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Brazil Offers Important Lessons for the Future of the GLP-1 Market in Latin America

(Source: An article by Vibha Ravi for Scrip)

As competition intensifies in the obesity and diabetes market, a recent analysis of GLP-1 receptor agonist use in Brazil—the largest pharmaceutical market in Latin America—provides valuable insights for pharmaceutical executives preparing for the next phase of growth in the region.

Brazil has emerged as the leading "pharmerging" market for GLP-1 therapies, with *semaglutide* driving much of the category's rapid expansion. However, new research suggests that demand is being shaped by more than clinical need. Consumption is concentrated in wealthier regions, with little correlation between GLP-1 utilization and obesity prevalence. This finding highlights how access, income, healthcare infrastructure, and physician availability may be stronger determinants of uptake than disease burden alone.

The study also identified significant off-label use and growing safety concerns. Between January 2024 and March 2025, Brazil recorded nearly 1,600 adverse event reports related to GLP-1 therapies, with *semaglutide* accounting for more than half. Notably, 38% of *semaglutide*-related adverse event reports were linked to off-label use, far above the global average reported by the World Health Organization. Regulators have also documented prescriptions originating from non-traditional prescribers, including dentists and veterinarians, raising concerns about oversight and appropriate use.

In response, Brazil's regulatory authority, ANVISA, has launched enhanced pharmacovigilance measures and adopted a more cautious approach toward approving follow-on *semaglutide* products. Although *semaglutide* patents have expired, regulatory scrutiny has slowed generic and follow-on market entry, effectively extending Novo Nordisk's commercial runway. ANVISA is requiring extensive evidence on quality, safety, immunogenicity, and efficacy for *semaglutide* analogs, creating a higher regulatory hurdle than many manufacturers anticipated.

At the same time, market dynamics continue to evolve. The launch of *Wegovy* has reduced off-label use of *Ozempic* for weight loss and is reshaping prescribing patterns. Meanwhile, Eli Lilly faces a different challenge: proposed legislation that could eventually enable compulsory licensing of *tirzepatide* products in Brazil, underscoring the tension between innovation, affordability, and access.

For pharmaceutical leaders, Brazil offers a preview of broader Latin American trends. Strong patient demand for obesity therapies is colliding with affordability constraints, regulatory vigilance, and political pressure for greater access. Companies entering or expanding in the region will need strategies that address not only clinical differentiation, but also pricing, access, safety monitoring, and evolving regulatory expectations.

In Brief...

- **Pfizer** has agreed to pay Innovent US$650 million up front to partner on cancer drug development, by entering a broad pact that positions Pfizer to leverage China's early development system. The deal, which features up to US$9.85 billion in development, regulatory, and commercial milestones, supports the development of twelve cancer medications and covers "a diverse portfolio of antibody-drug conjugates with novel differentiated payload and multi-specific antibodies with differentiated immune-engaging features and unique designs," company officials said in a release.
- **Toho Holdings** (Japan) announced that it has signed a memorandum of understanding with **DHL Supply Chain Japan** to explore a collaboration aimed at building an advanced healthcare logistics platform in Japan. The two companies will discuss ways to leverage DHL Group's global logistics network and expertise in the life sciences and healthcare sectors alongside Toho's pharmaceutical distribution network. The goal is to establish a framework that can strengthen manufacturer and clinical trial logistics while supporting one-stop services across the pharma supply chain.
- **Johnson & Johnson (J&J)** will purchase **Firefly Bio**, which specializes in the development degrader antibody conjugates and combines the specificity of anti-body drug conjugate technology with intracellular activity of protein degradation. The transaction, expected to close later this year, gives J&J a new way to reach difficult targets in hard-to-treat solid tumors.

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Drug Shortages May Be Easing, But Global Supply Chain Risks Are Growing

(Source: An article by Anju Ghangurde for Scrip)

New data from the United States Pharmacopeia (USP) suggest that while U.S. drug shortages declined for a second consecutive year in 2025, the underlying vulnerabilities of the global pharmaceutical supply chain may actually be worsening. For pharmaceutical leaders, the findings underscore the growing intersection of supply security, economics, and geopolitics.

Total U.S. drug shortages fell 23% in 2025, declining from 98 to 75 products. However, product discontinuations surged 60%, reaching their highest level since 2019. Most notably, many of the discontinued medicines were older, low-cost generic products. USP found that 65% of discontinued oral solid drugs were priced below $1 per unit, highlighting a fundamental industry challenge: essential medicines are becoming economically unattractive to manufacture.

This trend has implications far beyond the United States. As pricing pressure intensifies globally, manufacturers may continue to exit low-margin categories, reducing supply

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Shortages *(cont'd.)...*

redundancy and increasing the likelihood of future shortages. In effect, the market is signaling that affordability and supply resilience are increasingly in conflict.

The report also highlights the extent of global supply chain concentration. Of the drugs currently in shortage, 44% depend on a single country for at least one key starting material. China and India dominate upstream supply of key starting materials, while the European Union remains a critical source of active pharmaceutical ingredients (APIs). One cited example, *cefotaxime* injection, relies almost entirely on Chinese sourcing for key starting materials and Indian suppliers for APIs.

For multinational pharmaceutical companies, this concentration creates significant geopolitical exposure. Trade disputes, export controls, manufacturing disruptions, regulatory actions, or regional conflicts in a small number of countries can have immediate downstream consequences for medicine availability worldwide. The issue is particularly acute for sterile injectables, oncology therapies, and other essential hospital products.

The report further illustrates how supply challenges are becoming increasingly global. Shortages of important oncology agents such as *cisplatin* and *carboplatin* have affected both the U.S. and India, although for different reasons—from manufacturing compliance issues to rising raw material costs. In response, Indian regulators recently authorized substantial price increases to maintain supply viability, demonstrating how governments may increasingly intervene to preserve access to critical medicines.

The broader lesson for industry leaders is that supply chain resilience can no longer be viewed solely as an operational issue. Diversification of sourcing, sustainable pricing models for essential medicines, proactive supply-risk monitoring, and closer collaboration with regulators are becoming strategic imperatives. As geopolitical uncertainty grows and healthcare systems prioritize supply security, companies that build resilient and geographically diversified supply networks will be better positioned to navigate the next generation of global pharmaceutical challenges.

Five EU Countries Call for Unified Pharmaceutical Strategy Amid Growing Pricing Pressures

(Source An article by Zoey Becker for FiercePharma)

Belgium, the Netherlands, Luxembourg, Austria, and Ireland—through the Beneluxa Initiative—have called for a more coordinated European approach to pharmaceutical policy, arguing that rising pricing pressures and geopolitical uncertainty require greater collaboration to ensure both patient access and long-term sustainability of healthcare systems.

The group's statement comes as European governments face increasing pressure over drug affordability while simultaneously seeking to maintain incentives for pharmaceutical innovation. Rather than relying on fragmented national responses, the coalition is advocating for a stronger EU-wide framework to address shared challenges related to pricing, reimbursement, access, and supply resilience.

The timing is notable. Debate continues across Europe regarding the impact of U.S. drug pricing policies and broader efforts to reduce healthcare spending. At the same time, several pharmaceutical companies have raised concerns that cost-containment measures could affect future investment decisions and the attractiveness of Europe as a destination for research, development, and manufacturing.

For the global pharmaceutical industry, the initiative highlights a growing policy tension in that governments are seeking greater affordability and negotiating leverage, while manufacturers emphasize the need for predictable returns to support innovation. The outcome could influence future launch sequencing, pricing strategies, and investment flows across major markets.

More broadly, the Beneluxa proposal reflects a trend likely to extend beyond Europe. As healthcare budgets tighten worldwide, policymakers are increasingly exploring collaborative approaches to drug purchasing, pricing, and access. Pharmaceutical companies should expect growing scrutiny of pricing models and greater coordination among governments seeking to balance innovation incentives with affordability and healthcare sustainability.

In Brief (cont.)

The company expects the purchase to diversify its oncology pipeline. J&J already has an oncology drug development pipeline that spans hematologic malignancies and solid tumors, but the company said that the Firefly purchase will further diversify its cancer pipeline with preclinical candidates for the treatment of solid tumors.

- Germany's government is replacing plans that would have introduced variable discounts on pharmaceuticals, according to a government source. The variable discounts will be replaced with new discounts at a fixed level so that companies can plan ahead, the source said, without specifying the size of the new discounts. The federal health ministry said nothing had been decided yet.
- **GSK** has agreed to buy **Nuvalent** for US$10.6 billion, securing two near-approval cancer therapies that could challenge products from Roche, Pfizers, and other drugmakers. "Subject to FDA approvals, the acquisition will deliver revenue growth from 2027 going forward," said GSK CEO *Luke Miels*, "It will strengthen our operating profit for GSK through the dolutegravir loss of exclusivity period." Nuvalent filed for FDA approval of *zidesamtinib* in ROS1-positive non-small cell lung cancer patients who have previously received tyrosine kinase inhibitor.
- **Teva** is introducing two new generics, *sitagliptin* oral medication (a generic version of *Januvia*) and *budesonide* and *formoterol fumarate dihydrate* inhalation aerosol, a generic form of *Symbicort*. The company noted that *budesonide* and *formoterol fumarate dihydrate* is indicated to control asthma symptoms and COPD and help prevent wheezing in patient age six and older.

(Sources: Drug Store News, Fierce Pharma, Pharma Japan and Reuters)