WEEKLY REPORT



04/20/2024

SENATE APPROVES URGENCY FOR BILL ABOUT CLINICAL TRIALS TO BE VOTED DIRECTLY IN THE PLENARY

The bill that creates rules for research with human beings and the control of good clinical practices through research ethics committees (PL 6007/2023) will be analyzed directly by the Senate Plenary. The urgency request (REQ 1333/2024) for the bill was presented by senator Dr. Hiran Gonçalves (PP-RR), rapporteur of the text at the Constitution and Justice Commission (CCJ). The bill was approved by CCJ this Wednesday (17) with changes in the text passed by the House of Representatives last year. Read more.

MINISTER OF HEALTH DEFENDS CONEP'S AUTONOMY AND GUARANTEE OF POST-STUDY TREATMENT IN A BILL ON CLINICAL TRIALS

The Minister of Health, Nísia Trindade, participated in a public hearing at the Social Affairs Committee (CAS) of the Federal Senate, this Tuesday (16), to present the actions, challenges, goals, planning and government guidelines of the department. On the occasion, Senator Hiran Gonçalves (PP-RR) questioned about the Bill 6007/2023, which creates the legal framework for clinical trials in Brazil. According to Nísia Trindade, the creation of a clinical research framework will help Brazil to advance significantly on the agenda. Regarding the Bill, she highlighted the importance of strengthening the Conep system in the project and the right to access continued post-study treatment. In contrast, the senator explained that the medicines will be supplied five years after the medicine is available on the Brazilian market. Read more.

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CONITEC INDICATES TREATMENTS AGAINST PROSTATE AND OVARIAN CANCER

The National Commission for the Incorporation of Technologies into the Unified Health System (Conitec), of the Ministry of Health, gave initial approval to medicines for prostate and ovarian cancer treatments, in a meeting last Thursday (11/4). Abiraterone and Olaparib, respectively, remain for public consultation. In the case of ovarian cancer, Olaparib should be prescribed when the disease is at an advanced stage, recently diagnosed, high-grade serous or endometrioid, BRCA mutated, which has responded to first-line platinum-based chemotherapy. Conitec will still deliberate on the topic again. Abiraterone received two favorable indications: individuals with metastatic castration-sensitive prostate cancer (mCPSC); and castration-resistant, metastatic and treatment-naïve disease. In prostate cancer, there was an unfavorable opinion on the drugs abiraterone, apalutamide, daralutamide and enzalutamide for people with non-metastatic CRPC and with metastatic CRPC with earlier use of chemotherapy. Read more.

SPECIAL COMMITTEE WILL DEBATE THE IMPLEMENTATION OF THE LAW THAT CREATED THE POLICY FOR CANCER PREVENTION AND CONTROL IN THE SUS

The Special Committee about Cancer, in the House of Representatives, scheduled a public hearing for next Tuesday (23), at 2 pm, to discuss the implementation and regulation of the Law that created the Policy for the Prevention and Control of Cancer in the Unified Health System. Read more.

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PUBLIC HEARING MAY DISCUSS THE DELAY IN THE AVAILABILITY OF MEDICINES NEEDED TO TREAT CANCER

The Health Committee of the House of Representatives will be able to vote, in a deliberative meeting on Wednesday (17), at 9:30 am, on Request 81/2024, which requests the holding of a public hearing, to discuss the delay in the availability of medicines necessary for treatment of cancers in the Unified Health System – SUS. The request was sponsored by representatives Dr. Frederico (PRD-MG) and Doutor Luizinho (PP-RJ). Read more.

ANVISA HALTS INVESTMENT IN PHARMACEUTICAL COMPANIES

The lack of employees at Anvisa (Health Surveillance Agency) held back R\$17 billion in investments, according to estimates from laboratories awaiting authorization to produce new drugs in the country, highlighted an article in Folha de S. Paulo. Today, the main pharmaceutical companies complain that their processes for registering new drugs have been awaiting release for more than three years. Many have already invested in the development of new drugs, a process that, in many cases, takes more than a decade of research. However, most are still waiting for the agency's approval to gain commercial scale. This situation is due to the lack of technicians in the various committees that today analyze laboratory documents, the so-called dossier. Without this, medicines cannot be marketed. According to Anvisa, today this technical team has 187 employees, grouped into five divisions. Read more.

OPINION: NELSON MUSSOLINI - THE RISK OF ANVISA BEING DISMANTLED

The National Health Surveillance Agency (Anvisa) has never had so few employees. The agency responsible for around 20% of Brazilian GDP currently has 1,409 people, a smaller contingent than when it was created in 2000. At the moment, the estimated deficit is around 1,250 technicians. In other words, it works with just over 50% of its needs. The situation is very worrying because Anvisa's actions are especially relevant due to its scope and the fact that it ensures the health of Brazilians, in addition to its social and economic externalities, such as income generation, taxes and jobs. Read more.

MINISTRY OF HEALTH ISSUES PURCHASE ORDER FOR MEDICATION WORTH R\$17 MILLION FOR BOY WITH RARE DISEASE

Relações Governamentais

The Ministry of Health issued this Wednesday (17) a bank order worth R\$ 17.2 million for the purchase of the medicine 'Elevidys' for the treatment of the boy Enrico, aged 5, from Varginha, in the south of Minas Gerais state, diagnosed with Duchenne Muscular Dystrophy, highlighted an article on the G1 portal. The information was confirmed on social media by the family. According to the family's lawyer, Daniela Ávila, the measure follows a court order for the Union to provide the boy with medication. Elevidys only exists in the United States and consists of a single-dose gene therapy that was approved by the Food and Drug Administration (FDA), an American regulatory agency, in June 2023. It is in the experimental phase and is not yet approved by the National Agency of Health Surveillance (Anvisa). Read more.

DELAY OF UPDATED COVID VACCINE DRAWS CRITICISM OF LULA

The delay in buying the updated Covid vaccine made the Lula (PT) government the target of criticism that goes beyond the field of politics and groups such as the center parties, highlighted a report by Folha de S. Paulo. Members of the scientific community, health professionals, among other groups, launched a petition this week demanding that the Ministry of Health deliver vaccines prepared for new variants and more measures to strengthen the fight against Covid that killed at least 3,012 people in 2024 —about double the 1,544 deaths confirmed from dengue in the same period. Health attributes the delay in purchasing vaccines to the purchasing process and states that it does everything possible to speed up the contract. Read more.

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HEALTH PLANS HAVE A NET PROFIT OF R\$2.9 BILLION IN 2023

The Brazilian supplementary health market, which comprises hospital medical health plan operators, dental plans and benefit administrators - recorded a net profit of R\$2.98 billion in 2023, highlighted an article in the newspaper O Globo. The data that has just been released by the National Supplementary Health Agency (ANS) points to a recovery in the sector, which in 2022 had recorded a net profit of R\$606 million. ANS figures indicate that 73.9% of the 705 hospital medical health plan operators made a profit last year, with the best performance being found among medium-sized companies, classified by the agency as having between 20 thousand and one hundred thousand users. Jorge Aquino, director of Standards and Qualification of Operators at ANS, draws attention to the fact that the result was better than expected. It highlights the reduction by half of the loss recorded in the operating result - the difference between the revenues and direct expenses of the healthcare operation - of hospital medical health plan companies: the result was negative at R\$5.9 billion in 2023, compared to a loss of R\$10.7 billion from the previous year. The sector's net profit was guaranteed, once again, by the financial result that jumped from R\$9.7 billion in 2022 to R\$11.2 billion last year. Read more.

HEALTH PLANS TO BECOME INCREASINGLY LIMITED AS COSTS RISE

Medical insurance plans are deteriorating, with a smaller network, higher co-payment charges, a drop in reimbursement, and record increases. The number of complaints to Brazil's National Supplementary Health Agency (ANS) has more than doubled in the last three years. This scenario reflects the crisis facing operators, who have accumulated an operating loss of R\$18 billion between 2021 and 2023 (until September). The sharp slowdown in the sector began in 2021 with the resumption of medical procedures not carried out during the first year of the pandemic. In 2020, when there was social isolation and patients canceled medical procedures, operators had a record result, with an operating profit of R\$18.7 billion, three times more than that recorded in 2019, of R\$5.7 billion. This year, there is an expectation of financial improvement and a lower readjustment. However, medical insurance plans are unlikely to return to the same reality as before the pandemic. In the "new normal," medical insurance tends to be even more restrictive, especially in the adhesion and SME (small and medium-sized enterprises) modalities, products usually bought by individuals. In corporate medical insurance, which accounts for 60% of the market, there is still room for further downgrading and benefits, such as reimbursement covering a large part of the cost of the medical procedure and an extensive list of accredited hospitals, which should be limited to large corporate contracts or for a high-income public. Read more.

BRAZILIANS AGE AND INCREASE HEALTHCARE COSTS BY R\$67.2 BILLION BY 2034

The government is concerned about the pressure that population aging will bring to health expenses and the Continuous Payment Benefit (BPC) in the medium term. The statement was made in the Budget Guidelines Bill (PLDO) of 2025, by including a chapter on demographic changes as a fiscal risk to be monitored by the Executive. "In the coming decades, Brazil will undergo a profound change in its age structure, with an increase in the number of elderly people in the population and a reduction in the number of young people. Such demographic transformation poses challenges to public policies, as it directly influences the demand for different forms of state action", warns without, however, proposing alternatives to face this scenario. The government calculates that demographic evolution alone (population growth and aging) will increase public spending on the main health expenses by R\$67.2 billion from 2024 to 2034, given that the older population demands proportionally more medical care. Read more.

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OTHER HIGHLIGHTS

Anvisa approves generic drug for leukemia

Anvisa keeps the sale of electronic cigarettes banned in Brazil

The launch of the Parliamentary Intellectual Property Front and the formal session in honor of World Intellectual Property Day are confirmed for April 30th

Biomm to distribute Ozempic analog in Brazil

Dengue cases surge by nearly 50% in Americas amid 'emergency situation', UN says

BRAZIL NEWS

X reverses course, tells Brazil court it will comply with rulings

Congress analyzes bill to regulate streaming services

Brazil faces R\$453bn loss to illegal activities including piracy

Government resets 2025 surplus target, shakes fiscal confidence

IMF projects increase in Brazil's gross debt at least until 2029

Haddad blames external factors for weakened real

Market sees little room for further interest rate cuts in 2024

Key Brazilian economic activity index rises for fourth straight month

Brazil's proposal to tax super-rich gains momentum amid G20, next steps in July

German finance minister rejects Brazil's proposal to tax super-rich

G20 to review multilateral development banks reform roadmap in October, says Brazil

G20 thematic group will discuss information integrity, minister says

Brazil will support Palestine's bid for full UN membership

Lula advocates for L.A. trade integration during visit to Colombia

Brazil is losing AI investments to Paraguay, Nvidia says

'Amazonia' bonds in 2024 seen a tough sell for some

Brazil's plans to drill for oil in the Amazon hit stiff Indigenous resistance

Brazil court reinstates Petrobras chairman

Brazil great Romario to play for Rio de Janeiro team at 58