WEEKLY REPORT

02/01/2025

MINISTRY OF HEALTH PROVIDES INFORMATION ON THE ORDINANCES OF THE NATIONAL POLICY FOR CANCER PREVENTION AND CONTROL

The Tripartite Intermanagerial Commission agreed, in its 1st Ordinary Meeting of 2025, on the ordinances of the National Policy and Network for Cancer Prevention and Control. Initially, José Barreto presented some of the challenges for cancer care in Brazil, highlighting the lack of a structured service network to assist people with cancer at all points of care, in addition to the concentration of care in High Complexity services, with little interaction with other services in the Care Network. He also highlighted the fragmentation of care and the lack of a defined treatment schedule, as well as the late entry of patients into the Health System and late diagnosis of the disease. Another point addressed was the low capacity of the system to perform early diagnoses and implement screening strategies, combined with the fragmentation of information systems and the difficulty in implementing monitoring and evaluation of policies. In addition, José Barreto mentioned the failure to comply with legal deadlines between diagnosis and the start of treatment, as well as the disjointed provision of support, diagnostic and imaging tests within the Care Network. Read more.

ANS EXTENDS PUBLIC CONSULTATION ON CHANGES TO HEALTH PLANS

The National Supplementary Health Agency (ANS) has decided to extend the public consultation on the package of measures that change the pricing policy of health plans. The proposals include, among other points, the creation of rules for the increase in collective contracts and limits on the collection of co-participation and deductibles. The public consultation was due to end on the 3rd, a deadline that was extended until the 9th at a meeting held this Friday by the ANS Board of Directors. According to the agency, the idea is to ensure "broad social participation". Read more.

PROPOSAL THAT HEALTH PLANS RECOMMEND MAMMOGRAMS AFTER AGE 50 CLASHES WITH INCA AND MEDICAL ENTITIES

Following the controversy generated around the public consultation for the creation of a quality seal proposed by ANS (National Supplementary Health Agency) which suggests that health plans encourage mammography screening between the ages of 50 and 69, Inca (National Cancer Institute) published a statement endorsing this guideline on the grounds that it is based on the best scientific evidence available. In response, the CNM (National Mammography Commission), composed of the Brazilian College of Radiology and Image Diagnosis, Febrasgo (Federation of Gynecology and Obstetrics Associations) and the Brazilian Society of Mastology, released a technical note contesting INCA's position. It states that the recommendation disregards epidemiological evidence, flaws in the current screening program and the demographic characteristics of Brazilian women. Read more.

HEALTH INSURANCE PLANS OPPOSE CHANGES TO GROUP PREMIUM ADJUSTMENTS AND SAY THAT CO-PAYMENT LIMITS WILL INCREASE PRICES

In yet another chapter in the process of approving the package of measures from the National Supplementary Health Agency (ANS) that will change the pricing policy of health plans, health insurance companies spoke out against the regulator's proposals during a public hearing on Tuesday. The bill includes items such as the creation of rules for increasing group premiums and limits on co-payment and deductible charges. Cesar Sergio Cardim Junior, Superintendent of Regulation at the National Supplementary Health Federation (FenaSaúde), which represents

12 large health insurance groups in the country, said that the ANS bill is being processed "at a fast pace" and that the deadlines for each stage of the process were insufficient for health insurance companies to calculate the impacts of the proposals. Read more.

DRUG PRICE ADJUSTMENTS WILL BE IN THREE LEVELS; RETAILERS WILL BE NEGATIVELY AFFECTED

The adjustment of medicine prices in the country this year should occur at three levels, including below the accumulated inflation, for the first time since 2021. There will be a lower-than-expected effect on the nominal revenue of medicine retailers, affecting publicly traded chains, which have an immediate improvement in profitability in the second quarter, when the new tables come into effect. The information on the different ranges was obtained by Valor from industry sources, based on data from a technical note from the Secretariat for Economic Reforms of the Ministry of Finance, which makes up the Technical-Executive Committee of CMED (Council of Ministers of the Chamber for Regulation of the Medicine Market). The note was attached late Friday afternoon (24) to the website of the National Health Surveillance Agency (Anvisa). Read more.

OZEMPIC MANUFACTURER WANTS MORE TIME FOR DRUG PATENT IN BRAZIL

The patent for Ozempic expires in 2026 in Brazil, paving the way to produce cheaper, generic versions of the drug, but Novo Nordisk is trying to extend the deadline. The pharmaceutical company argues that it is seeking compensation for the 13-year delay in the process of examining and granting the patent for semaglutide — the active ingredient in Ozempic — in the country, which is used to treat diabetes and obesity. Registered in 2006, the patent was only granted in 2019. In 2021, the STF (Supreme Federal Court) limited the exclusivity period for drug patents to 20 years in all cases, regardless of the date of granting by the INPI (National Institute of Industrial Property). Therefore, the Ozempic patent expires in 2026. In a statement, the company states that it "does not demand changes to what was decided by the STF in the context of ADI 5529 regarding intellectual property in the country". "Novo Nordisk agrees that the term of validity of innovation patents should not exceed 20 years, which is the global standard", adds the pharmaceutical company. Read more.

BRAZILIAN GOVERNMENT STUDIES PARTNERSHIP TO PRODUCE INSULIN

The government of Luiz Inácio Lula da Silva (PT) is studying a partnership with the private sector, via the Health Economic-Industrial Complex, to expand national production of various types of insulin. The information, obtained by JOTA, was confirmed by Novo Nordisk. Discussions with the Ministry of Health and public laboratories are still in the initial stages, according to the company. In December, Novo Nordisk's global CEO, Lars Fruergaard Jørgensen, participated, via videoconference, in a meeting with the vice president and minister of the Ministry of Development, Industry, Trade and Services (MDIC), Geraldo Alckmin (PSB), the Minister of Health, Nísia Trindade , the secretary Carlos Gadelha and other members of the Government. The meeting was closed, as reported by JOTA on December 20, in the newsletter Bastidores da Saúde. Read more.

UNION FILES COMPLAINT WITH THE PGR ABOUT 'ILLEGAL OCCUPATION' AT ANVISA

The president of Sinagências, Fabio Gonçalves Rosa, filed a formal complaint with the PGR and the Federal Prosecutor's Office of Anvisa itself against what he accuses of being an “illegal and irregular use of directors” at the regulatory agency with the vacancy of seats after the end of their terms, at the end of last year. Currently, Anvisa is run by only two full members: Rômison Rodrigues Mota (as CEO and on the Fourth Board) and Daniel Pereira (on the Second and Fifth Boards), in addition to the substitute director on the list of three, Danitza Passamai Rojas Buvinich, (on the Third Board). The other names on the list of three did not take office. The complaint points to the accumulation as undue. Read more.

ANVISA PUBLISHES ADVANCED THERAPY PRODUCT MONITORING REPORTS

Anvisa informs that the Periodic Monitoring Reports for Registration of Advanced Therapy Products are available. These documents were prepared in partnership with the companies holding the registration, within the scope of the project "Monitoring and Periodic Analysis of Advanced Therapy Products: Reassessment of the Benefit-Risk Profile and Social Transparency". The project, which began in 2024, had the support of all companies holding registrations for Advanced Therapy Products (PTAs) in Brazil. The initiative reinforces the sector's commitment to monitoring the safety and effectiveness of these innovative medicines. The reports analyze all advanced therapy products registered with Anvisa since 2020, considering the data available after more than a year of approval, with the aim of increasing transparency and ensuring public access to information. Read more.

JUDICIALIZATION GROWS AS AN ALTERNATIVE FOR ACCESS TO MEDICINES AND PROCEDURES IN THE SUS

The growing judicialization to obtain access to medicines and procedures in Brazil involves cases of technologies not yet incorporated into the SUS (Unified Health System), but also those that are already part of the network's list, but for which patients face barriers. The number of lawsuits related to public health continues to increase significantly. From 2022 to 2023, the volume of new lawsuits increased by 16%, according to data from the CNJ (National Council of Justice), jumping from 295,920 to 344,212. Read more.

MINISTRY OF HEALTH ACQUIRES FIRST TREATMENTS FOR PATIENTS WITH DUCHENNE MUSCULAR DYSTROPHY (DMD)

In compliance with the determination of the Brazilian Supreme Court (STF), the Ministry of Health informs that, on Friday (24), the first two patients with Duchenne Muscular Dystrophy (DMD) began pre-infusion exams to receive gene therapy with the drug Elevidys. The exams assess the health conditions of patients for the treatment of DMD, a genetic disease that can lead to progressive loss of motor skills such as running, jumping, and climbing stairs. The first two patients underwent clinical evaluation by the Rare Disease Reference Service team at the Hospital de Clínicas de Porto Alegre (HCPA), in the first stage of preparation to receive the gene therapy infusion. This gene therapy was designed to restore, even if partially, muscle function in pediatric patients. It is indicated for children between 4 and 7 years, 11 months, and 29 days. The Ministry of Health emphasizes that therapy with Elevidys still requires the production of evidence that proves the real clinical gains of patients, requiring monitoring and evaluation of each of the infusions performed. The available evidence is still limited, and the treatment has been debated by the scientific community. Read more.

CLARIFICATION ON DECISIONS INVOLVING THE GRANTING OF THE DRUG ELEVIDYS

Minister Gilmar Mendes, dean of the Federal Supreme Court (STF), issued four decisions involving the granting of the drug Elevidys, intended for the treatment of children with Duchenne Muscular Dystrophy. In all cases, the rapporteur rejected the requests considering the risk to the child's health and safety, since Elevidys should only be administered to children aged between four years and seven years, eleven months, and 29 days. All patients were older. In one case, the child would reach the age limit on January 30, which would make it impossible to administer Elevidys. The age restriction was based on clinical criteria for the drug's effectiveness presented to the National Health Surveillance Agency (Anvisa), which approved the registration of Elevidys in December 2024. Read more.

FSH SELF-TESTS ARE SOLD IN DRUGSTORES AS A MEANS OF DETECTING MENOPAUSE

Rapid tests are a popular and often affordable way to find out about certain diagnoses, such as pregnancy, COVID-19, and even menopause. Working in a similar way to those already available on the pregnancy market for years, these tests to assess whether a woman has reached menopause measure hormone levels in a urine sample. The hormone responsible for regulating the reproductive system of men and women is follicle-stimulating hormone (FSH).

When it is found in large quantities in the urine, it may indicate menopause or pre-menopause. In the self-test, if the levels are above 25 mIU/ml, it is positive. Read more.

CARE POLICY IS A MILESTONE, BUT IMPLEMENTATION WILL FACE CHALLENGES

After more than a year of long debates and negotiations, the National Care Policy became law in December, after being sanctioned by President Luiz Inácio Lula da Silva (PT). Now, it will face the challenges of its implementation. By the end of this quarter, the national care plan should be launched, according to the national secretary of Care and Family Policy, Laís Abramo, detailing the actions and resources planned to expand the public supply of services in the area. The law establishes that the policy will be implemented in a transversal and intersectoral manner through the plan. Read more.

MORE HIGHLIGHTS

Health Minister details actions to strengthen the SUS in 2025

Hearing in the Chamber will discuss regulation of the National Policy for Cancer Prevention and Control

Reverse logistics of medicines grows 38.5%

Senator proposes creation of regulatory framework for cancer vaccine

Unifesp study reveals that cancer kills more than cardiovascular diseases in some cities in Brazil

Head and neck cancer has most advanced cases in the country

BRAZIL NEWS

New leaders elected to Brazil’s Congress promise independence from Lula

Brazil's Central Bank lifts benchmark interest rate to 13.25% per year

Brazil meets 2024 primary budget target, but critics warn of challenges

Brazil's jobless rate hits lowest yearly average ever in 2024

Brazil's Lula vows to reciprocate potential Trump tariffs, makes market-friendly remarks

Brazil seeking funds for Venezuelan migrant program after Trump freezes US aid

Chinese workers in BYD Brazil factory signed contracts with abusive clauses, investigators say

China's COFCO committed to Brazil soy-buying moratorium

Brazil's Petrobras hikes diesel prices for first time since 2023, shares rise