

WEEKLY REPORT

12/23/2023



BRAZILIAN GOVERNMENT ENACTS LAW THAT CREATES POLICY FOR CANCER PREVENTION CONTROL IN THE SUS

The Presidency of the Republic published in the Official Gazette of the Union, this Wednesday (20), Law 14,748/2023, which establishes the Policy for Cancer Prevention and Control in the Unified Health System (SUS) and the National Navigation Program of the Person Diagnosed with Cancer. The regulations come from bill 2952/2022, sponsored by the Special Committee to Combat Cancer of the House of Representatives. According to the text, the policy will be applied in the Unified Health System (SUS) with the purpose of reducing the incidence of cancer, improving patients' quality of life, reducing mortality and ensuring access to comprehensive care. [Read more.](#)

VIGIASUS PROJECT REVEALS DISPARITY IN PROSTATE CANCER RISK CLASSIFICATION

A strategy widely used and validated by health systems and international research institutes, active surveillance in prostate cancer is not yet a widespread therapy in Brazil, highlighted an article from the Medicina SA portal. To obtain data on the use of this methodology in patients with low-risk disease, the Ministry of Health develops, in partnership with Hospital Moinhos de Vento, in Porto Alegre, the VigiaSUS project, made possible through the Institutional Development Support Program of the Unified Health System (Proadi-SUS). This month, the preliminary results of the survey were presented. Active surveillance is a watchful observation strategy, with periodic examinations performed on the patient involving digital rectal examination, PSA test, biopsies and multiparametric prostate resonance imaging. Therapy aims to avoid or postpone the use of radical treatments, such as prostatectomy and radiotherapy, in patients with low-risk disease. Furthermore, it has a significant impact on the quality of life of these men, preventing problems such as urinary incontinence and impotence. Carried out in 18 centers in all regions of the country – another three are in the process of activation –, VigiaSUS is divided into three main axes: prospective – which aims to evaluate and collect data on the strategy –; retrospective – which evaluates the budgetary impact of surveillance active in the health system –; and a last one that analyzes the perception of urologists in relation to therapy. Currently, the project has 190 participants, of which 112 are under active surveillance. [Read more.](#)

GOVERNMENT AND FEDERATED ENTITIES REACH AGREEMENT IN THE STF ON THE SUPPLY OF MEDICINES

The Attorney General's Office of the Union (AGU), the Ministry of Health and federated entities signed a preliminary agreement within the scope of an ongoing conciliation in the Federal Supreme Court (STF) to establish concepts, flows and procedures related to the supply of medicines included in the Unified Health System (SUS) within the scope of legal proceedings, reported the Agência Brasil. Premises for the actions of entities were established in legal actions brought by patients to claim medicines that should be available in the SUS, but which for some reason were not available at the time of care. The preliminary agreement is the result of the first round of conciliation carried out by the Special Commission created by the STF with representatives of the Union, states, the Federal District, municipalities and

other entities within the scope of discussions involving Theme 1234 (RE 1366243/SC), which addresses the passive legitimacy of the Union and the competence of the Federal Court in demands that deal with the supply of another type of medicine, those not incorporated (which have not yet been made available by the SUS). One of the measures foreseen in the preliminary agreement is the development of a national digital platform that should centralize all information relating to administrative or judicial demands for access to drugs, easily accessible to citizens, which will contain basic data to enable analysis and eventual resolution. administrative. Thus, in addition to enabling public authorities to evaluate medications, the platform will enable the sharing of information with the Judiciary on the peculiarities of each case. [Read more.](#)

MINISTRY OF HEALTH ALLOCATES R\$100 MILLION FOR RESEARCH INTO CAR-T THERAPY TO TREAT CANCER

The Ministry of Health allocated R\$100 million for research into CAR-T (advanced cell therapy) for treating cancer. The studies will be carried out by the Fundação Hemocentro de Ribeirão Preto of the University of São Paulo in partnership with the Butantan Institute, highlighted Folha de S. Paulo newspaper. The financing is part of the PAC-Saúde (New Growth Acceleration Program). The announcement was made by the Secretary of Science, Technology and Innovation and the Health Economic-Industrial Complex, Carlos Gadelha, at an event this Wednesday (20). The technique has been authorized by Anvisa (National Health Surveillance Agency) since 2021 for so-called compassionate use in Brazil. [Read more.](#)

SINDUSFARMA AND INTERFARMA FILE A LAWSUIT AGAINST ANS DECISION ON ADVANCED THERAPIES

Sindusfarma filed a lawsuit in the Federal Court to annul the decision of the National Regulatory Agency for Private Health Insurance and Plans (ANS) that distinguishes advanced therapies from medicines in general, reported the Jota website. The lawsuit was filed on 12/14/2023, at the 10th Civil Court of São Paulo, with a request for urgent protection. The entity argues that the ANS deliberation is accompanied by formal defects and conflicts with deliberations by the Brazilian Health Regulatory Agency (Anvisa). Interfarma joined the action as Amicus Curiae. The classification of advanced therapies as a treatment distinct from general medicines may seem like a mere formality. Pharmaceutical industry associations, however, argue that this understanding represents a barrier to access to therapies. With the change, health plan operators would only be obliged to offer them when approved by Conitec and incorporated into the ANS List, being released from having to guarantee treatment to their patients. When the technical note was approved, on September 4, associations had already stated that they would question the ANS decision. Among the arguments used by Sindusfarma is that the ANS deliberation was not preceded by a Regulatory Impact Analysis, a step that the entity considers essential in this case. [Read more.](#)

ANS LAUNCHES PUBLIC CALL FOR PARTNERSHIPS IN THE VALUE-BASED REMUNERATION MODELS PROGRAM

The National Regulatory Agency for Private Health Insurance and Plans (ANS) promotes a public selection of legal entities under public law or civil society organizations to enter into technical cooperation. The objective is to stimulate the development and implementation of new value-based remuneration models, the agency's portal reported. The notice seeks to establish partnerships with institutions that have the technical and operational capacity to monitor the Value-Based Remuneration Models Program, which has just selected 20 projects, through its 2nd notice, launched in November 2023. [Read more.](#)

BILL AIMS TO EXEMPT DRUGS FROM TAX COLLECTION

Representative Gilvan Maximo (Republicanos-DF) proposed Bill 6153/2023, aiming to eliminate taxes on medicines. When justifying the presentation of the proposal, the author used data from the Brazilian Institute of Tax Planning from 2018, highlighting that Brazil leads the world ranking in tax burden on medicines. [Read more.](#)

MINISTRY OF HEALTH WILL PROVIDE INFORMATION ON MEASURES AND MEASURES ADOPTED TO CONTAIN THE INCREASE IN MEDICATION COSTS

Representative Amom Mandel (Cidadania-AM) sponsored application 3210/2023, which requires information from the Ministry of Health about the measures adopted to contain the increase in drug costs. [Read more.](#)

ANVISA APPROVES SPECIFIC RULES ON GOOD MANUFACTURING PRACTICES FOR ADVANCED THERAPY PRODUCTS

Anvisa updated the rules on good manufacturing practices (GMP) for advanced therapy products. Normative Instruction (IN) 270/2023 was published on December 18th, reported on the Agency 's portal. The standard harmonizes regulatory criteria, based on Annex 2A of the PIC/S Guide (Pharmaceutical Inspection Cooperation Scheme), called in English 'Annex 2A Manufacture of advanced therapeutic medicinal products for human use', which deals with the manufacture of medicines of advanced therapy for human use. [Read more.](#)

ANVISA STARTS CONSULTATION ON THE REGULATION OF DRUG DIGITAL LEAFLETS

The deadline for sending contributions for the public consultation of the National Health Surveillance Agency (Anvisa) on the regulation of drug digital leaflets began this Wednesday (20), reported Agência Brasil. Suggestions can be submitted until March 19, 2024. The measure paves the way for the exemption of leaflets printed on the packaging of certain drugs. The proposal is that a two-dimensional barcode (QR Code) be included on medication packaging for quick reading. The link will also allow access to additional information, such as videos and other instructions that help with the proper use of the medication. [Read more.](#)

ANVISA HAS NO DATA ON CONTROLLED MEDICINES SINCE 2021

Anvisa has been without national data on prescription and consumer sales of controlled medicines, such as narcotics, psychotropics and antibiotics, for two years. There is a risk of abusive consumption and diversion for illicit use, highlighted a report from the UOL portal. According to the report, in December 2021, Anvisa published a rule that led to the suspension of the SNGPC (National Controlled Products Management System). The reason given was 'instability' on the platform. [Read more.](#)

CONGRESSWOMAN SUGGESTS TO THE MINISTRY OF HEALTH SPECIALIZED PUBLIC CARE FOR WOMEN DURING MENOPAUSE IN THE SUS

Representative Rogéria Santos (Republicanos-BA) sponsored indication 1734/2023, which suggests to the Executive Branch, through the Ministry of Health, specialized public care for women during menopause in the Unified Health System (SUS). [Read more.](#)

OTHER HIGHLIGHTS

[Defined the rapporteur of the bill that guarantees actions for the prevention, detection and treatment of prostate cancer](#)

[Appointed the rapporteur to the bill that includes a representative of a civil society organization in the composition of Conitec](#)

[Ministry of Health publishes ordinance that changes the composition of Conitec members](#)

[Senator proposes public hearing in reference to World Day and National Rare Disease Day](#)

[Bills and requests from the final report of the Rare Diseases Subcommittee are presented](#)

[Bill aims to establish a deadline for diagnosing and treating patients with a rare disease](#)

[Approved the bill that ensures access to genetic counseling in cases where there is a clinical indication](#)

[Appointed rapporteur for the bill that obliges the SUS and health plans to provide comprehensive treatment for urinary incontinence](#)

[Appointed rapporteur for the bill that creates the National Registry of Research into Experimental Drugs for the Treatment of Cancer](#)

[Appointed rapporteur for the project that includes immunotherapy in clinical protocols and therapeutic guidelines for cancer](#)

[UnitedHealth agrees to sell Brazil unit Amil to Qualicorp founder - sources](#)

BRAZIL NEWS

[S&P upgrades Brazil to 'BB' following major tax reform](#)

[Brazil congressional committee approves 2024 budget bill](#)

[Brazil Senate passes changes on corporate tax rules to boost revenue](#)

[Brazil lower house approves tax on betting sites, carbon market regulation](#)

[Brazil economic activity down 0.06% in October](#)

[Brazil limits debt growth on revolving credit card lines](#)

[Brazil lawmakers pass bill to pave a highway through Amazon rainforest](#)

[Evaluation of Lula administration slightly down, survey says](#)

[Brazil's first lady to sue Musk's X over hacked account](#)

[Brazil airlines shares rise on relief amid Lula push for lower ticket prices](#)

[Brazil Supreme Court suspends \\$2 billion fine on JBS owner](#)