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Review Article

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Overview and Lifecycle Management of Generic Pharmaceutical Drugs in Mexico, Guatemala and Brazil

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Abstract

Objective: The generic pharmaceutical markets in Mexico, Guatemala, and Brazil are influenced by distinct regulatory frameworks, production and distribution dynamics, and marketing strategies, which shape lifecycle management. Regulatory policies, market competition, and healthcare initiatives impact accessibility, affordability, and quality, presenting both challenges and opportunities for enhancement in these areas.

Summary: This thesis offers an in-depth examination of lifecycle management strategies in the generic pharmaceutical markets of Mexico, Guatemala, and Brazil. Generic drugs are crucial for increasing access to affordable healthcare, especially in emerging economies. Through comparative analysis, this research explores the regulatory frameworks, market dynamics, and key challenges in the development, approval, marketing, and post-marketing surveillance of generic drugs in these three Latin American countries.

The study starts with an overview of the regulatory landscape for generic pharmaceuticals in Mexico, Guatemala, and Brazil, highlighting similarities and differences in registration requirements, approval processes, and post-approval obligations. It investigates the roles of regulatory agencies like COFEPRIS, DIGEMID, and ANVISA in ensuring the quality, safety, and efficacy of generic drugs throughout their lifecycle. Additionally, the research delves into the strategies used by pharmaceutical companies for lifecycle management of generic drugs, including variations, biowaivers, and labeling changes.

Real-world case studies illustrate post-approval changes and their regulatory implications in each country, providing insights into the complexities of managing generic drug portfolios in different regulatory environments. The thesis also examines the market dynamics affecting the availability, pricing, and accessibility of generic drugs in Mexico, Guatemala, and Brazil. Factors such as patent expirations, competition, healthcare policies, and public procurement practices are analysed to understand their impact on market entry, competition, and the affordability of generic drugs. Furthermore, the study addresses the challenges and opportunities in pharmacovigilance and post-marketing surveillance of generic drugs, emphasizing the need for robust systems to detect and manage adverse drug reactions and ensure patient safety.

Conclusion: The key findings highlight regulatory frameworks, market dynamics, and lifecycle management strategies in the generic pharmaceutical markets, identifying challenges and opportunities. The study reflects on implications for stakeholders and suggests areas for future research to enhance accessibility, affordability, and quality.

Keywords: Generic pharmaceuticals, Lifecycle management, Regulatory framework, Market dynamics, Healthcare policies, Accessibility, Affordability, Quality assurance, Supply chain management, Patents, Post-marketing surveillance, Market competition.

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1. Introduction

Generic pharmaceutical drugs are vital in addressing healthcare challenges, notably in developing nations like Mexico, Guatemala, and Brazil, where they offer affordable solutions. This thesis focuses on examining the lifecycle management of generic pharmaceuticals in these countries, considering their unique regulatory landscapes and market dynamics. By understanding how these drugs are regulated, produced, distributed, and marketed, we aim to uncover key insights into enhancing their accessibility, affordability, and quality within these diverse healthcare systems. Present an in-depth analysis of the regulatory frameworks governing generic pharmaceuticals in Mexico, Guatemala, and Brazil, highlighting similarities and differences.

Explore the market dynamics including key players, market size, growth trends, and factors influencing competition. Examine lifecycle management strategies

employed by regulatory agencies, pharmaceutical manufacturers, and other stakeholders, such as product development, registration processes, pricing strategies, marketing tactics, and post-market surveillance.

Discuss challenges faced by generic drug manufacturers and consumers, including issues related to patent protection, supply chain management, quality assurance, and affordability. Identify opportunities for improving the accessibility, affordability, and quality of generic drugs through policy interventions, industry collaborations, and technological innovations.

2. Objective

This thesis aims to offer a comprehensive understanding of the generic pharmaceutical drug markets in Mexico, Guatemala, and Brazil, examining the lifecycle management strategies involved in regulation, production, distribution, and marketing. By evaluating the impact of regulatory frameworks, market dynamics, and healthcare policies, it seeks to identify key challenges and opportunities for enhancing the accessibility, affordability, and quality of generic drugs in these regions. Through this analysis, the thesis endeavours to provide insights that can inform strategies for improving healthcare outcomes and addressing the unique needs of populations in these countries.

3 Discussion

3.1 Mexico

Geographical Overview

Mexico, located in North America, boasts diverse geography comprising deserts, plateaus, mountains, and coastal plains. Its capital, Mexico City, lies in the Valley of Mexico. The country experiences varied climatic zones, including tropical wet and dry, rainforest, desert, arid, highland, and temperate climates, influencing its biodiversity and ecosystems. (1,2)

Regulatory Framework

COFEPRIS, under the Ministry of Health, regulates health-related products and services in Mexico. Various commissions like CIS, COS, CAS, and CEMAR handle aspects such as registration, audits, authorizations, and pharmacovigilance. The Mexican Pharmacopeia (FEUM) serves as a vital reference in Mexican legislation for quality specifications of drugs and health products, guiding regulation and standards. It actively expands monographs and collaborates with international stakeholders for advancement. Stakeholder interaction is encouraged through open participation in committees, feedback on publications, and suggestions for monographs.

Pharmaceutical Industry Overview

Generic drugs play a crucial role in healthcare accessibility in Mexico, constituting 65% of the market share. Despite significant growth, challenges such as dependence on imports for pharmaceutical active components (APIs) persist, leading to disruptions in the medication supply chain. However, Mexico's pharmaceutical market is the second-largest in Latin America, projected to reach $30.04 billion by 2025, with strengths in antibiotics, analgesics, and anti-parasitic drugs. Government initiatives emphasize strategic investments and policies to establish domestic production capabilities and attract global pharmaceutical companies. Opportunities abound, driven by a growing market size, commitment to universal healthcare coverage, and recent regulatory changes attracting international firms. Medical tourism also thrives, offering cost-effective treatments compared to the US, enhancing Mexico's attractiveness. Regulatory changes aim to expedite approval processes for generics and biosimilars, while future growth is anticipated due to an aging population, rising chronic diseases, and government interventions. (3,4)

Generic Drug Market

The generic drug market is projected to rise from USD 3.2 billion in 2019 to USD 6.0 billion in 2029, with a compound annual growth rate of 6.2%. Regulatory improvements, including alignment with global guidelines and bioequivalent studies, ensure safety and quality, attracting foreign investments. However, challenges such as delays in market entry and competition with branded drugs persist due to legislation favouring multinational innovative drug manufacturers. The Indian pharmaceutical industry has a significant influence, dominating generic drug manufacturing and driving expansion in Mexico. (5)

Regulatory Landscape

COFEPRIS oversees the importation of medical devices and regulatory control of advertising, operating autonomously under the Mexican Secretariat of Health. The General Health Law governs the import and export of medical products and food, providing the regulatory framework. Digital systems have been introduced for product registration, enhancing efficiency and patient access to medicines. Approval timelines, although comparatively longer, are expected to improve with the acceptance of English-written documentation and streamlined processes. Local trials are mandatory for new molecules produced in Mexico, with decisions for molecules manufactured abroad made by COFEPRIS committees. (6,7)

Scope and Objective

Efforts to establish regulatory frameworks for generic drug submissions in Mexico aim to gather regulatory modifications, assess their effectiveness, understand registration processes, and analyse future prospects. The significance of these efforts lies in Mexico's substantial consumption of generics, driven by rising demand for economical medicines. While regulatory advancements attract investments, challenges such as delayed market entry and limited competition persist. Overcoming these obstacles could enhance accessibility to affordable medicines and foster a competitive pharmaceutical landscape in Mexico. (8)

Drug Registration and Approval Process

The registration process begins with the submission of a comprehensive application dossier to COFEPRIS, followed by meticulous review and potential deficiency

letters. New molecule classification involves substances new to the world or Mexico, with marketing authorization lasting five years. Post-approval changes for generic drugs are classified into major, moderate, and minor changes, each with its approval process. Post-market surveillance encompasses adverse event reporting, pharmacovigilance systems, quality control, periodic safety updates, and collaboration with international organizations. Communication and transparency are crucial for disseminating safety information effectively to all stakeholders. (9,10)

Product Registration

The dossier preparation adheres to COFEPRIS checklists, divided into administrative, quality, pre-clinical (for new molecules), and clinical (for new molecules only) modules. Generic drug registration requires fulfilling prerequisites, including committee evaluation and classification as new molecules or generics. Technical documents, accompanied by GMP certificates, are submitted for sanitary registry. (10)

Post-Approval Changes for Generic Drugs

Generic drugs can undergo post-approval changes (PACs) classified into major, moderate, and minor categories based on potential impact. Major changes, such as new API suppliers or significant process alterations, require Prior Approval Supplements (PAS) for COFEPRIS review. Moderate changes, like excipient alterations, may follow either a CBE-30 or a Supplement - Changes Being Effected process. Minor changes, with minimal impact, involve reporting to COFEPRIS within 30 days post-implementation. (11)

Post Market Surveillance

Post-market surveillance in Mexico includes adverse event reporting, pharmacovigilance systems, quality control inspections, periodic safety update reports (PSURs), risk management plans, and collaboration with international organizations. Regulatory agencies ensure effective communication and transparency regarding safety concerns, allowing for market withdrawal or suspension if necessary.

Examples of Case Studies:

Change in Manufacturing Site: A generic drug manufacturer relocated from Mexico City to Guadalajara to optimize efficiency and reduce costs. After notifying COFEPRIS and submitting comprehensive validation data, the approval was granted quickly, enabling a seamless transition without supply interruptions.

Change in Drug Formulation: A pharmaceutical company replaced an excipient to improve drug stability and shelf life. A Prior Approval Supplement (PAS) with extensive comparative and bioequivalence studies was submitted to COFEPRIS. After thorough review, the change was approved, enhancing the drug's market competitiveness.

Labeling Changes: A manufacturer updated product labels to meet new public health sector regulations. After notifying COFEPRIS and submitting the new designs, the updated labels were approved swiftly, ensuring compliance and continued supply without penalties.

Batch Size Changes: To meet rising demand, a company increased its production batch size. Detailed validation data and risk assessments were submitted to COFEPRIS, followed by an on-site inspection. Approval was granted within months, enabling the company to scale up production efficiently.

Transfer of Marketing Authorization: A multinational company transferred the marketing authorization of a generic drug to its local subsidiary in Mexico. The administrative process, facilitated by an Authorized Third Party, was completed quickly, ensuring uninterrupted distribution and enhanced market responsiveness.

3.2 Guatemala

Guatemala Overview

Situated in Central America, Guatemala shares borders with Mexico, Belize, Honduras, and El Salvador. Its diverse geography includes highlands, coastal plains, and the Petén plateau. The climate varies from hot and humid coastal plains to cool mountainous regions and temperate zones in urban areas like Antigua and Guatemala City.

The Ministry of Public Health and Social Assistance (MSPAS) in Guatemala oversees healthcare policies, services, and regulations. It manages public hospitals and clinics, conducts disease surveillance, and promotes health education. MSPAS faces challenges such as limited resources and health inequities. Priorities include addressing infectious diseases, improving maternal and child health, and tackling chronic diseases. Overall, MSPAS plays a crucial role in safeguarding public health and well-being in Guatemala. (13)

Pharmaceutical Market

Guatemala's pharmaceutical market is valued at USD 1.1 billion, experiencing a growth rate of 8.1%. Individual healthcare spending is significant at USD 62, with a notable consumption of non-prescription medications. Import reliance stands at 70%, signalling potential diversification opportunities, particularly for generics from Indian companies. Distribution channels are diverse, with 64% of drug purchases occurring in the private sector, emphasizing consumer choice and affordability. Despite individual spending, healthcare expenditure accounts for only 1.8% of GDP, suggesting room for increased public investment. (14)

Dossier Requirements

The regulatory process for pharmaceuticals in Guatemala requires a comprehensive dossier submission, including qualitative and quantitative formulas, finalized product specifications, analytical method validation reports, certificates of analysis, stability studies, packaging material specifications, working standard certificates of analysis and IR spectra, product literature, ingredient functions, and usage, storage conditions, and warnings.

Background of Generic Drugs

Guatemala faces challenges in the generic pharmaceutical sector, including strong IP laws delaying entry, dominance of branded generics leading to high prices, limited availability of essential medicines, especially for chronic diseases, and high out-of-pocket spending. Positive developments include government policies promoting affordable generics, the establishment of a national essential medicines list, market growth, and civil society advocacy efforts. (13)

Scope and Objectives

The scope of generic pharmaceutical drugs in Guatemala aims to increase access to essential medicines, reduce healthcare costs, promote rational drug use, and foster the domestic pharmaceutical industry. Objectives include strengthening IP regulations, enhancing regulatory capacity, promoting generic prescribing, and combating counterfeit drugs. Challenges include strong IP laws, branded generics dominance, limited essential medicine availability, and weak regulatory capacity. (14)

Generic Drug Registration Process

The registration process involves compiling comprehensive documentation, gathering data on quality, safety, and efficacy, submitting a complete application to the regulatory authority, undergoing meticulous review for compliance and completeness, in-depth evaluation of the drug's quality, safety, and efficacy, physical inspection of manufacturing facilities, decision-making by the regulatory authority, approval, and post-approval monitoring.

Preparation Phase: This phase aims to compile comprehensive documentation substantiating the application for generic drug registration. It involves gathering data on quality, safety, and efficacy while ensuring compliance with Guatemalan pharmaceutical regulations.

Submission Stage: The primary goal is to submit a thorough application to the regulatory authority, including all necessary forms, documentation, and supporting materials such as study results and manufacturing details.

Review Process: The regulatory authority meticulously reviews submitted documents for completeness and compliance with national pharmaceutical standards, ensuring accuracy and completeness of essential documentation.

In-Depth Evaluation: A comprehensive assessment of the generic drug's quality, safety, and efficacy is conducted, with a keen focus on scientific scrutiny of effectiveness and safety data, as well as examination of manufacturing practices and facilities.

Physical Inspection: On-site inspections of manufacturing facilities are performed to ensure compliance with Good Manufacturing Practices (GMP) and adherence to required standards and specifications.

Decision-Making Process: The regulatory authority deliberates on approving or rejecting the application, communicating the decision with detailed reasons to the applicant.

Approval Stage: Upon approval, the applicant obtains the coveted registration certificate, enabling them to market and distribute the generic drug in the Guatemalan market.

Post-Approval Monitoring: Continuous compliance is ensured, with vigilant monitoring of any alterations in product formulation or manufacturing processes, and adherence to post-approval requirements outlined by the regulatory authority.

Approval Process of Generic Pharmaceutical Drug

Dossier Preparation and Sample Submission: Comprehensive documentation on the pharmaceutical product is compiled, and samples are submitted for testing to an approved analytical laboratory in Guatemala.

Dossier Review: The regulatory authority assesses the submitted dossier for completeness and evaluates the quality, safety, and efficacy of the pharmaceutical product.

Sample Analysis: Rigorous testing is conducted on submitted samples to verify quality, composition, and compliance with standards.

Inspection of Manufacturing Facilities: Manufacturing facilities are inspected to confirm compliance with GMP and consistent production of high-quality products.

Query or Approval Request: The regulatory authority communicates with the pharmaceutical company, issuing queries or requests for additional data or clarifications.

Submission of Additional Information: The pharmaceutical company responds to queries with additional data or clarifications, addressing concerns raised during the review process.

Decision on Approval: Based on dossier review, sample analysis, and facility inspection, the regulatory authority makes a decision on approval.

Post-Approval Changes of Generic Drug in Guatemala

Moderate Changes: Alterations more significant than minor changes but less critical than major changes, requiring careful evaluation. Examples include adjustments to excipients, addition of new manufacturing sites, or moderate labeling revisions.

Minor Changes: Relatively minor modifications with minimal impact on the drug's quality, safety, efficacy, or regulatory status, such as administrative updates or minor packaging adjustments.

Examples of Case Studies

Change in Manufacturing Process: XYZ Pharma optimizes their manufacturing process, leading to increased efficiency and reduced costs without compromising drug quality, benefiting patients in Guatemala.

Change in Packaging Material: ABC Pharmaceuticals switches to biodegradable packaging, reducing environmental impact and enhancing their reputation for sustainability.

Addition of New Dosage Strength: DEF Pharma introduces a higher dosage strength, improving treatment flexibility for patients with diabetes and potentially enhancing medication adherence and clinical outcomes.

3.3 Brazil

Introduction

Brazil, the largest country in South America, possesses diverse climatic zones and maintains a robust regulatory framework overseen by The National Health Surveillance Agency (ANVISA) for drug registration. This agency plays a pivotal role in ensuring the safety, efficacy, and accessibility of pharmaceutical products across the nation. (15)

Geographical Location

Stretching across 26 states and the Federal District, with Brasília as its capital and São Paulo as its most populous city, Brazil shares borders with ten countries and boasts a vast coastline along the Atlantic Ocean. Its expansive territory encompasses various ecosystems and climates, ranging from the Amazon rainforest in the north to subtropical conditions in the south. (15,16)

Climatic Zones

Brazil's climatic diversity influences its ecosystems and agriculture, with regions experiencing distinct climate patterns such as tropical climates with wet and dry seasons, semi-arid climates in the northeast, and highland conditions. These climatic variations impact the country's biodiversity and agricultural productivity. (15,16)

Regulatory Framework

ANVISA, established in 1999, meticulously regulates Brazil's pharmaceutical landscape. It ensures the quality, safety, and efficacy of generic drugs while facilitating their accessibility. Key legislation such as Law 9.787/1999 and Resolution RDC 391/1999 underscores the importance of bioequivalence testing and therapeutic equivalence in the drug approval process.

Documentation Requirements (for Drug Registration)

The registration process for generic drugs entails comprehensive documentation, including petition forms, proof of payment, and manufacturing certificates. Essential documents cover aspects like active pharmaceutical ingredients, formulation development, manufacturing processes, stability studies, and pharmaceutical equivalence. Throughout the registration process, declarations, protocols, and reports demonstrating compliance with regulatory standards are imperative. (17)

Brazilian Health Surveillance Agency (ANVISA)

ANVISA's role extends to conducting priority and standard reviews of new drug submissions, ensuring timely evaluations within 180 business days for priority reviews. Evaluation involves thorough assessments by the Office of New Drugs, Research, and Clinical Trials (GEPEC), consultations with external consultants, and deliberations with the Technical Chamber of Medicine (CATEME) and the Chamber of Drug Market Regulation (CMED) regarding pricing negotiations. (17)

Brazilian Pharmacopeia

The Brazilian Pharmacopeia, managed by collegiate bodies, provides standards for pharmaceutical products. Its latest edition, approved in 2019, reflects advancements in pharmaceutical science and technology. Thirteen Thematic Technical Committees oversee the pharmacopeia's various aspects, ensuring that standards remain current and relevant. (18)

Pharmaceutical Industry and Market Trends

Brazil's pharmaceutical market ranks among the world's largest, generating substantial revenue. Regulatory developments, including decentralized healthcare management and price regulations by CMED, significantly shape industry dynamics. Generic drugs, constituting over 70% of the market share in 2022, are projected to continue their growth trajectory, reaching significant revenue figures by 2025. (19)

Emerging Market Power of Generic Drugs

Generic drugs play a vital role in reducing healthcare costs and enhancing accessibility in Brazil. Their economic impact fosters innovation and competition within the pharmaceutical sector. However, challenges persist, particularly regarding affordability and accessibility in rural areas, necessitating ongoing adaptations to regulatory frameworks to address these concerns effectively. (20)

Regulatory Landscape

ANVISA stands at the forefront of Brazil's regulatory landscape, safeguarding public health by overseeing pharmaceutical products and services. Its establishment in 1999 marked a significant milestone in ensuring the safety, efficacy, and accessibility of medications for Brazil's population. (21)

Scope

Generic drugs dominate Brazil's pharmaceutical market, offering affordable alternatives to branded medications. They are widely available in both public and private pharmacies, with government initiatives such as "Farmacias popular" focusing on enhancing affordability and accessibility. The stakeholders involved encompass manufacturers, distributors, pharmacies, and healthcare professionals. (22)

Objectives

Generic drugs aim to improve access to essential medicines, thereby reducing healthcare costs and fostering competition and innovation in the pharmaceutical industry. By enhancing access and affordability, generics contribute to better health outcomes for the population, addressing key public health challenges. (22)

Significance

The significance of generic drugs in Brazil lies in their pivotal role in addressing affordability challenges and ensuring widespread access to medication. By lowering costs, generics generate substantial savings for individuals

and the healthcare system, enabling resources to be redirected towards other critical healthcare investments. Furthermore, they contribute to a competitive pharmaceutical market, benefiting consumers and fostering continuous innovation. Brazil's experience with generics serves as a model for other developing countries seeking to expand access to affordable medicines. (22)

Drug Approval of Brazil

The drug approval process in Brazil is a meticulously organized series of activities that begins with project initiation, where businesses identify products for development and initiate research and development (R&D) efforts aimed at product registration. Subsequently, R&D conducts thorough research, imports samples, and optimizes formulation and manufacturing processes during the product development phase. Following this, exhibition and submission batches are manufactured for evaluation in the batch manufacturing stage. Samples are dispatched for validation at batch release sites during Brazilian site activities, with co-validation data submitted as necessary. Pharmaceutical Equivalency (PE) and Bioequivalence (BE) studies are then conducted at ANVISA-approved centres to ensure equivalence with reference products.

Comprehensive documentation is compiled for submission to ANVISA in the dossier preparation phase. This dossier is subsequently submitted for review by ANVISA, which meticulously assesses it for deficiencies and compliance with regulatory standards during the ANVISA evaluation stage. Any identified deficiencies are addressed by the Marketing Authorization (MA) holder in the response to deficiencies phase. ANVISA then evaluates the responses and either approves or queries further in the ANVISA query response stage. Finally, ANVISA grants approval for the new drug based on compliance with regulatory standards and satisfactory responses to queries in the approval stage.

Regarding post-approval changes for generic drugs in Brazil, administrative variations, minor variations, moderate variations, major variations, and biowaivers constitute different categories of changes that may occur. Administrative variations involve changes such as updates to contact information, which require notification to ANVISA without formal approval. Minor variations encompass low-risk changes like adjustments to process parameters, which may necessitate submission of documentation for ANVISA's review. Moderate variations involve changes with a moderate impact, such as alterations to excipients, requiring additional data submission for ANVISA's evaluation. Major variations entail significant changes like alterations to active pharmaceutical ingredients (API), necessitating comprehensive evaluation by ANVISA and formal approval. Biowaivers may be granted for changes in formulation, strength, or dosage form based on a similarity assessment with reference products, with scientific justification required following ANVISA's criteria. (23)

Post-approval changes for generic drugs in Brazil encompass various categories

Post-approval changes for generic drugs in Brazil span several categories, each with distinct evaluation processes. Administrative variations encompass minor adjustments such as updates to contact information, requiring notification to ANVISA but not formal approval. Minor variations involve low-risk changes like adjustments to process parameters, potentially necessitating submission of documentation for ANVISA's review. Moderate variations, with a moderate impact such as alterations to excipients, require additional data submission for ANVISA's evaluation. Major variations, entailing significant changes like alterations to active pharmaceutical ingredients (API), demand comprehensive evaluation by ANVISA and formal approval. Biowaivers, on the other hand, may be granted for changes in formulation, strength, or dosage form based on a similarity assessment with reference products, with scientific justification required according to ANVISA's criteria.

Examples of Case Studies on Post-Approval Changes for Generic Drugs in Brazil

- **Change in Manufacturing Location:** Shifting production to a different facility in Brazil requires ANVISA to ensure the new facility meets Good Manufacturing Practice (GMP) standards and maintains drug quality.
- **Addition of New Manufacturing Process:** Introducing new technologies or methods for production optimization necessitates ANVISA's evaluation to ensure compliance with regulatory standards.
- **Change in Packaging Material:** Switching to new packaging materials requires ANVISA's review to assess compatibility with the drug and its impact on safety.
- **Labeling Changes:** Updating product labeling to reflect new safety information or dosing instructions necessitates ANVISA's approval to ensure compliance with regulations.
- **Change in Finished Product Specifications:** Modifying specifications such as particle size or dissolution profile requires ANVISA's evaluation to maintain drug quality and performance standards.

Table 1. Difference between Regulatory requirements for Mexico, Guatemala & Brazil

Aspect	Mexico	Guatemala	Brazil
Geographical Overview	Diverse geography: deserts, plateaus, mountains, coastal plains	Diverse geography: highlands, coastal plains, Petén plateau	Diverse geography: rainforest, highland, coastal, semi-arid

Regulatory Framework	COFEPRIS regulates health-related products; Various commissions	Regulatory process involves comprehensive dossier submission	ANVISA oversees drug registration; Key legislation emphasized
Pharmaceutical Industry Overview	Generic drugs crucial; Challenges include import dependence	Challenges include strong IP laws, branded generics dominance	Generic drugs dominant; Regulatory developments significant
Generic Drug Market	Market share: 65%; Challenges include import dependence	Challenges include branded generics dominance, IP laws	Market share: Over 70%; Challenges include affordability
Regulatory Landscape	COFEPRIS oversees importation, regulatory control	Comprehensive dossier requirements; Weak regulatory capacity	ANVISA oversees regulation; Emphasis on bioequivalence testing
Scope and Objective	Aim to enhance accessibility to affordable medicines	Aim to increase access, reduce costs, foster domestic industry	Aim to improve access, affordability, foster innovation
Drug Registration Process	Begins with comprehensive dossier submission	Comprehensive documentation required; post-approval monitoring	Meticulously organized process with various evaluation stages
Changes in Generic Drugs	Categorized into major, moderate, minor alterations	Various categories; post-approval monitoring for compliance	Categories include administrative, minor, moderate variations

4. Conclusion

The thesis provides valuable insights into the overview and lifecycle management of generic pharmaceutical drugs in Mexico, Guatemala, and Brazil. Key findings underscore the critical role of regulatory frameworks, market dynamics, and healthcare policies in shaping the generic drug industry in these countries. Implications of the research findings extend to policymakers, regulators, industry stakeholders, healthcare providers, and consumers, emphasizing the need for informed decision-making and collaborative efforts. Recommendations include addressing challenges related to patent protection, supply chain management, and affordability while leveraging opportunities through policy interventions, industry collaborations, and technological innovations to enhance the accessibility, affordability, and quality of generic drugs in the studied regions.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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