Unified Health System) with national and international guidelines for five types of cancer (breast, prostate, colorectal, lung and melanoma). The research "Does my SUS continue to be different from your SUS?", released at the opening of the 14th National Oncoguia Forum, on Wednesday (8), in São Paulo, sought to identify patterns and differences in the treatment offered by SUS oncology hospitals to patients all over the country. Of the 318 hospitals that treat cancer through the SUS, 268 were contacted across the country. Of this group, 95 hospitals responded to the survey, 64 of which provided sufficient and satisfactory information to be analyzed. Regarding lung cancer, it is the 4th most common in the country, but comes first in number of deaths, according to data from Inca (National Cancer Institute). Read more.

ASTRAZENECA STOPS MANUFACTURING VACCINE AGAINST COVID-19

The pharmaceutical company AstraZeneca reported that it will stop manufacturing the vaccine against Covid-19. The vaccine can no longer be used in the European Union after the company voluntarily withdrew its "marketing authorization". The request to withdraw the vaccine was made on March 5 and came into force on Tuesday. In Brazil, the vaccine is produced by the public laboratory Fiocruz. Read more.

MORE HIGHLIGHTS

Bradesco Seguros, Rede D'Or create new hospital group

Result of the Working Group on the National Care Policy is presented at a public hearing in the Chamber of Deputies

Appointed rapporteur on bill about deadline for access to technologies approved in the public health system

Interfarma and Fifarma hold Innovation Day Brasil 2024

BRAZIL NEWS

Brazil polls show mixed scenario for Lula's approval ratings

Brazil to examine changes to pension benefit calculations in spending review

Brazil officials eye curbs on pension spending, but Lula may resist

Brazil inflation slightly exceeds forecasts in April as pace of rate cuts slows

Brazil markets fall as central bank split decision triggers concern about dovish turn

Brazil ex-president Bolsonaro hospitalized again with skin infection

Floods put Brazil's 2% GDP growth at risk

Death toll from floods in Brazil hits 126 as rain returns

Government plans to inject R$51bn into Rio Grande do Sul's economy

Government fears dismantling of environmental rules

Xi Jinping to promote Belt and Road during visit to Brazil