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09/28/2024

ANVISA PUBLISHES PANEL WITH LIST OF ACTIVE INGREDIENTS OF DRUGS AWAITING REGISTRATION

Anvisa has published a panel that allows users to consult the list of active ingredients of drugs with registration requests under analysis by the Agency. The tool includes generic, similar, specific, herbal, dynamized, biological, radiopharmaceutical, and advanced therapy products. From the panel, interested parties will be able to identify all active ingredients of drugs, by regulatory category and quantity, submitted for evaluation by Anvisa, with no decision yet published. The panel will be updated monthly. According to Anvisa, the initiative reflects commitment to active transparency regarding the registration of medicines, in accordance with the Access to Information Law (Law 12,527, of November 18, 2011). Read more.

RARE DISEASES: MINISTRY OF HEALTH BLOCKS 43% OF DRUGS THAT COULD BE INCORPORATED IN THE SUS

Ten of the 23 drugs for rare and ultra-rare diseases analyzed by the National Commission for the Incorporation of Technologies into the Unified Health System (Conitec) in 2023 and 2024 were blocked from entering the Unified Health System (SUS). This is equivalent to 43.4%, according to a survey by the column on data from the Ministry of Health. The data is equivalent to the average of the historical series and represents a drop in relation to the last two years of the previous government, when 65% of the medicines were denied. When contacted, the Ministry of Health added that "rare diseases" is the category with the highest number of incorporations since January 2023. Read more.

PUBLIC HEARING MAY DISCUSS REGULATION OF ACCESS BY PEOPLE WITH RARE DISEASES TO DRUGS, MEDICAL DEVICES AND TECHNOLOGIES IN THE SUS

Senator Mara Gabrilli (PSD-SP) sponsored the request 1/2024, which proposes holding a public hearing to discuss regulation of access by people with rare diseases to drugs, medical devices, and technologies in the SUS. When explaining the request, the senator highlighted problems such as access in different regions of the country, lack of information and lack of knowledge about rare diseases on the part of health professionals, which can delay diagnoses and make treatment difficult. In addition, she highlights the high cost and scarcity of technologies to treat many of these diseases, making the incorporation process more time-consuming and bureaucratic. Therefore, she emphasized that the objective of the debate is to strengthen public policies, increase funding and promote the development of new technologies. Read more.

ANS WILL ANALYZE THE POSSIBILITY OF HEALTH INSURANCE PLANS WITHOUT EMERGENCY HOSPITALIZATION

The National Supplementary Health Agency (ANS) will analyze the feasibility of an outpatient health plan without emergency hospitalization coverage for up to 24 hours — a demand from health plan operators, reported Valor Econômico. One of the reasons for the agency to analyze the feasibility of this product is because there is a decision by the Superior Court of Justice (STJ) determining that ANS regulate health cards, a type of prepaid service for simple medical care that can be issued by different types of companies, not operators, which makes it difficult for ANS, which is focused on the health plan market, to monitor. There is an expectation that this new type of health plan, which only provides access to consultations and exams, will serve the public that is currently purchasing health cards. Currently, there is already an outpatient health plan on the market, but with emergency hospitalization for up to 24 hours. However,

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this type of health plan is not widely available due to the high risk of legal action, given that it is extremely difficult to remove a patient from the hospital after 24 hours of hospitalization if they need to stay for longer. At a meeting of the ANS board held on Friday afternoon (27), the agency's president advocated a debate on the rules for selling exclusively outpatient plans. Read more.

MEETING BETWEEN NATS ALIGNS PREPARATION AND DELIVERIES FOR THE CONITEC EXECUTIVE SECRETARIAT

A workshop held by the Department of Management and Incorporation of Health Technologies (DGITS/SECTICS/MS) brought together representatives of the Health Technology Assessment Centers (NATS) at the headquarters of the Pan American Health Organization (PAHO) in Brasília. These centers are part of the Brazilian Network for Health Technology Assessment (Rebrats) and play a key role in carrying out technical analyses that support the National Commission for the Incorporation of Technologies into the Unified Health System (Conitec) in its recommendations on incorporation, monitoring, disincorporation, development of protocols and clinical guidelines of the Ministry of Health, as well as the use of technologies in the SUS. "Rebrats has an important and historic role in health technology assessment (HTA) in Brazil, because, with these technology assessment centers spread across all regions, in institutions such as universities, hospitals, research centers, and state and municipal HTA departments, we reach the point where HTA should actually be applied and implemented", stated the director of the Department of_ Management and Incorporation of Health Technologies (CITEC/DGITS/SECTICS/MS), Luciene Bonan. Read more.

JUDICIALIZATION OF HEALTH IS DEBATED IN THE TECHNICAL CHAMBER OF CONASS FOR HEALTH LAW

Conass has been holding a meeting of the Technical Chamber of the Health Law Council (CTDS) since yesterday (26) to discuss judicialization, especially the actions handled by the Federal Supreme Court (STF), such as Theme 1234, which judges the passive legitimacy of the Union and the competence of the Federal Court, in demands that deal with the supply of medicines registered with the National Health Surveillance Agency (Anvisa), but not standardized in the Unified Health System (SUS). Coordinated by the director of the SUS Audit Department at the Rio Grande do Sul Health Department, Bruno Naundorf, the meeting sought to clarify doubts about the STF's decision regarding Theme 1234 and to exchange experiences of the measures adopted between state entities. "We now have to think about how we will implement everything that was established as rules by the STF regarding this topic," he highlighted. Read more.

PHARMACEUTICAL COMPANIES WIN DISPUTE OVER ICMS EXEMPTION IN COURT

At least four pharmaceutical companies - Blowtex, Blau Farmacêutica, Inaltex and Semina - have obtained rulings in the São Paulo courts to maintain the ICMS exemption on condoms. There is also a decision by the State Court of Justice (TJSP), which ratified a favorable injunction. The tax benefit, which had existed since 1998 and was to last until April 2026, was revoked by a statement from the São Paulo government in May. The tax exemption for the product was R\$27.3 million per year, according to the Budget Guidelines Law (LDO) for the year 2025. Read more.

GOVERNMENT WANTS TO EXPAND NETWORKS QUALIFIED FOR ORGAN TRANSPLANTS, SAYS HEALTH MINISTER

Health Minister Nísia Trindade said this Friday (27) that the government wants to increase the number of establishments in the country authorized to perform organ transplants. The North has the largest healthcare gap, with only 11 qualified networks. In the region, Amapá and Roraima do not have organ transplant assistance networks, according to the Ministry of Health. Tocantins is only authorized to perform cornea transplants. In Brazil, there are 388 establishments authorized to transplant organs and 428 specialized in cornea transplants. Most of them specialize in kidney transplants (175) and liver transplants (102). The biggest deficit in the network is lung transplants. Only four states in the Federation have establishments

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specialized in the procedure: Ceará, Rio de Janeiro, São Paulo, and Rio Grande do Sul. Read more.

LOW VACCINATION COVERAGE IN BRAZIL IS A CONCERN, WITH RISK OF MEASLES OUTBREAKS

Despite the current government's efforts to restore vaccination coverage, national immunization campaigns have not met their target, and the possibility of new disease outbreaks is a concern. Let us talk about the challenges of child and adult vaccination in the country. About two months ago, I wrote about a report by UNICEF (United Nations Children's Fund) that placed Brazil in a favorable position in relation to childhood immunization: while vaccination coverage continued to fall after the pandemic in other countries in 2023, the country reversed the decline observed until 2022 and indicated a decrease in the number of children up to 5 years old who received zero doses – that is, who did not receive any of the recommended vaccines in childhood. Read more.

MORE HIGHLIGHTS

Congress receives projection of phrases and images for National Huntington's Disease Day

Bill proposes to establish Urologist's Day in Ceará

<u>Favorable opinion presented on the project that establishes the men's health care policy in the SUS</u>

BRAZIL NEWS

Lula at UN touts Brazil-China plan for Ukraine-Russia talks

China, Brazil press on with Ukraine peace plan despite Zelenskiy's ire

After China meeting, Blinken says Beijing's talk of Ukraine peace 'doesn't add up'

OPEC looking forward to working with Brazil, secretary general says

Brazil's Lula says he is ready to sign EU-Mercosur trade deal

EU deforestation ban creates a hazy trade future

Brazil to propose steps to block use of benefits for online bets

Petrobras' focus remains Brazil despite Africa plans, director says

Connecticut trader convicted in Petrobras bribery case

Brazil's top court imposes new fine before allowing X to resume service

Microsoft to make \$2.7 billion cloud, AI investments in Brazil

<u>Hybrid, electric car sales to outpace rest of the market in Brazil in 2030, study</u> shows

Brazil drought dries river and stops shipping on key grains corridor