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THE LATAM COUNTRIES ARE BOTH THE FASTEST GROWING AND LARGEST EMERGING MARKETS ECONOMIES. REASONS FOR THE EMERGENCE OF LATAM MARKET

B. Venkata Reddy, D. Jothieswari, N. Audinarayana and G. Neelima*

Sri Venkateshwara College of Pharmacy (Autonomus), RVS Nagar, Chittoor-517127.

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***Corresponding Author: G. Neelima**
Associate Professor, Sri Venkateshwara College of Pharmacy (Autonomus), RVS Nagar, Chittoor-517127.
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ABSTRACT

Latin America is a Region of paradox. It has unique conditions that make it one of the most attractive contexts worldwide for doing business, but it also faces serious challenges that severely underscore these opportunities. We apply a simple framework of analysis to describe the Latin American business environment and detect research opportunities. For that, we focus on four aspects of the region: (1) the institutional context, (2) the macroeconomic environment, (3) the consumer profile, and (4) the natural resource endowments. In the present study three countries from each region have been selected and their regulatory requirements were thoroughly collected, studied, compiled and compared. The three nations in the LATAM area are Brazil, Mexico, and Argentina. The research was undertaken with the aim of comprehending the regulatory framework for the licensing of generic drugs in these nations. The material was gathered from a multitude of websites and the official websites of regulatory bodies. After the completion of the study it is inferred that Brazil and Mexico have been the frontline contenders in the LATAM region with well established regulatory system, large population, expiration of several patents. Furthermore, local pharmaceutical businesses have a majority share of the market, accounting for about 55% of the industry's sales. In the present study the generic drug registration requirements of countries in LATAM regions were studied thoroughly and found to be self sufficient to carry out error free registration system. In LATAM, regions like Brazil and Mexico have their own methods while Argentina depends on other developed countries.

KEYWORDS: Mexico, Argentina, Brazil, Drug registration, Licence.

1.0. INTRODUCTION

Pharmaceutical sector is highly regulated, and no medicine may be launched without the diligent efforts of medical researchers and other professionals to ensure it obtains regulatory clearance. Regulatory affairs experts play a crucial role in the process of drug development, since they are responsible for gaining approvals and managing the life cycle of both branded and generic medications. They serve as the main channel of contact between the corporation and regulatory bodies such as USFDA, MHRA, CDSCO, and TPD, among others. They are mostly unaffected throughout Acquisition and Merger Regulatory Affairs departments have experienced continuous growth and development inside firms. processes, as well as during periods of recession. The use of worldwide standardization has led to a consistent method for receiving and assessing regulatory submissions.[1] The significance of regulatory affairs lies in its crucial role in ensuring compliance with regulations and standards set by governing bodies In the current highly competitive landscape, the ability to minimize the time required to bring a product to market is crucial for both the success of the product and the overall success of the organization. The company's Regulatory Affairs operations must be conducted properly, since they have significant economic value.[2]

An effective regulatory expert must possess a comprehensive understanding of the intricacies of rules on a global scale. Regulatory Affairs professional interacts with International and domestic drug regulators to assure Licensing, Registration, Development, Manufacturing, Marketing, Labeling of pharmaceuticals and medical products.[4] A regulatory agency is an agency of the government tasked with safeguarding public health in safety-related spheres and thus fulfill its function; it employs means include the following Ensuring the clear and open sharing of information and decision-making processes. Establishing procedures for seeking input and involving stakeholders in the decision-making process. Mandating that administrators provide justifications for their actions requiring administrators to adhere to principles that encourage fair and responsive decision-making.[5]

2. THE GLOBAL MARKET IS SEGMENTED INTO:

i. Regulated Market: United States, European Union (including the United Kingdom, Germany, France, Ireland, and Sweden), Japan, Canada, Australia, New Zealand, and South Africa.

ii. Semi regulated Market: (ROW Countries)

a) **Asia:** The countries included in the ASEAN 10 Countries group include Sri Lanka, India, Bangladesh, Philippines, and Vietnam. Countries included on the list include Singapore, Malaysia, Thailand, Indonesia, Laos, Cambodia, Brunei Darussalam, Bhutan.

b) **African countries:** These countries include Algeria, Zambia, Ethiopia, Ghana, Kenya, Malawi, Mozambique, Namibia, Nigeria, Sierra Leone, Tanzania, Zimbabwe, and others.

c) **Middle East countries:** Member states of the Gulf Cooperation Council include Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the UAE.

d) ***LATAM:*** The countries identified include Mexico, Brazil, Panama, Peru, Guatemala, Argentina, Chile, and the Dominican Republic.

e) **CIS** (common wealth of independent states): Federation of Socialist Republics (OFSUs) including Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kirghizstan, Moldova, Tajikistan, Turkmenistan, and Uzbekistan.

The objective of this paper is to examine the ROW Countries, namely ASEAN and Latin America (LATAM).

2.1. ROW (Rest of the world) Countries

In general, this region consists of countries from the Asia Pacific, Latin America, Eastern Europe, Africa, and Gulf countries. While countries in the Asia Pacific and Gulf regions have successfully attained a significant degree of regulatory uniformity through institutions like the Association of Southeast Asian Nations (ASEAN) and Gulf Cooperation Council (GCC), other regions have not yet developed fully consolidated regulations within their own territories.[5] The 17 developing markets mentioned below, known as "Pharmerging countries" according to IMS, have seen significant development, along with industrialized countries such as the U.S.A, EU, Japan, Canada, and UK. IMS categorizes these Pharmerging markets into three categories.[6]

Table 1: Classification of pharmerging countries.

Tires	Nationalities	2008 GDP ($ Trillion)	Value of the Incremental Pharmaceutical Market Growth From 2008-13 ($ Billions)
Tire-1	China	08	40 B+
Tire-2	**Brazil**, Russia, India	02-04	5-15 B
Tire-3	**Venezuela ,** Poland**, Argentina** Turkey, **Mexico**, **Vietnam**, South Africa, **Thailand**, Indonesia Romania, Egypt, Pakistan, Ukraine	<2	1-4 B
Source: "IMF GDD PPP in 2008; 'IMS market prognosis Oct 2009, 'For Venezuela, pharma value added is 5B+ but mainly attributed to unusual inflation and currency change. Countries in the tablet table are arranged in descending order of incremental market.			

3. REVIEW OF LITERATURE

In their study, Ramesh T et.al., 2011[7] highlighted the division of the world in terms of drug approval procedures. They emphasized the need for manufacturers, particularly generic companies, to thoroughly evaluate market demand, development costs, target regions, and regulatory requirements prior to drug development. In their 2013 study, Jitendra Kumar Badjatya et.al.[8] highlighted the difficulties associated with product registration in nations outside of the US, EU, and Japan. These countries lack integration, making the registration process complex. It results in a disparity in the regulatory framework in nations that are partially regulated. Emily Kimball et al., 2014[9] Latin America and other developing markets will continue to be of interest as the cost of compliance and quality standards rise on a worldwide scale. Governments seeking to reduce healthcare expenses by increasing their local capabilities will find more prospects for partnerships as manufacturers look for methods to cut costs and take advantage of these quickly expanding markets. Geraldine du Tilly et al., 2011,[10] many firms find the Mexican market to be particularly interesting, given that it is the 10th biggest market in the world for healthcare goods. The public sector is become more and more appealing as a result of government initiatives to increase population access to health care. Previously hesitant pharmaceutical corporations are now assessing potential and formulating entry plans. According to research done in 2010 by Lim Hock Chuan et al., the concept of an ASEAN Community goes beyond simple direction and form changes. What matters most is that mindsets are shifting from a loose coalition of member nations to a unified and harmonious society.[11] Rather of happening all at once, in a revolutionary way, this transition will happen gradually over time via planned, incremental modifications. AE. Prabahar & S. Bhavya Sri, 2017 The report included a short overview of license applications and the procedures for filling them out and submitting them to regulatory authorities, as well as the "current scenario of generic drug regulation and registration process in LATAM (Latin America)

countries." There are national regulations for submitting a generic medication registration for marketing in Latin America. It has been noted that the LATAM area lacks a unified or uniform drug registration process, 2017[12] The report included a short overview of license applications and the procedures for filling them out and submitting them to regulatory authorities, as well as the "current scenario of generic drug regulation and registration process in LATAM (Latin America) countries." There are national regulations for submitting a generic medication registration for marketing in Latin America. It has been noted that the LATAM area lacks a unified or uniform drug registration process.[13] The literature research primarily focused on gathering information on the regulatory requirements for generic medicine dossiers in Latin American and South East Asian countries. The sources often consulted include official government publications, newspaper articles, academic journals, internet journals, market research studies, and other relevant resources.

4. OBJECTIVE OF THE WORK

The biggest and fastest-growing emerging market economies are those in the LATAM region. Causes of the LATAM market's development

- The developed pharmaceutical market in developed countries is growing at a slower pace.
- R&D productivity declines.
- Patient population accessibility in developing economies.
- The accessibility of R&D resources
- To list out the basic reasons for the shift from the well-developed pharmaceutical markets to the LATAM markets.
- To comprehend the prerequisites for preparing a dossier for the registration of generic medications in Latin America (Brazil, Mexico & Argentina) countries.
- Comparative study of dossier requirements between above mentioned countries.
- To list out the problems currently faced by the pharmaceutical companies in reaching out the markets in these regions.
- A compilation of all Latin American regulatory modifications pertaining to generic medications. Summarize the differences between established laws and more recent ones.
- Draw attention to how the pharmaceutical industry's policies have changed in response to these regulatory adjustments.
- Assess the improvements' merits and drawbacks.
- Understand the specifics of the registration process and prerequisites for generic drugs.
- Future aspect speculation

5. METHODOLOGY

5.1. Drug Registration: Three categories comprise the regulatory regime in Latin American and the Caribbean (LATMA) countries: those that have established regulations requiring the demonstration of safety and efficacy through clinical trials or bioequivalence studies with the innovator's product during the drug approval process (Brazil, Mexico, and Venezuela). Although they are not as strict as those in the first category, Argentina, Chile, Columbia, Ecuador, and Paraguay also have requirements for the registration of new or generic drugs. The last group of nations—Guatemala, Barbados, Bolivia, Nicaragua, and Peru—has ill-conceived drug laws that must be followed in order for pharmaceuticals to be approved. The regulatory body has a relatively little window of time in many LA nations in which to register a product. Peru has the shortest registration period—just seven days. During this time, if the

regulatory body is unable to provide evidence that a certain product might be dangerous, the product is automatically registered. The majority of the nations for which we have information have fewer than 6 months to register a product, with the exception of Brazil and Chile, which required between 8 and 14 months.

Only Chile, Argentina, and Brazil provide incentives for the registration of generics, duplicates, and comparable products. The registration application cost for generic medications is waived in all three nations, and Brazil also provides a quicker examination period for generic and comparable pharmaceuticals. In Bolivia, registering a product costs fifty dollars for five years, but in Brazil, it costs twenty-seven thousand dollars. In comparison to the registration costs for new products, Argentina, Brazil, and Chile provide much reduced rates for the registration of generics and related products. The fees for registration and revalidation are different in Chile and Colombia. Ecuador charges national businesses $535 less for registration and $344 less for critical pharmaceuticals than it does for international businesses ($1,339). Nicaragua similarly gives preference to domestic manufacturers ($166 for a medication made in the country against $485 for a foreign product).

5.2. Spotlight on Research and Development: Due to the increasing focus on promptly introducing life-saving medications for illnesses in Latin American (Latam) nations, there has also been a rise in research efforts to identify treatments for diseases that are more common in this area compared to other countries.

5.3. Dossier requirements for submission to Regulatory bodies: CPP (Certificate of Pharmaceutical Product) / WHO GMP (World Health Organization Good Manufacturing Practices) / Manufacturing license • Free Sale Certificate • Letter of Authorization / Power of Attorney • Dossiers to be submitted in the local language • Legalization of administrative documents from the embassy • API (Active Pharmaceutical Ingredient) Technical package (Brazil, Mexico) • Specification and methods • Certificate of Analysis (COA) of API and Excipients from vendors • Manufacturing procedure and controls • Implemented the process of documenting and managing Batch production records and Batch Numbering system. • Collected and analyzed Stability data for three batches. Stability circumstances according to zone definitions.

5.4. Recommendations for important requirements

Brazil Requirement: A pharmaceutical equivalence study will be conducted in Brazil.

Recommendations: ANVISA will now accept the Pharmaceutical equivalent research provided by the Manufacturer, as long as the facility and lab have been examined by ANVISA. Advantages: Time savings.

Mexico Requirement: A bioequivalence study will be conducted in Mexico.

Recommendations: COFEPRIS will approve the bioequivalence research conducted in India comparing it to the reference product in Mexico. The laboratory has been authorized by the USFDA, ANVISA, and UK MHRA. Advantages: Time.

Chile Requirement: Ensure that process validation is completed before to the BE Batch.

Recommendation: Approval of the process validation/evaluation report for the display batches.

Other General recommendations: If the manufacturing facility receives approval from USFDA, UK MHRA, or ANVISA, Latam nations will accept the dossiers together with the FSC. (For example, Colombia and Chile.)

This includes comparison of administrative documents, fees, and time period for registration, product renewal, drug registration form, specific labeling requirements, and validity of cGMP certificate, production data, analytical data, API information, stability data, and packaging data.

6. RESULTS AND DISCUSSIONS

The research was carried out with the collected data by analyzing the terms of the below parameters types of study the research was done with the aim of formulating the regulatory framework for the registration of generic drugs in several LATAM nations. The primary focus has been placed on the regulatory needs of Brazil, Mexico, and Argentina in the LATAM region. The necessary guidelines have been collected and translated from the native language to English. These rules have been researched and comprehended in relation to generic medications in LATAM.

S. No		BRAZIL	MEXICO	ARGENTINA	Remarks
GENERAL INFORMATION					
1.	**Ministry of Health**	**ANVISA**	**COFEPRIS**	**ANMAT**	
2.	No of Registration Dossier Copies	1 original Hard Copy and 1 Electronic Copy	1 original Hard Copy and 1 Electronic Copy	1Hard Copy	
ADMINISTRATIVE OR GENERAL INFORMATION					
3.	Form if any	Application Form	Application Form	×	
4.	FSC	×	√	×	
5.	COPP	√	×	√	QQF
6.	Mfg License Copy	√	√	×	
7.	GMP Certificate	√	√	√	
8.	SmPC	√	×	√	
9.	Site Master File	×	×	×	
10.	Letter of Authorization	×	√	×	
11.	Reg. Status in other countries	×	×	√	
12.	TSE/BSE certificates	√	×	×	
13.	Patient information Leaflet	√	√	√	
BASIC CMC DOCUMENT					
DRUG SUBSTANCE					
14.	Specification & MOA	√	√	All documents from Annex I countries	
15.	Packing Details	×	×		
16.	Analytical Method Validation	√			
17.	Stability Report	×	√		
18.	COA	√	√		
DRUG PRODUCT					
19.	Excipient Specification & MOA	√	√	×	
20.	Excipient COA	√	√	×	
21.	In Process controls	×	√	×	
22.	Product Development Report	×	×	×	
23.	Finished Product Spec & MOA	√	√	√	
24.	FP COA	√	√	×	
25.	Packaging Material Spec	√	×	×	
26.	Stability Summary Report	×	×	×	
27.	Stability Protocol	×	√	×	
28.	Process Validation	×	×	×	
29.	Analytical Method Validation	×	√	×	
30.	No of sets required	×	1	×	
31.	BE Report or Product Interchangeability	√	×	√	

6.1. Internet using the web page content

The literature was gathered from several places such as Pharmabiz, RAPS, ANVISA, TFDA, IMS & BMI papers, Google scholar, and others. Online books are a valuable resource for obtaining knowledge. The search focused on generic medication registration standards, factors related to the pharmaceutical sector, names of regulatory organizations, and other related variables.

6.2. Criteria for selection of study parameters

Due to variations in generic medicine registration across LATAM nations, four characteristics were chosen to comprehensively analyze and examine the regulatory requirements in LATAM.

6.3. Part-I: Requirement for filing application

In order to promote their goods, it is essential for individuals to own their own production unit or local distributor. The application and dossier for generic medication registration must be submitted in the official language of the country where registration is sought.

6.4. Part-II: Documents and study information required for submission

1. Legal documents: Power of attorney, GMP certificate, certificate of pharmaceutical product (CoPP), free sale certificate (FSC), registration fee, timeline for registration, labeling information, product license should be notarized/legalized and attested by the embassy.

2. Pharmaceutical information: API & excipients information, finished product information, batch manufacturing record, batch packing record, stability studies, manufacturing details, process validation protocol and report, CoA's, Specifications.

3. Non - clinical and clinical documentation: It is necessary to include a literature search.

Part-III: Dossier compilation and submission: Format for submissions

Part-IV: Comparison study

This includes comparison of administrative documents, fees, and time period for registration, product renewal, drug registration form, specific labeling requirements, and validity of cGMP certificate, production data, analytical data, API information, stability data, and packaging data.

Where, QQF= Quantitative Quality Formula

- In the administrative section, FSC is required only for Mexico, SMF is not required for LATAM countries and SmPC is not required for Mexico.
- In the Drug Substance section, LATAM countries have to be given equally with open part of DMF while in case of Argentina those documents from Annex countries are sufficient.
- In the Drug Product section, Stability Summary Report and Product interchange ability are characteristic requirements not required for LATAM countries.
- By the above comparison it can be inferred that the LATAM countries have more requirements, while Argentina solely depends on the status of the product in its Annex countries.

7.0. Brazil Regulatory Requirements

Introduction

Brazil, with a population of 195 million, is the largest country in Latin America and the 5th largest country in the world. Its economy, with a GDP of $2.5 trillion, is the largest in Latin America and the 7th largest in the world, right behind the United Kingdom and just ahead of Italy. Brazil is one of the fastest growing economies in the world, with GDP up 18% per year over the last 5 years.

The Brazilian Pharmaceutical Market

According to business monitor international (BMI), the Brazilian pharmaceutical market reached $25.6billion in 2011 and accounts for approximately 38% of the Latin American pharmaceutical market and approximately 2.7% of the global market. According to IMS health, pharmaceutical spending in Brazil ranked #7 in the world in 2010 (up from #10 in 2005), and it is expected to climb to #6 by 2015. The main market research organizations (IMS health, business monitor) placed the Brazilian pharma market at $20-21billion in 2010, and estimate that this rises by 16- 22% in 2011, to reach $23-26bn. The below figure depicts the growth in the market, according to IMS, on which basis it reached $25.6bn in 2011.[16] Brazil – ANVISA (Agency Nacional de Vigilancia Sanitaria) On December 31, 1998 the Brazilian President signed Provisional measures #1791 that created ANVISA – Agencia Nacional de Vigilancia Sanitaria (National health vigilance agency) and Establishes a new user fees structure for companies and product registration. As per user fees and new certification rules medical devices and equipment, pharmaceuticals, vitamins and food products, cosmetics, tobacco and certain sanitation products, must be registered with ANVISA prior to sale in Brazil. Local representative of the foreign company should be responsible for the registration of product. The Ombudsman office is responsible for giving answers and information about topics related to ANVISA's attributions, as well as for conducting investigation about complaints regarding health surveillance. The office is not subordinated neither to any of the Agency's offices nor to the board of directors, which gives it total independence in its investigations. The Ombudsman is named by the president of the federative republic of Brazil and works during a two year mandate.[17]

Table 2: Different legislations used for registration of drugs.

REGISTRATION	RESOLUTION RDC NO
Similar Drugs	17/2007
Generic Drugs	16/2007
New Drugs	136/2003
Homeopathic Drugs	139/2003
Herbal Drugs	48/2004
Biological Drugs	315/2005

Table 3: Registration fee requirements for Brazil.

COMPANY	NEW DRUGS	SIMILARS	GENERICS
Large Company	80000	21000	6000
Small Company	8000	2100	600

Note: The size of the company is stipulated according with its annual revenue of the company.

7.1. MEXICO

Mexico has a population of 110 million people, the second largest in Latin America and 14th worldwide. Its economy is the second largest in the region, with a GDP of $1.2 trillion ranking 13th in the world, right behind Spain and just a head of Korea. Pharmaceutical sales in Mexico reached $13bn in 2011 and business monitor international (BMI)

expects this market to grow at a CAGR of 6% over the next five years. Mexico ranked fifth among the seven countries profiled in healthcare expenditure per capita at $604 – below Brazil ($990), Chile ($947), Argentina ($742) and Venezuela $663).[30]

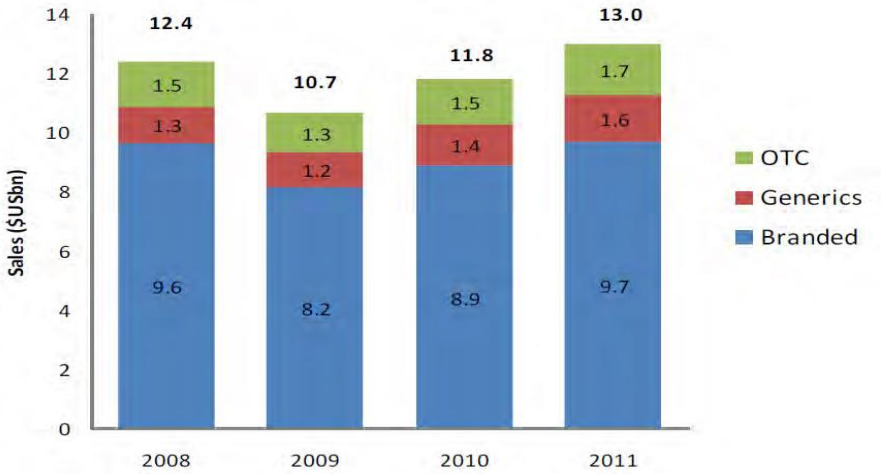

Fig 2: Mexico pharmaceutical segments trends.

7.2.1. Mexico Pharmaceutical Market Forecast

BMI expects the pharmaceutical market to grow from MXN161.5bn (US$13.0bn) in 2011 to MXN240.4bn (US$19.9bn) in 2016, with an 8.3% compound annual growth rate in local currency terms and 8.9% in US dollar terms. It is forecast that the OTC drug and generic sector will experience stronger growth than the patented drug sector, as expensive drugs can push patients either to forgo treatment or turn to low cost OTC and generic drug markets. It is note that Mexico's pharmaceutical spending per capita was only US$113 in 2011.[31]

7.2.3. Regulatory Authority

The regulatory authority is the *Comisión federal para la protección contra riesgos sanitarios* (COFEPRIS), which started operations in 2003. It is an autonomous entity, but it operates under the auspices of the Secretariat of Health. COFEPRIS is a decentralized organization of the department of health with technical, administrative and operational autonomy, whose mission is to protect the population against sanitary risks, through sanitary regulation, control and promotion under a single command, which provides unity and homogeneity to the policies which are determined.

7.2.4. Regulation and Procedure: The standards to be followed for the registration of drugs in Mexico are published in the official gazette. The lists of official standards are given below:

Table 5: Mexican official standard used for product registrations.

NOM-059-SSA1-2006	Good manufacturing practice for establishment's pharmaceutical chemical industry devoted to the manufacture of medicaments.
NOM-072-SSA1-1993	Drug labelling.
NOM-073-SSA1-2005	Stability of drugs and medicines.
NOM-164-SSA1-1998	Good manufacturing practices for drugs.
NOM-176-SSA1-1998	Health requirements to be met by manufacturers, distributors and suppliers of drugs used in the production of medicines human.
NOM-177-SSA1-1998	Procedures for testing and demonstrates that a drug is interchangeable.

Table 6: Guidelines for the registration of drugs.

The technical precepts and procedures for the registration of drugs are discussed in the following guidelines. These guidelines are published in Spanish Language.

COFEPRIS-04-004-A	Health and Sanitary Registration of Allopathic, Vaccines and Blood Products manufactured locally (New Molecule).
COFEPRIS-04-004-B	Health and Sanitary Registration of Allopathic, Vaccines and Blood Products manufactured locally (Generic).
COFEPRIS-04-004-C	Health and Sanitary Registration of Allopathic, Vaccines and Blood Products manufactured Foreign (New Molecule).
COFEPRIS-04-004-D	Health and Sanitary Registration of Allopathic, Vaccines and Blood Products manufactured Foreign (Generic).

Table 7: Registration Fee Requirements for Mexico.[37]

TYPE OF DRUG	GENERIC MEDICINES	NEW DRUGS
Registration fee	60,100$	107,462$
For any modification	45,075$	80,596$
Modification of business	30,050$	53,731$

DESCRIPTION & SERVICE	AMOUNT
For auditing of manufacturing site	70,839$
For modification or upgrading of CGMP certificate	53,129$
For auditing additional location of same company	400,115$
Sanitary permits prior to importation of raw materials or finished products of drugs	3,952$

8. SUMMARY AND CONCLUSIONS

In the recent years there has been an emergence of the LATAM markets due to the shift from the well developed pharmaceutical markets to the ROW markets. In the present study three countries from each region have been selected and their regulatory requirements were thoroughly collected, studied, compiled and compared.

The three nations in the LATAM area are Brazil, Mexico, and Argentina. The research was undertaken with the aim of comprehending the regulatory framework for the licensing of generic drugs in these nations. The material was gathered from a multitude of websites and the official websites of regulatory bodies.

After the completion of the study it is inferred that Brazil and Mexico have been the frontline contenders in the LATAM region with well established regulatory system, large population, expiration of several patents. The Saúde Não Tem Preço initiative is being implemented in Brazil to offer free medications for the treatment of hypertension and diabetes and also with a decent CAGR (Compound Annual Growth Rate). In case of Argentina the regulations are not as stringent as in Brazil and Mexico and it mostly depends on its Annex I and Annex II countries.

Furthermore, local pharmaceutical businesses have a majority share of the market, accounting for about 55% of the industry's sales. In the present study the generic drug registration requirements of countries in LATAM regions were studied thoroughly and found to be self sufficient to carry out error free registration system. In LATAM, regions like Brazil and Mexico have their own methods while Argentina depends on other developed countries. The drug registration process in the LATAM area lacks centralization and standardization. Significant disparities exist across nations in the area. With the rising worldwide quality standards and increasing compliance costs, there will be a continued emphasis on Latin America and other growing markets. Manufacturers are actively looking for methods to

reduce costs and take advantage of these fast-growing markets. This has resulted in more prospects for partnerships, as governments want to enhance their local skills in order to reduce healthcare expenses.

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