

WEEKLY REPORT

07/13/2024



HOUSE OF REPRESENTATIVES PASSES BILL ABOUT TAX REFORM INCLUDING ALL DRUGS AT REDUCED RATES

The House of Representatives passed, on Wednesday (10), the substitute text presented by representative Reginaldo Lopes (PT-MG) to Complementary Bill 68/2024, which defines rules for the Tax on Goods and Services (IBS), the Social Contribution on Goods and Services (CBS) and the Selective Tax (IS) created by the tax reform (Constitutional Amendment 132). The basic text was approved by 336 votes in favor, 142 against and 2 abstentions. In the approved text, all medicines registered with Anvisa or produced by compounding pharmacies were included, at reduced rates, with a 60% discount, or zero. Initially, a portion would be subject to the full tax, however, demands from the pharmaceutical sector pointed out that more than half of the most consumed medicines in the country would be excluded from the reduced rates. In total, 1,233 medicines had their rates reduced or zeroed. Of these, 850 received a 60% reduction and 383 received zero taxation. The 60% reduction still applies to operations supplying compositions for enteral and parenteral nutrition, special compositions and nutritional formulas intended for people with inborn errors of metabolism. Basic menstrual health care products, accessibility devices for people with disabilities and 92 medical devices also entered the differentiated tax. The approved report also modified the time for reevaluating the list of drugs covered by the reduced rate and established that it will be reviewed every 120 days. In the opinion presented last week, the review period was one year. In a detailed estimate by the Ministry of Finance, the inclusion of medicines in the lower rates should increase the standard rate, initially 26.5%, by 0.21 percentage points. This amount must be offset against the so-called Selective Tax. [Read more.](#)

PACEMAKERS, STENTS AND PROSTHESES ARE LEFT OUT OF THE LIST OF TAX-EXEMPT PRODUCTS

The Brazilian Alliance for the Innovative Health Industry (ABIIS) – which brings together medical device and diagnostic companies – is carrying out, this week, in the House of Representatives, an action with bench leaders to insist that health products be maintained with the current tax exemptions and reductions. Items such as pacemakers were left out; heart stents; probes, cannulas, catheters; joint prostheses and fracture appliances; osseointegratable implants; items used in hemodialysis; mass spectrometer (used in the Heel Test); diagnostic reagents; culture mediums; gloves, syringes and needles, among others. With the elimination or reduction of exemptions that currently exist from ICMS, PIS, COFINS, thousands of surgeries and procedures crucial to the population will be at risk. “PLP 68/24 promotes increased taxes on medical devices that are currently exempt. In Cardiology alone, the economic impact can reach 30%. Weapons will pay the same tax as vital products for Brazilians. It is completely incoherent”, says the executive president of ABIIS, José Márcio Cerqueira Gomes. [Read more.](#)

ONLY 34% OF MEN SEE A UROLOGIST WHEN THEY FEEL ANY SYMPTOMS OR DISCOMFORT, STUDY SHOWS

Research carried out by Qualibest, commissioned by the Brazilian Society of Endocrinology and Metabology (SBEM) shows that most men do not seek specialist doctors for preventive exams or when symptoms appear. When it comes to hormonal problems, for example, only 29% of men look for doctors such as endocrinologists and 34% for urologists. The number is discrepant

when compared to the number of women who seek a gynecologist at the first sign of changes: 53%. [Read more.](#)

MINISTRY OF HEALTH IGNORES DEADLINE TO INCORPORATE BREAST CANCER MEDICINES INTO THE SUS

Two years after the National Commission for the Incorporation of Technologies into the SUS (Conitec) approved the inclusion of medicines for the treatment of breast cancer in the Public Health System, patients still need to go to court to obtain the medicines, in a painful process that can last up to 6 months for delivery of medicines. Without adequate care, women are harmed in the fight against the disease. Despite having already submitted to public consultation and approved in April a protocol that guarantees the distribution of medicines by the Unified Health System (SUS), the ministry has not yet published the document in the Official Gazette of the Union (DOU). Therefore, there is no supply of medicines in the SUS. In the version submitted to public consultation, the new protocols provided for the incorporation of two types of medicines for the treatment of breast cancer in the SUS: cyclin inhibitors, which were approved by Conitec in December 2021 (offer in the SUS delayed for more than 764 days) and trastuzumab emtansine, which was incorporated in September 2022, which since approval has already accumulated more than 488 days without the start of its offer in the SUS. [Read more.](#)

MINISTRY OF HEALTH PLANS A SCREENING GUIDELINE FOR CONTROL OF COLORECTAL CANCER IN BRAZIL

The Health Committee of House of Representatives held a public hearing on the panorama and measures for the prevention and control of colorectal cancer. The debate was requested and chaired by representative Dr. Frederico (PT-PI). Suyanne Camille Caldeira Monteiro, technical advisor at the Ministry of Health, recognized the need for a National Screening Program for Colorectal Cancer in Brazil, the General Coordination of Strategic Actions in Oncology (CGCAN), in partnership with the National Cancer Institute (Inca), has been working to develop a national screening guideline. A working group has been working since 2023 in this regard. [Read more.](#)

PARLIAMENTARY FRONT FOR INNOVATION AND HEALTH TECHNOLOGIES FOR RARE DISEASES PRESENTS RESULTS FOR THE FIRST HALF OF THE YEAR

The Mixed Parliamentary Front for Innovation and Health Technologies for Rare Diseases held, this Wednesday (10), the technical meeting to close the 1st semester. The president of the Front, deputy Rosângela Moro (União-SP), presented a summary of the activities carried out in the first semester, highlighting the holding of five meetings. At these events, the ethical and regulatory challenges for expanding clinical research for rare diseases, the role of Conep, Anvisa's role in ensuring the registration of these research, the industry's vision as a developer of products for rare diseases and the process were discussed. incorporation of treatments by Conitec. Among the achievements on the rare diseases' agenda, Rosângela Moro mentioned the sanction of the bill on clinical trials. [Read more.](#)

JUDICIALIZATION IN HEALTH PLANS RAISES THE COST FOR BENEFICIARIES

The disclosure of cases of unilateral cancellations are among the reasons that explain the significant increase in the number of lawsuits against health plans in recent years, according to experts interviewed by Correio Braziliense newspaper. The processes form a triangulation that involves consumers, operators and the National Supplementary Health Agency (ANS). Data from the Procedural Statistics panel on the Right to Health of the National Council of Justice (CNJ) indicate a 65% increase in citizen lawsuits against operators between 2020 and 2023. According to the CNJ, in 2023, 219.34 were filed thousand new cases, compared to 132.53 thousand actions in 2020. Individual actions constitute almost 100% of processes since 2020, which resulted in a cost of R\$17 billion for the plans, in the last five years alone. The amount ends up being passed on to users, sector representatives warn. Brazilian Association of Health Plans (Abrange) says, in a note, that the judicialization of health occurs in an "improper" way and harms the beneficiary himself more. "The person most impacted by undue judicialization is the beneficiary himself, since the system works on a collective model: the use of one is paid

for by all. In other words, when there is misuse or undue judicialization that leads to legal action, there is an unforeseen increase in costs, which makes the use of the system more expensive for all beneficiaries", he writes. [Read more.](#)

FARMÁCIA POPULAR NOW OFFERS 95% OF MEDICINES FREE OF CHARGE

In celebration of the 20th anniversary of the Farmácia Popular program, starting today (10), the Ministry of Health will offer 95% of medicines and supplies free of charge to the entire population. With this, medicines indicated for the treatment of high cholesterol, Parkinson's disease, glaucoma and rhinitis can be taken free of charge by the population across the country. The expectation is that around 3 million people who already use the program will be impacted and, on average, this can generate savings for users of up to R\$400 per year. [Read more.](#)

BILL AIMS TO ESTABLISH THE NATIONAL CARE POLICY

The Executive Branch presented Bill 2762/2024, which establishes the National Care Policy. The proposal was initially prepared by the Ministry of Development and Social Assistance, Family and Fight Against Hunger, the Ministry of Women and the Ministry of Human Rights and Citizenship. The article defines that the National Care Policy will be aimed at guaranteeing the right to care, through the promotion of social and gender co-responsibility for the provision of care, considering intersectional inequalities. The Policy will be the duty of the State, including the Union, the States, the Federal District and the Municipalities, within the scope of their competences and attributions, in co-responsibility with families, the private sector and civil society. [Read more.](#)

ANVISA APPROVES PILOT PROJECT TO TEST DIGITAL LEAFLETS FOR MEDICINES

The National Health Surveillance Agency (Anvisa) approved this Wednesday, 10th, a pilot project to test the replacement of the leaflet printed on paper with a digital version in some medicines. The proposal involves printing a QR Code on medication packaging so that consumers can access the leaflet online. According to the project, the code will also allow access to additional information, such as videos and instructions that help with the proper use of products. At first, the digital leaflet will only be permitted in the following cases: - Packaging of free medicine samples; - Medicines intended for healthcare establishments (such as hospitals and clinics), except pharmacies and drugstores; - Medicines that do not require a medical prescription; - Medicines intended for government use, in packaging with specific inscriptions from the Ministry of Health. [Read more.](#)

PUBLISHED ORDINANCE ESTABLISHING THE OBLIGATION FOR ANS PUBLIC SERVANTS TO FILL OUT THE E-AGENDAS SYSTEM

The National Supplementary Health Agency (ANS) ordinance was published in the Official Gazette of the Union, this Wednesday (10), which establishes the obligation for public servants working at the agency to fill out the e-Agendas system. [Read more.](#)

MORE HIGHLIGHTS

[ANS updates proposal submission tool to update the list of mandatory coverages](#)

[At an ANS meeting, a draft standard on the Management and Performance Program \(PGD\) is approved](#)

[Anvisa publishes standard operating procedure for the Medicines area](#)

[Anvisa extends CP deadline on risk classification of economic activities](#)

[Check the list of the most consumed generics in Brazil](#)

BRAZIL NEWS

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