

10/12/2024

#### SIX TRANSPLANT PATIENTS IN BRAZIL CONTRACT HIV FROM INFECTED ORGANS

Six transplant patients tested positive for HIV after receiving infected organs from the Rio de Janeiro organ donation service, state officials said on Friday. The Rio Health Secretary's office said a laboratory responsible for conducting tests on donated organs had been suspended after the organs from two donors were transplanted into six people on the states waiting list for transplants. Other transplant patients were being screened to see if the organs they received were infected, and all stored organs from donors are being tested back to December 2023 when the lab was hired, the health secretariat said. "This has no precedent," it said in a statement. Police are investigating who was responsible for the two erroneous organ tests. Health authorities were alerted to the problem when a heart transplant recipient complained he was having health issues and tested positive for HIV. Two other patients who received one kidney each also tested positive, they said. Read more.

#### PATENT EXTENSION REQUESTS GREW 23% IN ONE YEAR

From September 2023 to September of this year, the number of patent extension requests in the Brazilian courts grew 23%, according to a survey by the FarmaBrasil Group, highlighted in an article by the Panorama Farmacêutico. According to the entity, 63 lawsuits are currently underway filed by foreign pharmaceutical companies that want to maintain the exclusivity of their drugs for more than 20 years. "This attempt generates negative effects for society and directly impacts the budget of the SUS", points out the executive president, Reginaldo Arcuri. "It is a movement that brings legal uncertainty to Brazilian companies and delays the production of cheaper and more effective medicines", he adds. According to the FarmaBrasil Group, 90% of the prevalent diseases in the country can be treated with generic medicines. Read more.

#### COURT BREAKS PATENT FOR DRUG FOR CROHN'S DISEASE

Judge João Carlos Mayer Soares, of the TRF1, ruled that the patent for Stelara (ustekinumab), a drug used to treat autoimmune diseases such as Crohn's Disease, psoriasis, and ulcerative colitis, has expired since 2021. For three years, Johnson & Johnson appealed provisional court decisions to prevent the entry of biological products based on ustekinumab into Brazil. An appeal is still possible. Read more.

### CMED PUBLISHES YEARBOOK WITH DATA ON THE NATIONAL PHARMACEUTICAL MARKET IN 2023

The Executive Secretariat of the Chamber for the Regulation of the Pharmaceutical Market (SCMED) released the 7th edition of the Statistical Yearbook of the Pharmaceutical Market. The information generated aims to strengthen transparency, expanding society's capacity to participate in regulatory processes and in the formulation of public policies in the health sector. The data includes all companies and pharmaceutical products regulated by the Chamber for the Regulation of the Medication Market (CMED). Read more.

### CONITEC'S MEMBERS HIGHLIGHT THE STF DECISION ON THE JUDICIALIZATION OF DRUGS AND ANNOUNCE ADMINISTRATIVE MEETING ON THE TOPIC

During the 134th Ordinary Meeting of the Conitec Medication Committee held on October 2, members discussed the decision of the Supreme Federal Court on the definition of the parameters to be observed for the judicial concession of medications registered with the

National Health Surveillance Agency (Anvisa), but not incorporated into the Unified Health System (SUS), regardless of the cost. The video of the meeting was made available last Tuesday (8). The topic was highlighted by Luiz Henrique Gomes de Almeida, member of the Health Working Group of the Federal Public Defender's Office. He emphasized that one of the main points for Conitec is that, from now on, in actions requesting medications not incorporated into the SUS, it will be necessary to discuss the reason for non-incorporation after Conitec's recommendation or, if applicable, to explain the lack of recommendation or the delay in the process. He emphasized that this decision significantly enhances the role of Conitec and improves the institutional dialogue between Conitec and the Judiciary. For Almeida, judicial decisions can no longer ignore Conitec's analyses of medications. He also mentioned that Conitec's recommendations should receive more attention from legal professionals. Finally, he pointed out that an internal meeting is planned to discuss the cost-effectiveness limit established by Conitec. Luciene Fontes Schluckebier Bonan, director of the Department of Management and Incorporation of Health Technology at the Ministry of Health, stated that Conitec participated in all meetings at the STF on the subject and considers the decision important. According to her, the measure values the work developed by Conitec over the last 13 years, a period in which the institution has made progress in terms of reporting, transparency, and social participation. Read more.

### MINISTRY OF HEALTH: STF DECISION ON GRANTING OF DRUGS STRENGTHENS SCIENCE AND REINFORCES THE COLLECTIVE ROLE OF THE SUS

n an unprecedented move, the Brazilian Supreme Federal Court (STF) has defined guidelines for granting medicines not incorporated into the Unified Health System (SUS) through legal proceedings. As a rule, the Court ruled that the courts can no longer order the provision of medicines that have not been incorporated by the National Commission for the Incorporation of Technologies (Conitec), except for certain conditions. This is the first time that parameters have been established to guide legal decisions on judicializations in healthcare – a growing phenomenon that has generated major impacts on the management and financing of public health services. Read more.

## DMD: GILMAR MENDES PRESENTS PROPOSAL FOR ACQUISITION OF MEDICINE AND SCHEDULES NEW ROUND OF NEGOTIATIONS

On Tuesday (10/8), in another round of negotiations, Justice Gilmar Mendes of the Federal Supreme Court (STF) presented a conciliation proposal for the parties interested in the acquisition by the Unified Health Service (SUS) of Elevidys, a medication indicated for the treatment of Duchenne Muscular Dystrophy (DMD). The matter is being discussed at the Supreme Court through Complaint (RCL) 68709, of which Mendes is the rapporteur and conductor of the conciliation process. Read more.

#### SENATOR ROMÁRIO DEFENDS BILL ON HIGH-COST MEDICATIONS

Senator Romário (PL-RJ) made a statement this Wednesday (9) to defend Complementary Bill 149/2024, on the supply of high-cost medications. The proposal foresees the cooperation of federative entities and establishes requirements for medications not incorporated into the Unified Health System (SUS) or not registered with the National Health Surveillance Agency (Anvisa), in addition to exempting the supply of experimental medications. "The PLP does not bring anything new, but only gives the force of law and, therefore, more legal certainty to understandings that until now have guided and referenced the decisions of our Supreme Court on the matter, which had as their object the lives of millions of people who use medications not yet incorporated into the SUS", clarified the parliamentarian. Read more.

#### SENATORS CALL FOR URGENT APPROVAL OF BILL SPONSORED BY ROMÁRIO

In a session of the Federal Senate this Tuesday (8), senators called for urgent approval of Complementary Bill 149/2024, which defines the criteria for federative entities to provide medicines not yet incorporated into the guidelines of the Unified Health System (SUS) or that are not yet registered with the National Health Surveillance Agency (Anvisa). The bill, authored

by Senator Romário (PL-RJ), was initially forwarded for analysis by the Committees on Social Affairs and Constitution, Justice, and Citizenship, but the process was interrupted by order of the President of the Senate, Rodrigo Pacheco. Read more.

## CONGRESSWOMAN ROSÂNGELA MORO CRITICIZES STF DECISION ON CRITERIA FOR PROVIDING DRUGS NOT INCORPORATED INTO THE SUS

During the deliberative session of the Chamber of Deputies this Tuesday (8), Congresswoman Rosângela Moro (União-SP), president of the Joint Parliamentary Front for Innovation and Health Technologies for Rare Diseases, highlighted her concern with the decision of the Supreme Federal Court. The parliamentarian warned that the measure compromises the right to health of people who need medications not included in the list of those approved by Conitec. Read more.

#### **GOVERNMENT WORKS TO GET WADIH DAMOUS AS NEW ANS PRESIDENT**

Wadih Damous, a member of the Workers' Party (PT), who heads the National Consumer Secretariat (Senacon), which is subordinate to the Ministry of Justice and Public Security (MJSP), is the favorite of the Luiz Inácio Lula da Silva (PT) government to take over as president of the National Supplementary Health Agency (ANS). The Executive is moving to appoint Damous to the position, but the nomination will depend on the agreements that the Planalto Palace will negotiate with the centrist parties after the municipal elections. The Ministry of Justice states that "there is no political or administrative movement" for the change. After the information was published in JOTA PRO, Damous said that Lula is the one who decides his future, but declared that he had no knowledge of the matter and that he will not "take his concentration" away from his work at Senacon "due to speculation about my future in the government." Read more.

## PRESIDENT OF ANS SAYS PROPOSAL TO REVIEW INDIVIDUAL PLAN ADJUSTMENTS IS NOT AIMED AT PROFIT FOR HEALTH INSURANCE COMPANIES

The CEO of the National Supplementary Health Agency (ANS), Paulo Rebello, denies that the proposals to reformulate the pricing policy of health insurance plans are aimed solely at profit for health insurance companies. The so-called "combo price", which involves a technical review of individual plan adjustments, is facing resistance from consumer protection agencies, which see a possibility of price increases. The topic was the public consultation held last Monday, the 7th. Read more.

## ENTITIES QUESTION SPEED AND LEGALITY OF DISCUSSION ON REVIEW OF INDIVIDUAL PLANS

Several consumer protection entities were against the public hearing held this Monday, the 7th, by the National Supplementary Health Agency (ANS), highlighting that reviewing individual plans and allowing technical reviews is rewarding the "inefficiency" of plans that cannot sustain themselves financially. The coordinator of the Health program of the Brazilian Institute for Consumer Protection (Idec), Lucas Andrietta, recently stated during a public hearing held by ANS to discuss the pricing and adjustment policy of health plans that the discussion regarding individual and family plans is illegal. Read more.

## HEALTH INSURANCE MECHANISMS FACE SETBACKS AND POSE RISKS TO THE SECTOR, SAYS STUDY

The insurance mechanisms offered by the SUS (Unified Health System) and health plans are facing a gradual process of regression in the country, which brings systemic risks to the entire sector, according to an unprecedented report by Ieps (Institute of Studies for Health Policies) and Umane released this Thursday (10). Read more.

### DIAGNOSIS IS THE BIGGEST PROBLEM IN THE FIGHT AGAINST CANCER, SAY DEBATERS

At a seminar held at the House of Representatives, experts stated that the delay in diagnosing breast and cervical cancer continues to represent the greatest challenge to controlling the disease in Brazil. Participants highlighted that there can be a delay of up to six months between the suspicion of a tumor and the start of treatment in the Unified Health System. Read more.

### CANCER PATIENTS NEED TO TRAVEL ACROSS THE COUNTRY FOR TREATMENT, STUDY FINDS

A study by the Institute for Health Policy Studies (Ieps), a private non-profit organization focused on improving public health policies, shows that in 2023, the proportion of patients seeking treatment outside their health regions will be 15.3%. Of these trips, 35% involve complex cases. The research, which used data from the FluxSUS platform, an Ieps project that maps the flow of patients in the SUS, indicates that diagnoses such as congenital malformations and neoplasms (tumors) are those that most force patients to migrate beyond the limits of their regions. Read more.

### MORE THAN 50% OF BRAZILIANS ONLY GO TO THE DOCTOR WHEN THEY HAVE SERIOUS PROBLEMS

A survey released on Monday (7) showed that more than 50% of respondents seek medical care only when they experience some discomfort or serious health problem. The survey was conducted by Grupo Bradesco Seguros, in partnership with the Locomotiva Research Institute, and focuses on evaluating aspects related to the longevity of Brazilians. According to the survey, preventive health care is even worse among men: 60% of respondents only seek medical care when they have symptoms or serious health conditions. Only 43% of respondents attend regular and preventive checkups. Read more.

#### DOCTORS SHOW DISSATISFACTION AND DISTRUST WITH HEALTH PLANS

Ipsos, in partnership with Fine Research, conducted a study with the medical profession to analyze perceptions about the future of health plans in Brazil. The survey included the participation of 60 doctors, whose data collection was carried out in July 2024. At the same time, 1,003 Brazilians were interviewed with a representative sample of the general population, in August 2024, using data from the Healthcare Screener, an annual survey conducted by Ipsos. The study showed that 75% of doctors' time is spent treating patients with health insurance plans, reinforcing the importance of this model in clinical practice. Read more.

#### USE OF TELEMEDICINE IN ICU DOES NOT REDUCE LENGTH OF HOSPITAL STAY, STUDY SAYS

A study by the Hospital Israelita Albert Einstein, carried out through Proadi-SUS (Program to Support the Institutional Development of the Unified Health System), of the Ministry of Health, in partnership with ISGlobal (Barcelona Institute for Global Health), concluded that the use of telemedicine in the ICU (Intensive Care Unit) does not contribute to the treatment of hospitalized patients nor does it reduce the length of hospital stay. Read more.

#### **MORE HIGHLIGHTS**

<u>Public hearing on regulating access to medicines, medical devices, and technologies</u> for people with rare diseases in the SUS has been cancelled

At G7 meeting. Health Minister discusses healthy aging policies

Ministry of Health advances in the implementation of the SUS Digital Program

Anvisa will prioritize requests for registration of tests against dengue and oropouche

New ICMS calculation in Paraná reduces medicine prices

#### **BRAZIL NEWS**

Lula's approval rating in Brazil rises to 36% in Datafolha poll

Brazil mayoral elections bolster center-right ahead of 2026 presidential race

Sao Paulo mayoral vote goes to runoff between center-right incumbent, leftist challenger

<u>Brazil Senate confirms Lula's pick for central bank head, Galipolo assures independence</u>

Brazil tax reform could include millionaires tax, says finance minister

Brazil suggests reform to tighten antitrust regulation for big techs

**Brazil retail sales fall less than expected in August** 

Brazil consumer prices pick up in September amid drought

**Drought blocks shipping in another grains corridor in northern Brazil** 

UN agency launching platform to help small farmers meet EU deforestation rules

<u>Indigenous groups in Brazil: We were not consulted on carbon credits</u>

Brazil's Lula says he will ban sports bets if 'addiction' not regulated

Lula slams US request for information on Brazil fighter jet deal

Musk's X back online to some Brazil users after suspension lifted

Brazilian nun awarded UN refugee prize for work with migrants