WEEKLY REPORT

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BRAZIL PHARMACEUTICAL INDUSTRY EXPECTS GROWTH AND REGULATORY SHIFTS IN 2026

Brazil's pharmaceutical market is forecast to grow about 10.6 % in 2026, continuing a robust expansion trend after significant gains in recent years, according to industry data from IQVIA and sector analyses. This projected growth comes amid regulatory debates, legislative proposals and changes in patent dynamics that are expected to shape the competitive landscape for domestic manufacturers and multinational players alike. Industry stakeholders say that discussions in the National Congress and regulatory shifts will have a notable impact in 2026, touching on issues such as patent extensions and incentives for innovation and local production. A key legislative effort referenced by sector leaders is PL 2583/2020, which aims to strengthen production incentives for medicines, vaccines, devices, and critical inputs, potentially boosting Brazil's industrial autonomy and supply chain resilience. Other points of attention include pending proposals on patent term adjustments and broader debates on strengthening the regulatory framework for advanced therapies. Read more.

BRAZIL HEALTH MINISTRY BEGINS STUDY ON PRICE LIMIT FOR INCORPORATING MEDICINES INTO SUS

The Brazilian government, through the Ministry of Health's Secretariat of Science, Technology and Innovation, has launched a technical study to explore the feasibility of establishing price-impact thresholds for incorporating medicines and health technologies into the Unified Health System (SUS). This initiative — cited as a priority policy area for 2026 — seeks to define an explicit budget impact limit that could help guide decision-making on whether high-cost drugs should be added to public coverage lists. The proposal comes amid ongoing debates about the costs of high-priced treatments and fiscal sustainability in the public health system. One idea under review is the adoption of a "budget-impact threshold" — a maximum level of projected spending per patient or technology beyond which incorporation would not automatically proceed. Proponents argue such thresholds could enhance predictability, transparency, and efficiency in health technology assessment (HTA) processes, while critics caution that rigid limits might hinder access to innovative therapies for serious conditions. Read more.

BRAZIL MINISTRY OF HEALTH LAUNCHES PUBLIC CONSULTATION ON PRODUCTION AND DELIVERY TIMES FOR STRATEGIC MEDICINES

Brazil's Ministry of Health has opened a public consultation to gather strategic and logistical information on the time it takes to produce and deliver 301 medicines and strategic supplies destined for the Unified Health System (SUS). The initiative, published in the Official Gazette, is coordinated by the Secretariat of Science, Technology and Innovation in Health (SCTIE) and aims to enhance governance, planning, and decision-making in pharmaceutical procurement for the public health system. The consultation, which runs from January 19 to February 18, 2026, invites contributions from manufacturers, suppliers and distributors of medicines and strategic health inputs purchased by the ministry. Inputs will be submitted via two electronic forms and analyzed technically to produce a consolidated report to improve SUS supply planning and reduce risks of shortages. The exercise also seeks to strengthen dialogue with industry to align production timelines with public procurement needs. Read more.

ANVISA LAUNCHES DIRECTED CONSULTATION ON DRUG TRADE NAMES

The Brazilian Health Regulatory Agency (Anvisa) has launched a directed consultation aimed at collecting technical contributions and public perceptions on the naming of medicines marketed in Brazil under the current regulatory framework (RDC 59/2014). The initiative seeks input from citizens, health professionals, regulated companies, researchers, and other stakeholders to support a forthcoming Regulatory Impact Analysis (AIR) and may inform future revisions to the naming rules. The consultation — open from January 22 to March 22, 2026 — invites responses via an online form and is part of Anvisa's 2026-2027 Regulatory Agenda, reflecting ongoing efforts to ensure that commercial names for medicines comply with safety, clarity and distinction principles that reduce confusion and enhance patient safety. The current regulation establishes criteria to minimize look-alike or sound-alike names and guide the formation of medication families. Read more.

ANVISA DENIES ALL PHARMACEUTICAL APPEALS AGAINST FINES IN 2025

The Brazilian Health Regulatory Agency (Anvisa) denied all appeals filed in 2025 by major pharmaceutical companies against administrative fines, maintaining R$ 4.6 million in penalties originally imposed for regulatory breaches. The decision reflects Anvisa's continued enforcement stance amid ongoing sector scrutiny over compliance, supply reporting, and public health obligations. Fines upheld included sanctions tied to failures in mandatory notifications, such as a lapse in informing authorities about supply shortages of an essential medicine, underlining the regulator's insistence on strict adherence to reporting obligations. Read more.

NEW NON-HORMONAL MENOPAUSE DRUG AWAITS ANVISA REVIEW

A new medication developed by Japanese pharmaceutical company Astellas to treat menopause symptoms is currently under evaluation by Brazil's regulatory authority, the National Health Surveillance Agency (Anvisa), and could be approved for the Brazilian market in the coming months. The treatment is notable for being non-hormonal, differentiating it from traditional hormone-replacement therapies commonly used to address vasomotor symptoms such as hot flashes and night sweats. Formulated with fezolinetant, the once-daily oral pill has shown positive results in international clinical studies involving over 900 women aged 40–75 years. Preliminary findings from the OPTION-VMS study suggest reductions in the frequency and severity of vasomotor symptoms, improvements in sleep quality, daily activities, and work productivity after 12 weeks of use. The drug works by targeting neural pathways in the hypothalamus that regulate body temperature, blocking neurokinin B interaction and thereby reducing symptom intensity. Read more.

ANVISA APPROVES EMPAVELI FOR RARE KIDNEY DISEASE

Brazil's Brazilian Health Regulatory Agency (Anvisa) has approved Empaveli (pegcetacoplan) for the treatment of primary immune complex membranoproliferative glomerulonephritis (IC-MPGN), a rare and progressive kidney disease. The decision, published on January 19, 2026, follows a regulatory review of the medicine's quality, safety, and efficacy. Empaveli was already authorized in Brazil for paroxysmal nocturnal hemoglobinuria (PNH). The drug is marketed by Pint Pharma. Read more.

BRAZIL SUS TO OFFER ARTIFICIAL URINARY IMPLANT FOR SEVERE INCONTINENCE

Brazil's Unified Health System (SUS) will begin offering artificial urinary sphincter implants as a treatment option for patients with severe urinary incontinence, particularly cases that have persisted after prostate surgery or other complex conditions. The move follows a favorable recommendation from the National Committee for Health Technology Incorporation (Conitec), which assessed the clinical and quality-of-life benefits of the technology and approved its inclusion in the public health system's list of covered procedures. The artificial urinary sphincter is considered the gold-standard treatment for severe urinary incontinence by urology societies and supported by clinical evidence — restores continence by mechanically controlling bladder emptying. Read more.

BRAZIL ACUTE MYELOID LEUKEMIA TREATMENT FACES INEQUITY IN HEALTH SYSTEM

Treatment for acute myeloid leukemia (AML), an aggressive blood and bone marrow cancer, is facing inequities in Brazil's health system, with disparities in access to modern therapies and care pathways noted across the country. The condition has been classified by the Ministry of Health as a priority for updating clinical guidelines, reflecting concerns about unequal availability of advanced treatments and diagnostic tools between regions and care settings. AML treatment typically involves intensive chemotherapy and, when possible, targeted therapies and bone marrow transplantation — options that are often less accessible in the public health care system (SUS) compared to private settings, contributing to uneven outcomes for patients. Experts argue that expanding access to comprehensive diagnostics, innovative drugs and standardized care protocols is critical to reducing these disparities and improving survival rates, especially in underserved regions. Read more.

BRAZIL'S HEALTH BUDGET FOR 2026 GROWS BUT RAISES CONCERNS OVER STRUCTURE AND PRIORITIES

The health budget for 2026 in Brazil was approved with a 10 % increase over the previous year, setting R$ 271.3 billion for financing the Unified Health System (SUS) after presidential sanction of the annual budget law on January 14, 2026. The figure is higher than the R$ 254.1 billion earmarked for health in 2025, reflecting continued policy emphasis on public health funding within the broader R$ 6.54 trillion federal budget. Despite the headline growth, analysts and sector stakeholders highlight structural concerns about the composition and adequacy of the allocations. While attention to primary care and specialist services increased (and the Farmácia Popular program saw a significant rise) strategic areas such as research, development and innovation registered cuts compared with 2025 levels. The prominence of parliamentary amendments in shaping final allocations has also drawn scrutiny for potentially skewing planning and execution priorities away from cohesive national health strategies. Read more.

BRAZIL SUPREME COURT JUSTICE DEMANDS SUS AUDIT TO OVERSEE HEALTH AMENDMENTS

Flávio Dino, a justice of Brazil's Supreme Federal Court (STF), has ordered the Ministry of Health to present an emergency plan to restore the operational capacity of the National Department of SUS Audit (DenaSUS) to oversee the use of parliamentary amendments allocated to the public health system. The decision highlights concerns over transparency and control as amendments account for a growing share of federal health spending. The ruling, issued on January 16, gives the ministry 30 days to propose measures to strengthen auditing and monitoring mechanisms in response to what the court describes as the increasing parliamentarization of health expenditures. The move seeks to reinforce oversight of public resources and reduce the risk of irregularities in funds directed to the Unified Health System (SUS). Read more.

BRAZIL HEALTH PLANS REPORT SHARP RISE IN ONCOLOGY TREATMENT COSTS

A new industry survey from the National Union of Self-Managed Health Care Institutions (UNIDAS) shows a sharp increase in oncology treatment costs among self-managed health plans in Brazil, with per-capita spending rising 50% between 2021 and 2024. The findings point to mounting financial pressure driven by the incorporation of new technologies and demographic changes affecting cancer care. According to the UNIDAS National Health Survey 2025, the average monthly per-capita cost of oncology drugs increased from about R$6.10 in 2021 to R$13.54 in 2024, while 7.55 per 1,000 beneficiaries underwent oncology-related procedures over the period. The data highlight growing challenges for plan sustainability as operators balance cost containment with access to innovative therapies. Read more.

BRAZIL ANS APPROVES NEW OVERSIGHT MODEL FOR SUPPLEMENTARY HEALTH PLANS

Brazil's National Supplementary Health Agency (ANS) has approved a new oversight model for the supplementary health sector aimed at modernizing supervision, speeding up responses to beneficiary complaints, and strengthening compliance incentives for health plan operators. The reform was approved in December 2025 and is scheduled to take effect on May 1, 2026. The model adopts a risk-based and proactive approach, replacing predominantly reactive complaint handling with statistical sampling of claims, targeted inspections, and planned enforcement actions. According to ANS, the framework is designed to identify recurring non-compliance patterns more quickly, reduce regulatory backlogs and encourage preventive corrections by operators before sanctions are applied. Read more.

BRAZIL CONSUMERS SPEND BILLIONS ON WEIGHT-LOSS PENS AMID RISING DEMAND

Brazilians are spending billions of reais on weight-loss injectable pens such as Wegovy and Ozempic, reflecting a rapid surge in demand for GLP-1-based therapies used for obesity and diabetes management. According to industry data and market reports, the market for these medications moved approximately R$ 10 billion in 2025, representing an emerging and influential segment of the pharmaceutical retail sector. The popularity of these GLP-1 agonist drugs — including brands like Wegovy, Ozempic and others — has grown sharply as patients seek treatment options that help reduce appetite and support weight loss, contributing to significant out-of-pocket spending among Brazilian consumers. Reports suggest that import volumes for these pens have surged to levels comparable to other high-demand consumer goods, and that aggregate spending may already surpass previous categories historically dominant in the market. Read more.

BRAZIL EMS FORECASTS R$250 MILLION IN REVENUE FROM "WEIGHT-LOSS PENS" IN 2026

Brazilian pharmaceutical company EMS projects that revenue from its weight-loss injectable pens will reach R$250 million in 2026, more than double the R$120 million forecast for 2025. The company says this robust growth reflects strong market demand for its product designed to support obesity management. EMS attributes the anticipated increase to expanding distribution and sales channels, greater physician adoption of the therapy and rising patient awareness of treatment options. The injectable pens, which are positioned as adjuncts to lifestyle changes in weight management, have gained traction in the Brazilian market amid heightened focus on obesity as a public health issue. Read more.

BRAZIL TALKS ADVANCE ON LOCAL PRODUCTION OF HIV PREVENTION INJECTION AFTER INDUSTRY-FIOCRUZ AGRÉMENT

A memorandum of understanding signed between Gilead Sciences, the pharmaceutical company behind the lenacapavir injectable — a long-acting HIV pre-exposure prophylaxis (PrEP) medicine — and Fundação Oswaldo Cruz (Fiocruz) could pave the way for future local production of the treatment in Brazil. The agreement, framed with Fiocruz's Farmanguinhos unit (the Institute of Technology in Drugs), focuses on evaluating technology transfer and cooperation options that might enable manufacturing of the semestrial HIV prevention injection within the country. While the memorandum does not yet constitute a formal production commitment, it establishes a basis for technical and economic feasibility studies that could reduce dependence on imported supply and lower production costs if fully implemented. The lenacapavir injection, already registered by the Brazilian Health Regulatory Agency (Anvisa), is being studied in the ImPrEP LEN Brasil project coordinated by Fiocruz across seven Brazilian cities — including Campinas, São Paulo, Rio de Janeiro, Salvador and Manaus — to assess its implementation as a PrEP alternative to daily oral therapy. Read more.

BRAZIL PATENT DELAYS HINDER INNOVATION AND COMPETITIVENESS, INDUSTRY SAYS

Slow patent examination and backlog issues in Brazil are seen as key obstacles to innovation and competitiveness across technology-intensive sectors, including health and pharmaceuticals, according to a branded content piece published by CNN Brasil and industry stakeholders. The commentary highlights that lengthy processing times at the National Institute of Industrial Property (INPI) have contributed to a decline in Brazil's ranking on the Global Innovation Index and reduced the number of patents granted, signaling broader structural challenges for research and development. The report notes that Brazil has fallen to 52nd place among 139 economies in the index, with the patent delay (often exceeding a decade in some cases) cited as a factor that reduces investment, dampens productivity, and discourages international research centers from operating locally. Critics argue that the lack of predictability and regulatory certainty weakens incentives for long-term innovation projects and can delay the arrival of new technologies, including medicines, to the market. Industry groups such as the Movimento Brasil pela Inovação are advocating for regulatory reforms and legislative adjustments, including mechanisms like Patent Term Adjustment (PTA), to mitigate the negative effects of examination delays and align Brazil more closely with global practices. Read more.

BRAZIL SINDUSFARMA LEADER ENDORSES CLOSER TIES WITH EUROPEAN PHARMACEUTICAL FIRMS

Nelson Mussolini, president of Sindusfarma, says the Mercosur–European Union trade agreement approved on January 9 could bring significant opportunities for Brazil's pharmaceutical sector, especially through enhanced interaction and cooperation with European pharmaceutical companies. In an article outlining his analysis, Mussolini argues that tariff reductions and strategic integration may strengthen the local industry's competitiveness and foster technological partnerships. According to Mussolini, a diversified industry ecosystem — combining national and foreign players — is poised to benefit from lower import tariffs on pharmaceutical inputs, potentially reducing production costs and boosting export potential. He also highlights that increased cooperation with European firms could stimulate innovation, research and development, and scientific exchange, while cautioning policymakers to ensure safeguards that protect fair competition for domestic producers. Read more.

BRAZIL MINISTRY OF EDUCATION SAYS MEDICAL COURSES FACE SANCTIONS AFTER POOR EVALUATION

Brazil's Ministry of Education says that around 30% of medical courses evaluated in 2025 may face sanctions after receiving unsatisfactory results in the first edition of the National Medical Training Assessment Exam (Enamed). This measure is part of a broader government effort to strengthen quality control in medical education and curb the expansion of low-performing programs. According to the ministry, 99 out of 351 medical courses assessed fell into the lowest performance brackets, with fewer than 60% of students meeting the minimum proficiency threshold. These programs will be subject to graduated administrative measures, which may include limits on increasing student intake, suspension of access to Fies student-loan funding and reduction of available seats until new evaluation results are released, expected in October 2026. Read more.

BRAZIL MEDICAL BODIES INTENSIFY PUSH FOR PROFICIENCY EXAM AFTER POOR MEDICAL SCHOOL RESULTS

Two major developments in Brazil's medical education debate have emerged following the recent release of results from the National Medical Training Assessment Exam (Enamed), which showed that about 30 % of medical courses had unsatisfactory outcomes. In parallel moves, the Brazilian Medical Association (AMB) renewed its call for a national proficiency exam for doctors, while the Federal Council of Medicine (CFM) is considering a resolution to restrict professional registration for students who fail the evaluation. The AMB argues that introducing an "OAB-style" proficiency test for medicine would help ensure that newly trained doctors meet consistent standards of knowledge and skill before entering practice, citing concerns that the current Enamed results reflect weaknesses in both training and oversight. The proposal aligns

with parallel legal initiatives in Congress that would require mandatory proficiency testing for medical graduates before they can legally practice. Meanwhile, the CFM has studied measures that could prevent about 13 000 medical graduates who performed below proficiency thresholds in the Enamed from obtaining their registration, which is required to practice medicine in Brazil. The council's leadership says such steps are aimed at protecting patient safety, although legal and regulatory questions remain regarding the authority of professional bodies to impose additional requirements beyond diploma recognition. Read more. Read more.

BRAZIL GOVERNMENT PROPOSES MAKING ENAMED A NATIONAL PROFICIENCY EXAM FOR DOCTORS

The federal government has announced plans to propose to the Brazilian National Congress that the National Medical Training Assessment Exam (Enamed) be formally recognized as a national proficiency exam to determine whether newly graduated physicians are qualified to practice medicine in Brazil. Under the proposal, a doctor's professional registration would be conditional on satisfactory performance in the Enamed assessment. According to Alexandre Padilha, Brazil's Minister of Health, the government aims to leverage ongoing congressional debate over a proposed proficiency exam by showcasing the Enamed — conducted by the Ministry of Education at multiple points in medical training (second, fourth and sixth years) — as a comprehensive alternative that evaluates progress throughout a course rather than a single end-of-training test. While the proposal must be approved via legislative change and would not affect the 2025 Enamed results, it underscores broader efforts to strengthen medical education quality and oversight. Critics have debated the plan's scope and its relationship with initiatives under consideration by the Federal Council of Medicine (CFM), which has looked at using Enamed outcomes to regulate professional registration independently. Read more.

MORE HIGHLIGHTS

Brazil medical device industry projects growth in early 2026

Brazil polylaminin study progresses with local production ahead of clinical trials

Brazil ANVISA highlights importance of pharmacovigilance and VigiMed reporting in new vídeo

Brazil cannabis medicinal regulation remains contested as Anvisa review continues

Brazil Supreme Federal Court debates whether cannabidiol is a medicine or health product

Brazil nursing council authorizes nurses to prescribe continuous-use medications under protocols

Brazil Health Ministry launches courses to strengthen early cancer detection in primary care

BRAZIL NEWS

Brazil central bank to start cutting rates in March to boost weak economy

Brazil finance minister wants deputy Durigan as successor, sources say

Brazil police target Rio pension fund in probe linked to Banco Master, sources say

Brazil court suspends antitrust ruling against Meta over WhatsApp Business

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EU-Mercosur deal likely to take effect provisionally from March, says EU diplomat

India's Modi speaks to Brazil's Lula on strategic partnership