

WEEKLY REPORT

10/21/2023



LACK OF RULES HINDERS THE PURCHASING MODEL THAT CAN BRING EXPENSIVE DRUGS TO THE SUS

The ACR (Risk Sharing Agreement) has become a bet to pay for high-value medications and treatments, including in the SUS, but its expansion is hampered by few public agreements, while the format has advanced in the private system, highlighted a report from Folha de S. Paulo. The agreement only applies to medicines approved by Anvisa (National Health Surveillance Agency). There are two types of ACR, by performance and by volume. In the first case, more common in Brazil, the medicine is available for a limited time while its effect on patients is monitored. In the second, the medicine is offered in limited quantity and, if there is greater demand, the manufacturer provides additional doses at no cost. Both aim to mitigate uncertainties about the availability of medicines in the healthcare system. In the case of the volume-based agreement, there are doubts about the number of patients who will be treated. In Brazil, there is difficulty in obtaining epidemiological data on a national scale. Therefore, when incorporating a medicine, the Ministry of Health or hospitals may not know exactly how many people are eligible for treatment, which creates budgetary pressure on the system. The performance agreement model can be applied, for example, in the case of innovations recently launched on the market, for which there is uncertainty about their long-term effects. Despite being useful, there are still obstacles to the wider use of these agreements in the country. Studies indicate that a fundamental aspect for the ACR is the preparation of medical centers and health professionals to monitor clinical outcomes, which requires qualification from the government. The first attempts to implement such an agreement in the country came from public authorities. The most recent is from 2022, when the incorporation into the SUS of the most expensive drug in the world, Zolgensma, for type 1 spinal muscular atrophy was announced. The cost to the public coffers would be R\$5.7 million per patient. In the agreement with the manufacturer, Novartis, payment would be made in five annual installments of 20% of the value, conditional on the patient's health improvement. It is up to the Ministry of Health to purchase the medicine centrally and distribute it to states and municipalities. The 180-day deadline for making the therapy available expired in June this year. [Read more.](#)

FEDERAL GOVERNMENT SPENDS R\$575 MILLION ON THE PURCHASE OF THREE DRUGS FOR RARE DISEASES BY COURT ORDERS

In 2022, the Ministry of Health spent around R\$1.1 billion on the direct purchase of medicines by court orders. More than half (53.25%) of this total (R\$575 million) concerns three medicines for rare diseases, according to a report by Folha de S. Paulo. Topping the list is ataluren, sold under the name Translarna. R\$257 million was spent on the legalization of the drug, which treats Duchenne muscular dystrophy (DMD). The second largest expense was R\$216 million, with Soliris (eculizumab), used to treat two blood diseases, paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (Shua). Zolgensma (onasemnogene abeparvovec-xioi), used to treat spinal muscular atrophy (SMA), is in third place, with R\$101 million. The medicine is considered the most expensive in the world. Each single dose costs the government up to R\$6.9 million. SMA causes progressive loss of movement and has an incidence of 1 in every ten thousand babies born alive. The R\$6.9 million corresponds to the most recent update of the average sales price to the government (PMVG)

with the lowest applicable tax (ICMS of 12%, which is the rate in São Paulo and Minas Gerais). The PMVG is the price ceiling for all medicines purchased under court orders. In December 2022, the Ministry of Health decided to incorporate Zolgensma into the SUS for type 1 SMA patients, the most severe form in children. The ministry announced an agreement with Novartis, the drug's manufacturer, and defined payment in installments over five years. [Read more.](#)

ANS APPROVES REPRESENTATION FROM THE PHARMACEUTICAL INDUSTRY IN THE SUPPLEMENTARY HEALTH CHAMBER

The National Supplementary Health Agency (ANS) held, this Monday (16), the 596th Meeting of the Collegiate Board of Directors. On that occasion, the directors approved the proposal to change the Normative Resolution on the internal regulations of the Supplementary Health Chamber (CAMSS), to include representation from the pharmaceutical industry in its composition. [Read more.](#)

MINISTER NÍSIA TRINDADE DEFENDS PARTNERSHIP BETWEEN PUBLIC AND PRIVATE SECTORS FOR THE SUSTAINABILITY OF THE SUS

The Minister of Health, Nísia Trindade, participated, this Wednesday (18), in São Paulo, in the opening of the National Congress of Private Hospitals (Conahp 2023). The event, which brings together more than 5 thousand people, has this edition dedicated to the debate on public and private integration in health services, a topic dear to the minister who took the opportunity to highlight the importance of the agenda. "SUS showed its power with all the problems we faced during the Covid-19 pandemic, but we must move forward in its entirety. The organization, starting from primary care, has to become a reality. And medium and high complexity health care needs to advance with the same understanding. For this, the partnership between the public sector and the private sector is fundamental", said the minister. At the meeting, Nísia also emphasized that public-private integration is essential for achieving the development of the Economic-Industrial Health Complex. "When we announced with President Lula the strategy for the health complex, we stated that this strategy needs to interact with the entire the services sector. So, this is one of the challenges for us, knowing how to move forward at this point," she added. [Read more.](#)

TCU POINTS OUT LOSSES OF R\$1.2 BILLION WITH EXPIRED VACCINES

Brazil wasted more than 28 million doses of vaccines that had expired, resulting in a loss of R\$1.2 billion. The data comes from a ruling by the Federal Audit Court (TCU), approved this Wednesday (18), reported Agência Brasil. In the municipal health departments, a total of 23,668,186 expired doses were found, with a loss of R\$1.1 billion. In state departments, there were 2,296,096 doses and losses of R\$59.2 million. In the warehouse of the Ministry of Health, in Guarulhos (SP), there were 2,215,000 expired doses, corresponding to financial losses of R\$55.6 million. According to the report, the causes for the losses were not effectively and individually identified by the Ministry of Health, which attributes them solely to the failure to reach the vaccination target. [Read more.](#)

ANVISA ORDERS THE DESTRUCTION OR RETURN OF A BATCH OF R\$30 MILLION OF IMMUNOGLOBULIN DELIVERED TO THE SUS

Anvisa (National Health Surveillance Agency) has banned a batch of immunoglobulin valued at around R\$30 million purchased by the Ministry of Health to supply the SUS (Single System of Health), reported Folha de S.Paulo. The agency states that around 30,000 vials of the medicine, made from blood plasma, arrived in Brazil without the equipment used to monitor temperature variations during transport. The ministry did not pay for the batch and says that current stocks of immunoglobulin are satisfactory. 'The supply of SUS with products whose quality has been

certified and assistance to patients who depend on treatment will not be interrupted as a result of the process', states the ministry in a note. The agency's technical area ordered the destruction of around half of the lot after inspections conducted on Wednesday (18) and Thursday (19). The rest of the cargo must be returned. The ban can be reversed if the agency accepts an administrative appeal or by a court decision. The ministry signed contracts worth around R\$370 million, in April, to purchase immunoglobulin with two companies that do not have products certified by Anvisa. The ministry argues that it made emergency purchases after frustrated attempts to purchase products validated by the agency, decisions by the TCU (Federal Audit Court) and to avoid shortages. The medicine is considered strategic for the SUS, as it can be used to treat various diseases, including AIDS and other immunodeficiencies. [Read more.](#)

ANVISA APPROVES PROCEDURE FOR OPTIMIZED EVALUATION PROJECT

Anvisa Board of Directors approved a resolution that will define the general guidelines for the pilot project to implement the optimized evaluation procedure, the agency's portal reported. This procedure, based on risk criteria, aims to confirm the adequacy of the documentation submitted to the Agency in requests for registration and post-registration change of drugs. [Read more.](#)

CHILD CANCER SERVICE AT SUS WINS INTERNATIONAL AWARD FOR EXPANDING ACCESS TO PRECISION MEDICINE

Thanks to a partnership between Tucça and Santa Marcelina, which has existed since 2001, children and adolescents with cancer treated by the SUS have had access to genetic mapping of tumors and more personalized treatments. Developed by the pathology and molecular biology laboratory, maintained by Tucça, this work has just received an international award (Bayer Popia 2023), aimed at initiatives that tackle inequalities and improve access to oncological care for children with cancer around the world. One of the few in the country specialized in pediatric tumors, the Tucça laboratory is responsible for analyzing tumors in children and adolescents undergoing treatment at Santa Marcelina. It also investigates, free of charge, samples from partner institutions not only in Brazil but also in other Latin American countries. [Read more.](#)

STATE OF RIO HAS THE WORST SUS BASIC CARE COVERAGE IN THE COUNTRY, PIAUÍ THE BEST

A new survey by the Institute of Health Policy Studies (IEPS) shows that the State of Rio de Janeiro has the worst coverage of the Primary Health Care (PHC) network in Brazil, reaching only 57.2% of the population of Rio de Janeiro, highlighted O Globo newspaper. At the other end, Piauí leads the ranking with 99.9% of its inhabitants covered by health services. — PHC is the population's gateway to the health system. The new bulletin evaluated three indicators linked to primary care based on consolidated data from 2021: coverage of the population by PHC services; vaccination coverage against polio and the percentage of adequate prenatal care. [Read more.](#)

NUMBER OF MEDICAL STUDENTS RISES, BUT TRAINING OF SPECIALISTS DOES NOT KEEP UP

While the graduation rate reached 1.05 students for every thousand inhabitants, that of medical residents was just 0.21 per thousand, a rate that should reduce the impact of the policy of expanding vacancies for the area, especially in care to the public health system. The alert comes from the Medical Demography Radar in Brazil, prepared by researchers from USP (University of São Paulo) in partnership with the AMB (Brazilian Medical Association) and updated this month with new data from the National Education Census. [Read more.](#)

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