WEEKLY REPORT

11/23/2024

CONSULTORES
Relações Governamentais

ANVISA PROVIDES INFORMATION ON THE REGISTRATION OF THE DRUG VEOZA

The National Health Surveillance Agency (Anvisa) responded, by means of an official letter, to the request from Congresswoman Laura Carneiro (PSD-RJ), who requested information on the registration of the drug Veoza, indicated for the treatment of moderate to severe vasomotor symptoms (SVM) associated with menopause. The registration request was filed with Anvisa in May 2023. However, the agency clarified that the drug is not among the priority treatments for registration analysis, being classified in the ordinary analysis category. In addition, Anvisa reported that the reason why there has not yet been a decision on registration is the lack of staff, since there is no forecast of replacing the workforce in the short term, which has made it difficult to meet the goals, especially with regard to the publication of registrations and post-registration monitoring within the established deadlines. Read more.

ANVISA BACKTRACKS AND AUTHORIZES HORMONAL IMPLANTS; DECISION DIVIDES DOCTORS

The National Health Surveillance Agency (Anvisa) revoked, this Thursday, the 21st, Resolution No. 3,915, which suspended the commercialization, manipulation, advertising, and use of hormonal implants in Brazil. The decision was published in the Official Gazette of the Union, without a detailed position from the regulatory agency. Contacted by Estadão to clarify the reasons for the change, Anvisa stated that the measure "is still under investigation". The ban on hormonal implants was implemented in October of this year, when the agency warned about the risks associated with the indiscriminate use of anabolic hormones, such as testosterone, oxandrolone and gestrinone. Such substances were often administered through implants produced in compounding pharmacies and inserted under the skin, usually in the buttocks or abdomen. Among the adverse effects mentioned by the agency at the time were hypertension, dyslipidemia, stroke, cardiac arrhythmias, and hormonal changes, including hirsutism (increased hair growth) and alopecia. In addition, Anvisa also highlighted the lack of control over the quality, safety, and efficacy of the manipulated products, determining factors for the ban. Read more.

PHARMACEUTICAL ENTITIES JOIN FORCES IN MANIFESTO FOR REGULATORY AGENCIES

Several pharmaceutical entities have signed the Manifesto for Regulatory Agencies, a text that seeks to expose obstacles faced by government agencies in Brazil and indicate possible actions for improvement, guiding the debates that have begun in the National Congress. The Legislative Assembly recently began to debate the functioning of public agencies such as Anvisa, which has been constantly criticized for a crisis of inefficiency and slowness. The health agency was even called out by President Lula, at an event organized by EMS in August. The text, supported by entities such as ABIIS, ABIMED, ABIMO, ABIFINA, ABIFISA, ABIQUIFI, ABRALDI, ABRASP, ACESSA, ALANAC, CBDL, Grupo Farma Brasil, Interfarma, PróGenéricos, Sinfar-RJ, Sindicis, Sindifargo and Sindusfarma, makes them available for an in-depth discussion and exposes topics highlighted as fundamental by them. Read more.

LEGAL DISPUTE OVER PATENTS FOR ESSENTIAL MEDICINES INCREASES AFTER STF DECISION

In the wake of the COVID-19 pandemic, a legal battle has intensified between pharmaceutical giants and generic drug manufacturers, disputing the extension of patents for 62 essential

drugs, such as Saxenda, Ozempic and Stelara. The companies that own the original formulas are seeking to extend the exclusivity of sales beyond the 20 years provided for by law, facing a significant obstacle after a decision by the Brazilian Supreme Court (STF) in 2021. The decision deemed a previous legal understanding unconstitutional. This scenario directly impacts the availability of lower-priced drugs on the market. Read more.

ANS SIGNS TECHNICAL COOPERATION AGREEMENT WITH CNJ

The National Supplementary Health Agency (ANS) has just signed a technical cooperation agreement with the National Council of Justice (CNJ) with the aim of preventing judicialization in the supplementary health sector. The document was signed on Thursday, November 21, by the Agency's CEO, Paulo Rebello, and by the president of the CNJ and the Federal Supreme Court (STF), Minister Luís Roberto Barroso, during the opening of the 3rd Congress of the National Judiciary Forum for Health (Fonajus), in São Paulo. In addition to its main objective, the agreement aims to ensure speed in the judgment of existing cases and to offer technical and scientific support for judges' decision-making. "The agreement signed with the CNJ is a milestone for regulation and supplementary healthcare in Brazil. The instrument demonstrates a joint effort by both bodies in the search for efficient and consensual solutions to the challenges faced by the sector," declared Rebello. Read more.

FUX ORDERS GOVERNMENT TO PAY R$17 MILLION FOR MEDICINE FOR CHILD WITH RARE DISEASE

Supreme Court Justice Luiz Fux ordered payment for treatment with Elevidys, a drug worth between R$15 million and R$17 million, for Paulo Azevedo Soares Varela, 6 years old. The boy was diagnosed with Duchenne Muscular Dystrophy, a rare and deadly genetic disease. "In the always complex weighing up of, on the one hand, the important financial arguments and, on the other, the realization of the right to access to health care, the relevance of the right to life cannot be disregarded. This is the maxim of social justice advocated by the 1988 Constitution, based on the values of solidarity so dear to Brazilian society," said Fux. In the sentence, Fux also commented on the decision of STF minister Gilmar Mendes, who established limitations for the release of treatment with Elevidys by the Union. In addition to restricting access, Gilmar Mendes' ruling also determined dialogue between the Supreme Court, representatives of the Union, the PGR, the Ministry of Health, Anvisa, the Brazilian Society of Medical Genetics and Genomics, and the pharmaceutical laboratory producing the medicine in search for fair prices that are more compatible with the Brazilian market. Read more.

BARROSO DEFENDS 'MORE MODEST' ACTION BY JUDICIARY IN HEALTH CASES

The president of the Federal Supreme Court (STF), Minister Luís Roberto Barroso, defended the reduction of excessive litigation in the health sector. In addition to the overload caused to the Justice system by the high number of lawsuits in the country, for the magistrate, the Judiciary may not provide the best solution to the cases. He highlighted cases involving high-cost medications. "This balance is very complex. The Judiciary is not the right place to define the best way to handle these expenses. We have been trying to create a certain awareness that the Judiciary should act when it has to and be more modest, when perhaps it should be the health authorities who should decide," he told journalists this Thursday (11/21) at an event held by the Brazilian Association of Health Plans (Abramge) in the capital of São Paulo. Read more.

HEALTHCARE COSTS FROM LEGAL ACTIONS REACH CLOSE TO R$2 BILLION, SAYS NÍSIA TRINDADE

The Minister of Health, Nísia Trindade, highlighted this Thursday (21) that the cost of the Ministry of Health with legal actions is close to R$ 2 billion, and that this value needs to be reduced. "Integrated action in healthcare is important, whether in the public sector or in supplementary healthcare. […] To give you an idea, the costs for the Ministry of Health in 2024 with legal actions will be close to R$2 billion," said Nísia Trindade. "It is important that we reverse, for the benefit of the population, the use of resources that are falling short of meeting

the great needs of our population," added the minister during an event at the National Forum of the Judiciary for Health, taking place in São Paulo. Read more.

MINISTRY OF HEALTH PROVIDES INFORMATION ON THE NATIONAL NEONATAL SCREENING PROGRAM

The Ministry of Health responded, through Official Letter 1637/2024, to Request 3042/2024, authored by Congresswoman Rosangela Moro (União-SP), which requests information on the National Neonatal Screening Program - PNTN. The Ministry of Health highlighted that, when restructuring the PNTN, it also assumed responsibility for the logistics of transporting samples, with an estimated investment of R$15,249,943.00 to contract this service. The program is funded by the federal government, with resources allocated via the National Health Fund to the states, which apply the resources in accordance with the SUS Procedures Table. However, the purchases of supplies are not centralized since the states use different brands of equipment and reagents. Furthermore, the implementation of new diseases in the program, such as congenital toxoplasmosis, has required adjustments to care flows in several states. Read more.

'BRAZIL IS NOT INVOLVED IN MOST CLINICAL STUDIES THAT WILL PRODUCE SCIENTIFIC EVIDENCE', SAYS PHYSICIAN LUDHMILA HAJJAR

Cardiologist and full professor at the University of São Paulo (USP) School of Medicine Ludhmila Hajjar stated at the Brazilian Association of Health Plans (Abramge) Congress that part of the country's difficulty in correctly incorporating new drugs and technologies for health treatments is due to the lack of multicenter clinical studies (which take place in various parts of the world) in the country. "Brazil is extremely passive (in its relationship with the pharmaceutical industry). Why don't we participate in multicenter clinical studies? A country with 210 million inhabitants that spends a lot on health care," she asks. "You can see that Brazil is not involved in most multicenter clinical trials that will generate scientific evidence." The reasons for the country's lack of participation in developments of this type, says the physician, are linked to the lack of historical investment in science and innovation of this type and the lack of consensus among health entities. The effect of this low participation ends up harming the country's access to innovative drugs that end up reaching the care systems at a very high cost. Read more.

MORE HIGHLIGHTS

Bill aims to create a National Men's Health Policy

Ministry of Health may provide information on prostate cancer screening

All Brazilian municipalities have joined the Digital SUS, says Secretary Ana Estela Haddad

Conitec releases new data panel on demands assessed by the Committee

BRAZIL NEWS

Brazilian police uncover military plot to kill Lula before 2023 inauguration

Bolsonaro knew of plot to kill Lula, Brazil police find, CNN Brasil says

Brazil police accuse Bolsonaro and ex-ministers of 2022 coup plot

Bolsonaro's coup indictment postponed by Brazil's top prosecutor, sources say

Lula's approval rating in Brazil rises to 36% in Datafolha poll