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Brazil's Over-the-Counter Market Welcomes Long-Awaited Regulatory Changes

Today's Latin American Over-the-Counter (OTC) market is riding tailwinds of social ascension and positive regulatory change, enabling healthy category growth despite choppy economic conditions. OTCs in Latin America have long competed against prescription drugs that were commonly sold "under the counter" without the necessary prescription. It is a common tale that if a consumer felt a sore throat coming on, they could stop by their local pharmacy to pick up antibiotics without a confirmed diagnosis, leading to mounting concerns in the region over bacterial resistance.

However, this began to change in 2010 when both Brazil's National Health Surveillance Agency (ANVISA) and Mexico's Ministry of Health stepped up enforcement by requiring prescription duplicates and imposing hefty fines on noncompliant pharmacies. In 2012, Brazil's ANVISA passed a new regulation that

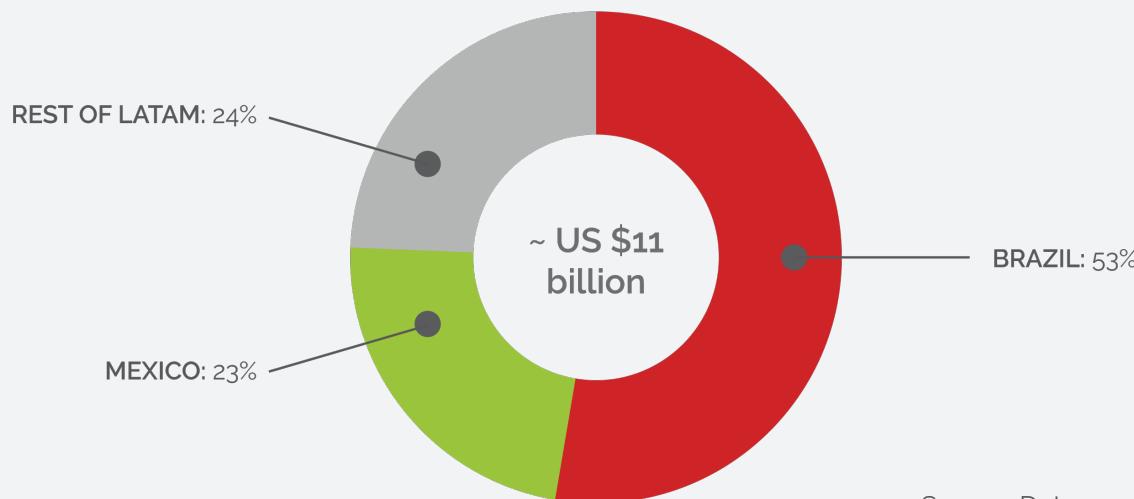
allowed OTCs to come out from behind the pharmacy counter to be sold on retail shelves in drugstores, making them more accessible to consumers.

Now the regulatory landscape is changing again for Brazil, a country that already comprises over 50% of the US\$ 11 billion OTC market in Latin America. Key players and industry experts are predicting a boost in category consumption driven by some significant regulatory changes on the horizon:

- **Expansion of OTC drug list and reformed selection criteria:** In July 2016, ANVISA passed a new policy establishing a clear, timely process and more relaxed criteria for new products to be included on the OTC list. A new classification system for OTCs will streamline the approval process, which currently takes an average of 1.5 years to complete. This would include an immediate

BRAZIL PHARMA REGULATION

Latin American OTC Markets: Country Breakdown (2014)



Source: Datamonitor, 2015

"switch" from prescription to nonprescription status for hundreds of products. For example, products already sold as OTCs for over 5 years in other countries will be reclassified from prescription to OTC in Brazil. The current OTC wait list includes antacids, antifungals, antihistamines, expectorants, decongestants and hair loss products, among others.

Industry leaders and OTC producers have been waiting 12 years for this legislation to pass. They believe the inclusion of new products already sold as OTCs in the U.S. could replace up to 200 million prescriptions per year in Brazil. The Brazilian association of both domestic and multinational OTC producers (ABIMP) anticipates that the OTC share of the overall Brazilian pharmaceutical

market may expand from 27% currently to as high as 35%. One major local player, Ache Laboratories, believes it could double the size of its OTC portfolio.

- **Pharmacists who "prescribe" OTCs:** Major pharmacy chains in Brazil, in partnership with the academic community, are piloting new in-store programs that enable pharmacists with specialized knowledge of OTCs to "prescribe" them to consumers. Post-graduate courses are being created to train pharmacists on OTCs, allowing them to diagnose and accompany customers as if they were patients, and all from within the store. The idea behind this initiative is to provide professional guidance for consumers who self-medicate, particularly those with lower

education levels, in an effort to reduce OTC misuse.

- **Increased potential for new retail channels:** In 2012, the Brazilian senate passed a law that would allow OTCs to be sold in general stores and supermarkets, but it was halted by a veto from then-president Dilma Rouseff. Now that she has been impeached, the new and more business-friendly administration of Mr. Michel Temer may revisit the legislation in a more favorable light. The Brazilian Association of Supermarkets (ABRAS) is actively promoting this legislation, while the Association of Pharmacy and Drug Chains (ABRAFARMA) and wider pharmaceutical community strongly oppose it. Yet, it is likely a matter of time before Brazil adopts the same retail environment as is common in the U.S. and Mexico, and giving OTCs expanded retail opportunities in new markets and underserved areas. However, each state must adopt the new policies in their laws before change can occur so the market impact may be slow.
- **Rosy outlook attracting more R&D and value growth:** The Brazilian economic recovery to be realized more fully in 2018 should have a net positive effect on the OTC market. Although some consumers may

"upgrade" from OTC to prescription drugs, an overall spending boost on consumer health from higher employment and rising incomes will boost the category. Major players like Ache in Brazil are planning to capitalize on the positive outlook by investing in R&D for new products within dietary supplements. Hypermarcas is also planning to focus new launches on the OTC segment which they see as having pent up demand.

Looking ahead: Gaining an early position to ride growth momentum.

Unlike before, foreign OTC manufacturers have the opportunity to bring product lines sold elsewhere into the Brazilian market relatively quickly and painlessly. With much needed regulatory change on the horizon, the category will enjoy long-term benefits from continued income growth, aging dynamics and increased investment focused on the region. Players should position themselves into these tailwinds by building brand strength with customers today to reap dividends as the market grows.

About Global Health Intelligence

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- Best practices
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profiled



Coverage in 11
countries



Over 100 data
points per hospital



Raw data exports
to Excel



Integration into
your CRM



Prebuilt Tableau
dashboards



Available
immediately!