WEEKLY REPORT

10/26/2024

CONSULTORES
Relações Governamentais

PHARMACEUTICAL COMPANIES FIGHT FOR EXTENSION OF 62 DRUG PATENTS AFTER STF DECISION

Pharmaceutical companies, manufacturers of branded and generic drugs, are engaged in a fierce dispute in court over patents for 62 drugs - including Saxenda and Ozempic, used in weight loss treatments, and Stelara, for autoimmune diseases. The owners of the original formulas want to maintain the extension of the exclusive sales term of their drugs beyond the legal 20 years of patent protection. But a change in understanding by the Supreme Federal Court (STF) in 2021 is an obstacle for them. The dispute between these two groups began to heat up in the context of the COVID-19 pandemic, when there was a growing clamor among politicians, judges, and governments to speed up and make medical treatments cheaper. It was in this scenario that the Supreme Federal Court ruled that the sole paragraph of article 40 of the Industrial Property Law (LPI) of 1996 was unconstitutional. The wording of this section allowed a loophole for patents to be valid for more than 20 years after their registration was requested - in some cases, even exceeding 30 years. Read more.

LULA'S MINISTER CONFIRMS TO BUSINESSPEOPLE THAT BRAZILIAN GOVERNMENT IS PREPARING A BILL TO CHANGE REGULATORY AGENCIES

The Minister of the Civil House, Rui Costa, confirmed to a group of businesspeople in São Paulo that the Lula government is preparing a project to change the structure and functioning of regulatory agencies, and that it wants to do so quickly. The proposal, he said, has not yet reached his department and will be presented after the Attorney General's Office (AGU) gathers suggestions from various ministries. According to reports obtained by Estadão, the minister said there was "full agreement" in the Planalto and among the other ministers involved in the discussion about the need to change, for example, the appointment of directors. Rui complained that "everyone who is in the agencies today was appointed by the previous government". When contacted, the Minister of the Civil House did not comment. During lunch, the main target of attacks was the National Health Surveillance Agency (Anvisa). The businesspeople complained about the delay in regularizing medications, including those that have already been approved in other countries, and said that the agency acts "as a handbrake" on the expansion of the pharmaceutical industry in Brazil. According to some people present, Minister Rui Costa endorsed the criticism. He said it made no sense for Anvisa to re-request all studies already approved by American and European authorities with the same scientific knowledge profile, delaying the process by another four or five years. Read more.

ANVISA ADOPTS MEASURES TO SPEED UP DRUG REGISTRATION, SAYS AGENCY DIRECTOR TO CNN TALKS

The director of the National Health Surveillance Agency (Anvisa) Daniel Pereira said during CNN Talks: Health in Brazil, this Monday (21), that the agency adopts measures to approve registrations of medicines and treatments more quickly. "Anvisa is adopting measures to increase speed. The intention is for all requests received by the agency to be approved as quickly as possible," he said at the event, held in São Paulo. According to the director, one of the main areas of action is to work more closely with the registration holder. There is an effort, for example, to help them "navigate" the Agency, learning details of its procedures and organization, in order to facilitate approval. Despite this effort for speed, Pereira indicates that Anvisa continues with "very strict" criteria. "Everyone can be sure that the drugs approved by Anvisa are safe and have proven efficacy," he said. Read more.

COSAÚDE ANALYZES TECHNOLOGIES FOR THE TREATMENT OF PROSTATE CANCER

On Tuesday (22) and Wednesday (23), the National Supplementary Health Agency (ANS) held the 33rd Technical Meeting of the Committee for Updating the List of Procedures and Events in Supplementary Health (Cosaúde). On the occasion, technologies proposed by Astellas were analyzed: Enzalutamide in combination with leuprolide and Enzalutamide as monotherapy. Read more.

MINISTRY OF HEALTH PUBLISHES ORDINANCE THAT PROMOTES CHANGES IN THE COMPOSITION OF CONITEC

The Ministry of Health published in the Official Gazette of the Union this Friday (25), the ordinance to amend the GM/MS Personnel Ordinance No. 149, of February 16, 2024, regarding the designation of indicated members who will compose the Committees of the National Commission for the Incorporation of Technologies in the Unified Health System - Conitec. Read more.

JUSTICE GILMAR MENDES ADVOCATES A SINGLE AGENCY TO EVALUATE NEW TECHNOLOGIES IN PUBLIC AND PRIVATE HEALTHCARE

STF (Supreme Federal Court) minister Gilmar Mendes said he is in favor of creating a single agency for evaluating and incorporating new treatments that serve both public and private healthcare. This agency would unify the work of Anvisa (National Health Surveillance Agency) , which authorizes a new medicine for use in the country, and Conitec (National Commission for the Incorporation of Technologies), linked to the Ministry of Health and which decides whether the new medicine is cost-effective to be offered in the SUS. Read more.

JUSTICE GILMAR MENDES KEEPS DECISIONS TO RESTRICT AGE AND SUSPEND THE SUPPLY OF R$17 MILLION WORTH DRUG

Minister Gilmar Mendes, of the STF (Supreme Federal Court), determined the restriction on the granting of the high-cost medication Elevidys to children aged 4 to 7 diagnosed with Duchenne muscular dystrophy. In the same decision, the minister kept the injunctions that determine the supply of the medicine paid for by the Ministry of Health suspended. The exception applies to injunctions already granted for children who were at least 6 years and 6 months old on September 6, 2024. The medicine must also be purchased in cases of injunctions granted by STF ministers. The financing of this medicine has caused a stalemate between the federal government and the pharmaceutical company Roche, in negotiations mediated by the Supreme Federal Court. Families have resorted to the courts to have the Ministry of Health cover the costs. Read more.

BILL ON RULES FOR THE SUPPLY OF DRUGS OUTSIDE THE SUS LIST WILL BE ANALYZED BY THREE COMMITTEES AT THE FEDERAL SENATE

A new complementary bill (PLP) under analysis in the Senate, authored by Senator Romário (PL-RJ), creates rules so that medicines that are not yet available through the Unified Health System (SUS) or not registered with the National Health Surveillance Agency (Anvisa) can be distributed by states and municipalities. The text is currently in the Constitution and Justice Committee (CCJ) and will then be sent to the Social Affairs Committee (CAS) and the Economic Affairs Committee. Read more.

CONGRESSWOMAN PRESENTS BILL TO ESTABLISH CRITERIA FOR THE PROVISION OF MEDICINES NOT INCLUDED IN THE SUS

Congresswoman Rosângela Moro (União-SP), president of the Joint Parliamentary Front for Innovation and Health Technologies for Rare Diseases, presented Complementary Bill 168/2024, which establishes criteria for the provision of medicines not included in the Unified Health System (SUS). The PLP intends to require that, in order to access non-incorporated medicines, a medical report must be presented proving the need for the medicine; the non-existence or ineffectiveness of the treatment provided by the SUS; and proof of the patient's

financial incapacity. According to the proposal, if all requirements are met, the Judiciary may request an assessment of the inclusion of the medicine in the SUS. The proposal was presented after a decision by the Federal Supreme Court (STF) that defines the judicialization process for medicines not included in the list of dispensing of the Unified Health System (SUS). Read more.

JUDICIALIZATION IN HEALTHCARE NEEDS TO BE ADDRESSED, SAYS ANS PRESIDENT TO CNN TALKS

The CEO of the National Supplementary Health Agency (ANS), Paulo Rebello, stated during CNN Talks: Health in Brazil, this Monday (21), that "excessive" judicialization needs to be addressed in Brazil. "It is a problem. We are living in a time of hyperjudicialization, both in the public and private sectors," he said. According to Rebello, last year there were almost 60 thousand lawsuits linked to private healthcare every month. Read more.

BRAZILIAN GOVERNMENT EXTENDS TAX EXEMPTION FOR IMPORT OF DRUGS

The federal government published in an extra edition of the Official Gazette of the Union this Friday a provisional measure (MP) to extend the import exemption for medicines sold digitally. The MP will be valid until March 31 of next year. According to the text of the provisional measure, the rate will be zero for imports by individuals of medicines worth up to US$10,000 for personal use. If the new MP had not been issued, medicines would be taxed at a rate of 60%. Read more.

MORE HIGHLIGHTS

Pharmaceutical companies want Anvisa to revoke authorization for patients to import cannabis

Representatives will hold a seminar on the role of Pharmaceutical Industry

BRAZIL NEWS

Brazil's Lula cancels BRICS trip to Russia after minor brain hemorrhage

Brazil's Lula urges BRICS to create alternative payment methods

Brazil launches platform to attract foreign investment for ecological projects

Brazil fines meat packers $64 million for buying cattle from deforested land

France's Danone cuts out Brazilian soy ahead of tough new EU rules

How sustainable soy is critical to saving the Cerrado

Brazil seals $30 billion compensation deal with BHP, Vale over 2015 dam collapse

Brazil to calculate potential GDP to balance debate on rates, says minister

Tight US election clouds scenario for Brazil's next interest rate decision

Brazil to partly address fiscal concerns soon, central bank chief says

Brazil's central bank committed to lowering inflation to target, policymakers say

Brazil inflation picks up in mid-October with higher electricity costs

Foreign debt financing by Brazilian issuers surges in 2024

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