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SYMPOSIUM

Rethinking Pharmaceutical Policies in Latin America and the Caribbean

GUEST EDITED BY Martín Rama and Verónica Vargas

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Journal of Law, Medicine & Ethics, 765 Commonwealth Avenue, Suite 1704, Boston, MA 02215 USA
Phone: 617-262-4990; Fax: 617-437-7596
E-mail: thutchinson@aslme.org

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Symposium Articles

SYMPOSIUM

Rethinking Pharmaceutical Policies in Latin America and the Caribbean

Guest Edited by Martín Rama and Verónica Vargas

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Letter from the Editor

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INTRODUCTION
Rethinking Pharmaceutical Policies in Latin America and the Caribbean: An Overview
Martín Rama and Verónica Vargas

The demographic and epidemiological transitions are driving pharmaceutical expenditures up in Latin American and the Caribbean, with much of the cost falling on households. The domestic developmentand manufacturing of biosimilars could make medicines more affordable. However, physicians,pharmacists, and patients often prefer the more expensive originator products, while the growingjudicialization of access to medicines is expanding their scope. Besides, only a few countries in theregion have the necessary scientific, technological and manufacturing capacity, and their incentivesystems are often inadequate. Argentina, Brazil, and Cuba have done comparatively better, but thesustainability of their models is a concern. Meanwhile, countries in Europe have valuable experiences on containing the price of pharmaceuticals, and countries in Asia on boosting local capacity. This paper reviews the issues and sketches an integrated policy agenda to address them.

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Out-of-Pocket Spending and Financial Equity in the Access to Medicines in Latin America: Trends and Challenges: 2010-2020
Rafael Cortez, Andre Medici, and Rucheta Singh

Background: There is limited availability of data on the out-of-pocket (OOP) expenditures in drugs in Latin America. The actual evidence shows that OOP expenditures creates equity of access and financial protection challenges, and many pharmaceutical products in Latin America have limited access and are unaffordable to most people. Policies that promote equitable access to medicines can be relevant to prolong lives of citizens and reduce the risk of impoverishment for the lowest income groups.

Methods: The article performed a systematic literature review of previous studies on drugs expenditures using PubMed and Google Scholar, and gray literature, such as websites of multilateral organizations (WHO, World Bank, IDB). The WHO annual health expenditure data series was used for the comparative analysis among Latin American Countries. Household and population income and expenditure surveys were used to analyze equity in drug access and expenditure, as well as household financial protection in three countries: Peru, Brazil, and Costa Rica.

Results: There is evidence of persistent inequalities in household financial protection of health and drugs spending in Latin America. Despite the expansion of coverage, strong inequalities persist in access to health and family spending on drugs in the region. Out-of-pocket spending in medicines is regressive in greater need for affordable medicines. This implies not only better logistics for the acquisition and purchase of medicines but also the creation of mechanisms to improve access through broader insurance coverage and fiscal transfers, to reduce expenses with medicines of the most vulnerable and poor populations.

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The Pharmaceutical Market for Biological Products in Latin America: A Comprehensive Analysis of Regional Sales Data
Esteban Ortiz-Prado, Juan S. Izquierdo-Condoy, Jorge Eduardo Vasconez-González, Gabriela Dávila, Trigomar Correa, and Raúl Fernández-Naranjo

The global market for biologics and biosimilar pharmaceutical products is experiencing rapid expansion, primarily driven by the continuous discovery of new molecules. However, information regarding Latin America's biological market remains limited. Employing a cross-sectional descriptive study design, we scrutinized the market share of biological products per country, concentrating on units sold, expenditure per country, and per capita spending, using IQVIA data from 2017 onwards.

Our findings reveal that over $16.1 billion has been spent on biologics and biosimilars in Latin America, with an average yearly expenditure of $3.2 billion. Per capita spending is highest in Brazil at $9.2, followed by Mexico and Ecuador at $3.5 and $2.5 respectively. We observed significant regional price variability, with Central America displaying the highest prices per unit sold. Conversely, Uruguay, Chile, and Colombia exhibited more stable and lower average prices.

Latin America occupies a crucial role in global consumption of biological molecules, marked by significant per capita expenditure and market share. While a few countries like Cuba, Brazil, Mexico, and Argentina have emerged as notable producers, the majority of Latin American countries primarily function as consumers. Despite this, the biologics market in Latin America offers promising prospects, particularly for biosimilars.

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From Pharmaceutical Innovation to Revenue Generation: The Asian Experience
Subir Kumar Basak

Asia's pharmaceutical sector has experienced remarkable growth over the last two decades, with companies in the region producing bulk of the world's specialty generics, biologicals, and active pharmaceutical ingredients (APIs). The Asian pharma growth story has had several pillars for a strong and sustainable foundation that provided non-linear growth. This report introduces three models showing how Asian countries at different development stages — India, South Korea, and Singapore — have nurtured their own, self-sustaining pharmaceutical sectors. Their respective governments adopted specific policies that suited their economies and supported revenue-generating industries. Latin America and the Caribbean face huge health and pharmaceutical needs for greater health care coverage and population aging disease burdens. The models presented in this paper not only offer valuable lessons to Latin America and the Caribbean but also could present unique opportunities for growth and cooperation in pharmaceutical research, development, and manufacturing.

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How to Price and to Reimburse Publicly Funded Medicines in Latin America? Lessons Learned from Europe
Christine Leopold, Sergio Poblete, and Sabine Vogler

Sparked by the unaffordability of medicines due to tremendously high prices of several new pharmaceuticals, the discussion of price regulations and limiting coverage is on top of the political agenda around the world. Huge differences exist across Latin America on how they regulate and reimburse medicine prices, with Brazil and Colombia having the most elaborated systems. The European experience of decades of assessing medicines and regulating their prices is of tremendous value. This paper reviews the main pricing policies in Latin American countries, discussing their shortcomings. It also gives an overview of the most common pricing and reimbursement policies in Europe and describes in detail three well-established approaches –international price referencing, value-based pricing, including setting up of health technology assessment, and generic and biosimilar policies – building on country examples. The analysis is based on a pragmatic literature search in PubMed and Google Scholar and unpublished data by the Pharmaceutical Pricing and Reimbursement Information (PPRI) network. In conclusion, the European experience is comprehensive and involves a combination of pricing, reimbursement and demand policies with an important lesson learned on the promotion of the use of generics and biosimilars.

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On the Judicialization of Health and Access to Medicines in Latin America
Roberto Iunes and Augusto Afonso Guerra Junior

In Latin America, citizens frequently seek the courts when they perceive a failure of the state or a violation of their health rights, a phenomenon known as health judicialization. Medicines tend to be the main object of health litigation and in the majority of cases, citizens seek the courts to access products that the health system was expected to provide but fails to do, an unacceptable scenario that should be a top priority of policy makers, as there are successful examples of measures implemented in the region. On the other hand, physicians, the pharmaceutical and medical industries, and the connections between the two play an important role in the judicialization of products that are not provided or have not been prioritized by the health system. These litigations can strain healthcare budgets and affect the allocation of health resources, as health officials are legally forced to provide costly medications that were not originally planned. Measures to strengthen the decision-making capacity of judges have been the main path followed in the region to address the challenges posed by this type of litigation. However, the paper argues that we need to recognize that physicians and other health decision-makers also need more knowledge and better information. In a context of rapid technological innovation and expensive new products, the paper calls for the generation real-world data to inform decision-making and an international discussion on the affordability of new medicines, particularly for low- and middle-income countries. Without these, the challenges of health judicialization will continue to grow.

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Knowledge, Perceptions, and Utilization of Generics and Biosimilars in Latin America and the Caribbean: A Scoping Review
Bernardo Aguilera, Sebastián Peña, and Juan Pablo Morales

Generic drugs and biosimilar products can provide cost-effective alternatives to their reference products and support reductions in pharmaceutical expenditure. As countries from Latin America and the Caribbean (LAC) have implemented policies to promote the use of generics and biosimilars, one reported barrier to their success relates to a lack of understanding and negative perceptions about these products. We conducted a scoping review to map and critically examine the knowledge, perceptions and utilization of generics and biosimilars, among physicians, pharmacists, patients, the general population, and other stakeholders from LAC. After screening 668 studies, 22 studies were included in this analysis. Seventeen studies (77%) corresponded to generics and 17 studies (77%) were from Brazil. Generally, physicians, patients and the general population hold negative perceptions regarding the efficacy, quality and safety of generics, which are likely to influence their utilization. Perceptions were relatively more positive among pharmacists and other stakeholders. Patients and the general public expressed relatively good knowledge of generics. Regarding biosimilars, both physicians and patients had negative perceptions of these products. Our study reveals gaps in the literature regarding the knowledge, perceptions, and utilization of generics and biosimilars in LAC and calls for more research. Countries in the region should

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adopt or strengthen policies aimed at closing knowledge gaps, improving confidence in generics and biosimilars, and increasing prescribing of these products.

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Biosimilars and Heterogeneous Technological Trajectories in the Argentine Biopharmaceutical Industry
Pablo José Lavarello, Graciela Gutman, and Juan José Pita

Biotechnology is an important potential segment in the structure of the Argentine pharmaceutical industry. Its emergence was associated with a previous bioprocessing and pharmaceutical trajectory, a strategic regulatory and intellectual property approach, and industrial and technological policy instruments – in particular, a set of actions to accelerate the adoption of biotechnological capacities. This paper will review the strategies and learning trajectories followed to tap the opportunities opened by the successive waves of biotechnologies: early imitators followed by late imitators in the first generation of biosimilars (erythropoietin, insulins, interferons), and then sequential entry and skipping stages during the second generation (monoclonal antibodies). The analysis will be based on a set of investigations carried out at CEUR CONICET on the emergence of the biopharmaceutical industry in Argentina. One of the main findings of this research is the absence of a dominant trajectory. Instead, different evolutions prevail depending on the biotechnological wave and the capacities on which each strategy is based. While sequential entry aligns with S&T infrastructure, stage skipping entry tends to align more with international networks of CROs and vendors. In all cases, the national technological base – private or public – was mobilized by local private capital in the context of growing market rivalry and oligopolistic consolidation.

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The Brazilian Pharmaceutical Industry: Actors, Institutions, and Policies
Julia Paranhos, Lia Hasenclever, and Fernanda S. Perin

The Brazilian pharmaceutical market is the largest in Latin America and the Caribbean and the 7th largest globally. The sector has a concentrated structure, with the ten largest companies responsible for 41.2% of the products registered with the Brazilian Health Regulatory Agency (ANVISA). Since the 1990s, several important institutional developments have changed this structure, which caused different responses from companies. This paper aims to characterize the main actors in the Brazilian pharmaceutical industry – national companies, foreign companies, and public laboratories – and analyze how they were affected and how they reacted to changes over the last 30 years in the institutional framework. The results show that national companies have been gaining prominence in the Brazilian pharmaceutical market with their internationalization movement and their strengthening of innovation strategies. On the other hand, foreign companies have drastically reduced their local production of medicines in Brazil. They keep the technological efforts within their headquarters and only import innovations launched to Brazil. Public laboratories have a smaller market share, since they can only sell to the Unified Health System (SUS). They produce mature products, and their budgets are unstable, but they are vital in the local production of vaccines, as seen in the production of the COVID-19 vaccines.

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The Development of Cuba's Biotechnology: Mechanisms and Challenges
Omar Everleny Perez Villanueva and Juan Carlos Albizu-Campos Espiñeira

Cuban biotechnology has developed on a solid scientific basis and meets high-quality standards. Part of this success was due to the abundance of qualified human resources and its low cost compared to more developed countries. But Cuba was also able to counteract the problems of coordination and appropriation of added value that typically hinder the development of the sector. It did so through a state-owned business model in which the industry is vertically integrated, uses patent licensing and management for its financing, and reverts part of the profits to its inventors to stimulate research. This model was perfected over several decades, and its effectiveness was confirmed during the Covid-19 pandemic when Cuba introduced new vaccines and highly effective treatments on a par with the most advanced countries. However, given the size of the domestic market, the viability of this model crucially depends on the ability to export, which is being affected by the tightening of US sanctions. In this context, Cuba faces a dilemma between continuing its current portfolio of biotechnology drugs and vaccines with lower profitability or renewing its product portfolio with the associated costs and risks.

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Pharmaceutical Innovation in Latin America and the Caribbean
Verónica Vargas and Jonathan Darrow

This study assesses Latin America and Caribbean countries' capacity to innovate new pharmaceuticals, defined as developing new drugs and vaccines, reverse engineering and repurposing existing drugs, and inventing around patents to produce new drug variations. Vaccine innovation includes reengineering existing vaccines, developing new manufacturing methods, and the clinical development of unapproved vaccine candidates initiated elsewhere.

Research and development expenditures, as well as the number of patents, researchers, life sciences and chemistry publications, and drug development projects, were collected per country using the UNESCO research and development expenditure database, WIPO patents database, Nature Index, and company and scientists' publications and websites.

As of April 2023, the region had 309 therapeutic projects in development or on the market. Vaccines and other biologics comprised over 78% of the portfolio, with the remainder including naturally-derived products and repurposed small-molecules. Countries with solid vaccine portfolios showed strength in non-vaccine biologics innovation. Collaboration between universities and local private companies affects biosimilar development positively. Public institutions and universities played a significant role in original biologics and natural-derived products R&D. Countries incorporating the Biological Diversity and Nagoya rules into their Bilateral Trade Agreements may increase the probability of reaching the market with naturally-derived products.

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