WEEKLY REPORT

12/14/2024

TAX EXEMPTION ON DRUGS MOBILIZES PHARMACEUTICAL ASSOCIATIONS

The tax exemption on drugs within the Tax Reform gained another chapter this week. This is because Senator Eduardo Braga, the rapporteur of the bill, passed the text demanding another complementary law to regulate the absence of taxes on drugs. This fact led to a mobilization by Interfarma and Sindusfarma, which released a joint manifesto against the suggestion. In the view of the entities, such a change would make it difficult to access innovative medicines. They state that determining by law which medicines will not be subject to taxes makes access difficult, restricts supply and strengthens legal action. "Leaving the definition of the list of medicines to a complementary law is equivalent to making it difficult to update products, depriving patients of innovative medicines and new treatments for neglected diseases", says an excerpt from the note. The entities add that the measure serves to restrict the supply and incorporation of drugs into the public and private health system, compromising the sustainability of the system. "This is about persisting in the absurd and dramatic situation that has harmed families' treatment for decades and paved the way for the judicialization of health care," the note states. Read more.

"ANVISA HAS NO PEOPLE TO WORK", SAYS THE AGENCY'S CEO

The CEO of the National Health Surveillance Agency (Anvisa), Antônio Barra Torres, is counting down the days until he leaves the position he has held for five years. His term expires on the 21st, ending one of the most turbulent periods in the history of the regulatory agency. About this period heading the Agency he recalls the tensest period, during the covid-19 pandemic, and sees the loss of employees and the consequences of climate change on health as challenges for the agency. Read more.

GOVERNMENT AUTHORIZES APPOINTMENT OF 50 CANDIDATES APPROVED IN PUBLIC EXAMINATIONS FOR ANVISA

The Minister of Management and Innovation in Public Services (MGI), Esther Dweck, authorized the appointment of 50 specialists in health regulation and surveillance, approved in public examinations, to join the staff of the National Health Surveillance Agency (Anvisa). Read more.

CONGRESSWOMAN PROPOSES PUBLIC HEARING TO DISCUSS DELAYS IN ANVISA'S EXPORT AND IMPORT APPROVAL PROCESSES

Congresswoman Dr. Mayra Pinheiro (PL-CE) presented, in the Health Committee, request 270/2024, which proposes holding a public hearing to discuss the impacts of delays in Anvisa's export and import approval processes. When justifying the request for the public hearing, the congresswoman explained that the time for approval of exports by Anvisa is currently around 5 days, while the import process can take up to 7 days. According to her, the agency faces the lack of an efficient system of its own. In addition, she highlighted that Anvisa faces problems such as a lack of personnel and resources, which compromises its ability to respond. Read more.

ANVISA COMPLETES MONITORING STAGE FOR ADVANCED THERAPY DRUGS

Anvisa concluded the project Monitoring and Periodic Analysis of Advanced Therapy Products: Reassessment of the Benefit-Risk Profile and Social Transparency. Launched in 2024, the project had the support of all companies holding advanced therapy product (ATP) registrations in Brazil, reinforcing the sector's commitment to the safety and efficacy of these innovative

medicines. The first five products registered with Anvisa since 2020, with more than a year of approval, were analyzed. Every year, the Agency receives the results of the monitoring of the products. This year, however, the discussions addressed the prospect of publicizing the results available to date. Read more.

ANVISA ANNOUNCES INITIATIVES TO PROMOTE ACCESS TO NEW MEDICINES

Anvisa released, this Thursday (12/12), the document Reflections & Perspectives: Regulation, Clinical Research and Innovation on strengthen the clinical research ecosystem in Brazil, in addition to boosting innovation in the health sector. The initiative is part of the Agency's commitment to promoting the health of the Brazilian population by encouraging the development and innovation of new medicines. In this context, Director Meiruze Freitas, upon concluding her term as head of the Second Directorate, shares this comprehensive document, which reflects the strategic vision built over the last few years. Among the main initiatives addressed in the document, the following stand out: review and modernization of regulatory frameworks for clinical research and drug registration; simplification and flexibility of the regulatory framework for biosimilars; launching of notices for technical and scientific monitoring and guidance; development of strategic partnerships, such as the creation of a center dedicated to regulatory science; strengthening national capacities for conducting clinical research. Read more.

'BEAUTY CHIP': SEE WHICH HORMONAL IMPLANTS WERE BANNED BY ANVISA AND WHICH CAN STILL BE USED

Following an appeal from the country's main medical societies, the National Health Surveillance Agency (Anvisa) changed the rules regarding manipulated hormonal implants in Brazil. In practice, it banned those for aesthetic purposes, for sports performance and muscle mass gain, and kept those for medical treatments allowed. However, it established new rules to make prescription and sale more rigid and banned any advertising about manipulated hormonal implants in the country, whether they are allowed or not. Implants are a type of hormone therapy – which can also be done orally, with injection, topical gels, among other application routes. In the case of "chips", they are inserted under the skin and gradually release the substance over time, often for months or even years, which makes them more practical and gains appeal among certain audiences. However, the only implant that was developed by the pharmaceutical industry and approved by Anvisa as a medicine, after analyzing clinical studies that proved its efficacy and safety, is called Implanon. It uses the hormone etonogestrel and is intended solely for contraceptive use. Read more.

STF HOLDS NEW ROUND OF CONCILIATION ON ELEVIDYS DRUG

The Federal Supreme Court (STF) held this Thursday (12) a new round of conciliation on compliance with preliminary decisions involving the drug Elevidys, indicated for the treatment of Duchenne Muscular Dystrophy. During the meeting, the parties reached consensuses that should support an agreement to be assessed by Minister Gilmar Mendes, rapporteur of Complaint (Rcl) 68709. The parties must submit the final information by December 16. After receiving this information, Justice Gilmar Mendes will decide whether to approve the agreement. If approved, the proposal will be submitted to a referendum by the other justices in the Supreme Court's Virtual Plenary. Read more.

AUTHORITIES AND EXPERTS DISCUSS THE INCORPORATION OF NEW TECHNOLOGIES IN HEALTH AT THE SUPREME COURT

The Federal Supreme Court (STF) hosted, this Monday (9), the seminar "Impacts of the Incorporation of New Technologies in Public Health", with the participation of authorities and experts from the sector. The opening was given by Minister Gilmar Mendes, rapporteur of Extraordinary Appeal (RE) 1366243 (Topic 1234), which deals with the issue. He highlighted the challenges faced and the solutions reached throughout the 23 conciliation sessions on the incorporation of high-cost medications and therapies into the Unified Health System. "Whether from the perspective of the effectiveness of the medication, or in the form of costing in the

proceedings and subsequent reimbursement among the federative entities, the members of the special committee realized that the issue deserved an institutional rearrangement," he stated. The final proposal of the conciliation committee, approved unanimously by the STF Plenary, foresees the creation of a national platform for easy consultation to centralize demands for access to medicines, allowing for administrative analysis and resolution and eventual judicial control. The measure, according to Mendes, will allow for better monitoring of the processes, bring greater transparency and will help the Judiciary to make more efficient decisions. The dean highlighted that the Court's move aims to reduce judicialization, promote the efficiency of the system and guarantee equal access to essential medicines. "Clear rules were established on the competence of the federative entities to provide medicines, the criteria for the incorporation of new medicines into the SUS and the price limits for medicines acquired through court decisions," he pointed out. Read more.

BILL TO CREATE A SINGLE AGENCY OF HEALTH TECHNOLOGY ASSESSMENT IS SPONSORED IN THE HOUSE OF REPRESENTATIVES

A few months after being resumed, the discussion of creating a single incorporation agency gained a new status. A bill on the subject was presented by federal deputy Dr. Luizinho (PL-RJ) and the expectation is that a public hearing will be held soon. The Minister of Health does not welcome the idea, Nísia Trindade. Today, during a seminar held by the Supreme Federal Court (STF) on the incorporation of technologies, Nísia was emphatic: "I do not support a single agency". With arguments very similar to those of the Secretary of Science, Technology, Inputs and Economic Complex, Carlos Gadelha, Nísia stated that the National Commission of Technologies in the Unified Health System (Conitec) must be strengthened. "Conitec is structured in a way that allows for in-depth debate from a scientific point of view. It is also an important asset of the SUS; on par with what is done in other countries," she said. Read more.

MEDICAL ENTITY ASKS THE SUPREME COURT TO REVERSE RULES FOR JUDICIALIZATION IN THE SUS

The Brazilian Society of Medical Genetics and Genomics (SBGM) issued a statement requesting that the Supreme Federal Court (STF) reverse the decision that defined the new requirements for patients to have access through legal system to treatments not included in the SUS. Read more.

MINISTERS ANNOUNCE NEW ACTIONS AIMED AT PEOPLE WITH AUTISM AND RARE DISEASES

The Lula government announced this Tuesday (10), during an event in the House of Representatives, new actions aimed at people with autism spectrum disorder (ASD), rare diseases and other neurodiversities. The Minister of Development and Social Assistance, Family and Fight Against Hunger, Wellington Dias, said that the initiatives will be launched as soon as the National Care Policy, provided for in Bill 5791/19, comes into force. "Brazil still lacks a better, more adequate network, both for rare diseases and autism, so that it is better prepared to support those who need care and their families," said Wellington Dias in an interview. Read more.

GOVERNMENT SETS DEADLINE FOR HEALTH PLANS TARGETED BY LAWSUIT TO CORRECT IRREGULARITIES IN SERVICE PROVISION

The National Consumer Secretariat (Senacon) of the Ministry of Justice and Public Security (MJSP) has set a 60-day deadline for health insurance companies that have been notified to explain failures in their service provision. The companies were the target of an administrative process by the government for unilateral cancellations of contracts and practices considered abusive. The decision was made after a meeting held on Tuesday by Senacon with representatives from the sector. At the time, a working group was set up with the participation of operators, who must develop definitive solutions to the service problems within 60 days. Read more.

ANS TECHNICAL OPINION FROM 2023 HAD ALREADY CALLED FOR CHANGES TO PREVENT UNJUSTIFIED TERMINATION OF HEALTH INSURANCE PLANS

Documents from ANS (National Supplementary Health Agency) show that, since last year, there has been a technical recommendation to change the rules for canceling group health plans in order to mitigate risk selection practices, that is, the operator preventing a person from acquiring a plan or excluding them due to health conditions that demand high healthcare costs. This year, unilateral terminations of collective contracts were at the center of debates in supplementary health, with an increase in complaints , lawsuits and administrative processes , in addition to several user mobilizations, which led to the approval of a request for a CPI (Parliamentary Commission of Inquiry) , which is currently stalled in the Chamber of Deputies. Read more.

HEALTH INSURANCE PLANS REVERSE LOSSES AND HAVE OPERATING PROFIT OF R$3.3 BILLION IN THE FIRST 9 MONTHS

Health plan operators and health plan administrators by adhesion recorded an operating profit of R$3.3 billion in the first nine months, reversing the operating loss of R$5.7 billion recorded in the same period of 2023. Net profit (which considers financial gains) tripled to R$8.2 billion, between January and September of this year, according to data from the National Supplementary Health Agency (ANS). The sector's revenue increased 12%, to R$257.8 billion, in the accumulated total of the first nine months. The claims rate, an indicator that measures the use of health insurance, was 85.3% in the third quarter, compared to 88.6% in the same period of 2023. Read more.

WHY CANCER COULD BECOME THE BIGGEST KILLER IN BRAZIL - AND WHAT CHALLENGES THIS BRINGS

Brazil is going through a major epidemiological transition: cancer is gradually gaining ground, becoming the leading cause of death in many cities in the country and leaving behind cardiovascular diseases, which have topped this ranking in recent decades. This phenomenon was captured by a study carried out by several national and international institutions, published in November in the scientific journal The Lancet - Regional Health Americas. The authors calculate that, in the year 2000, cancer was only the number one cause of death in 7% of the country's municipalities — and it was not in first place in any of the states. Read more.

MORE HIGHLIGHTS

Nísia Trindade presents actions of the Ministry of Health at a hearing in the Federal Senate

Project aims to establish rules for appointments to presidency positions at Anvisa

At CAS, experts advocate investment and training in radiology

More Access to Specialists Program will receive investments of R$2.4 billion in 2025

Health Commission approves the Preliminary Report of the Special Subcommittee on Cancer Prevention and Control

Health Commission approves the Report of the Special Subcommittee on Telemedicine, Telehealth and Digital Health

Novo Nordisk, manufacturer of Ozempic, will invest another R$500 million in a factory in Minas Gerais

BRAZIL NEWS

Brazil's Lula has head drain removed after second surgery, doctors say

Brazil's left caught in the long shadow of ailing patriarch Lula

Brazil’s Senate approves tax reform rules with higher VAT rate

Brazil government edits regulations aiming to unlock Congress agenda

Brazil lawmakers approve wind energy bill that includes fossil fuel incentives

Forensic technology aids Brazil's crackdown on illicit Amazon gold trade

Brazil farmer lobby asks to lift soybean ban from deforested Amazon rainforest