

# Introduction of pharmaceutical industry business essay

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## **INTRODUCTION**

### **2. 1 INTRODUCTION OF PHARMACEUTICAL INDUSTRY**

The Pharmaceutical Industry (the Pharma industry) is an integral part of the healthcare system in every country. The industry consists of companies licensed to research, develop, market and distribute medicine for the prevention, treatment and cure of diseases and other health conditions. The development of the health sector in every nation is critical in promoting the development of other sectors and general socio-economic development of the nation. Pharmaceuticals are an integral component of health care systems worldwide, thus, regulatory weaknesses in governance of the pharmaceutical system negatively impact health outcomes especially in developing countries. Mexico is one of the most attractive pharmaceutical markets in the Latin American region. It is increasingly aligning its regulations and legislation with US standards, and in 2008 abolished the requirements for pharma companies to have a manufacturing plant in Mexico, therefore lowering barriers to market entry for multinationals. Mexico is a developing country, but its economy is actually fairly robust compared to other developing and even some developed countries, as the following statistics indicate. Although a high percentage of Mexicans lives below the poverty level, the gross domestic product (GDP)—a measure of economic strength—has recently been estimated to be about \$1 trillion with an annual growth rate of 3%. In comparison, Mexico's southern neighbour, Guatemala, has a GDP of just under \$60 billion and an annual growth rate of 3.2%. Mexico's economy ranks nearly even with Canada's in terms of GDP (total gross, not

per capita) and Mexico's GDP is growing faster than Canada's. Mexico's population is young; the median age is approximately twenty-five years, and there is a relatively high literacy rate of 92.2%, roughly equivalent between males and females. In addition, Mexico has close economic ties to the United States, the result of both geographic proximity and the common market created by the North American Free Trade Agreement (NAFTA). Given these factors like: a young, literate work force a growing economy, a powerful trading partner in the United States Mexico has an excellent opportunity to expand its position in the high technology industries, including the pharmaceutical industry. By developing its own pharmaceutical industry, Mexico will be able to serve this market and potentially even expand to supply pharmaceutical products to markets in other countries as well. To accomplish these objectives, Mexico must implement and enforce patent protections in a way that balances the interests of drug companies with the Mexican public's need for affordable and accessible medicines. The estimated value of the market for pharmaceuticals in Mexico is \$7 billion with a projected annual growth rate of 10%. In 2009, Mexico issued a variety of technical trade measures on the products such as mechanical medicines, herbal remedies, distribution transformers, electric washing machines, and others. On May 5, 2009, the Federal Commission for Health Risk Protection of Mexican Ministry of Health published the notification G/TBT/N/MEX/174, setting forth the minimum requirements for the processing of herbal remedies marketed in Mexico. Patent protection is necessary for the development of any technology-based industry. This is especially true of the pharmaceutical industry, which depends on the enormous investment of

resources in the development of new drugs. In fact, the patent system is considered essential to the business model of the pharmaceutical industry. First, patent protection allows a pharmaceutical company that develops a new drug to sell it at a price that better reflects the true cost of producing it. Second, that company then has the potential to realize a profit from sales of the drug, and, thus, there is the incentive for the company to continue investing in drug discovery. In 2003, for example, the average cost of bringing a new drug to market was more than \$900 million. 5 The bulk of this cost goes into research and development (hereinafter referred to simply as "R&D"), including extensive testing for safety and efficacy. In the United States, only one of five drugs that reach the clinical trials stage will get Food and Drug Administration (FDA) approval, and, of these, only three of ten will earn back the average cost of R&D. R&D costs contribute a significant portion to the prices set by pharmaceutical firms for their products. Drug prices are initially high for consumers because patents give companies the power to set prices that are reflective of the massive R&D costs for new products. The business of developing and manufacturing pharmaceuticals is very risky in terms of the success rate of finding new drugs. Every new drug that arrives on the market represents a company's enormous investment of time and resources in discovering and testing compounds. Because so many compounds turn out to be dead ends, pharmaceutical companies rely on the few successful drugs to fund continued R&D. It has been shown that more than 55% of industry profits may come from as few as 10% of marketed drugs. For this reason, a lack of patent protection is more damaging to the pharmaceutical industry than to most other industries. The medicines that

are currently available came about because the pharmaceutical companies that developed them were able to rely on the patent systems in the developed world. Mexico's pharmaceutical industry generates revenues of around \$11 billion, making it the 11th largest pharma market in the world. In Latin America, Mexico comes in second after Brazil, which leads the region with \$16 billion. In Mexico, the sector has been traditionally stable with large profit margins, but it is currently undergoing a rapid transformation. Although these changes were expected, companies are just now starting to adapt their strategies to the new conditions in very different ways. The changes cut across a number of areas including product development, competition, distribution, and regulation.

## **2. 2 THE ROLE OF PHARMA INDUSTRY IN ECONOMY OF MEXICO**

There is a large market for drugs in Mexico. Out of over 130 existing pharmaceutical manufacturers only 60 are in active manufacturing. This is despite the installed capacity of the industry to produce between 50% and 75% of the nation's drug needs. Capacity utilization is below 30% and about 70% of the drugs are thus imported. The Sales revenue of pharmaceutical industry is tripled over last decade. Mexico becomes US's largest market in pharmaceutical industry and having 40 % of worldwide sales. Pharmaceutical industry having 16. 4% profit margin in 2000 (\$24 billion). It's 4 times greater than average return of all fortune 500 companies and 8 out of 25 most profitable U. S. companies are pharmaceutical companies. Drug availability in the public and private health care delivery system in Mexico is in a poor state. Various reasons have been add for this trend these include:(i)

Inadequate funding of hospital Pharmacies and the —out of stock syndrome

- (ii) Involvement of unqualified persons in the procurement and distribution of drugs.
- (iii) Inadequate storage facilities, transportation and distribution.

## **2. 2. 1 Manufacturing**

In terms of who is doing what in Mexico, most brand-name drugs sold in neighbor state are shipped into the country. The vast majority of generic drugs sold in neighbour are made right here. In fact, the majority of the pharmaceutical manufacturing capacity that exists in Mexico is generic. A dollar spent on a generic drug supports more jobs, more R&D investment, and more investment in pharmaceutical manufacturing capacity in Mexico than a dollar spent on a brand-name drug.

## **2. 2. 2 Innovation**

The generic pharmaceutical industries ponds approximately \$615-million each year on research and development in Mexico. Generic pharmaceutical companies in Mexico invest approximately 15% of sales in research and development, which compares to just 7. 5% for brand-name companies. Brand companies in Mexico invest just 1. 8% of domestic sales in to domestic R&D that could lead to the discovery of a new therapy.

## **2. 3 STRUCTURE OF MEXICO PHARMA INDUSTRY**

According to the Pharmacists Council of Mexico (PCN), there were 128 registered drug manufacturers, 1, 534 retail pharmacies, 724 drug distributors and 292 drug importers in Mexico in 2010. Mexico has a total of 14, 607 public and 9, 034 private healthcare facilities (National Bureau of

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Statistics). However, it has been estimated that there are over 10, 000 unregistered patent and proprietary medicine stores, which are thought to sell over the counter (OTC) products only. Most such stores are located in villages and poor communities throughout the country, in areas where fully fledged pharmacies do not exist. The Pharmaceutical industry has been constantly evolving due to globalization, consolidation and regulatory compliances. Manufacturing needs to incorporate more efficient, quality-centric processes. A pharmaceutical supply chain has to be scalable and agile enough to accommodate changing scenarios and partners across the globe. Research and development (R&D) is under pressure to cut costs and cycle time.

## **2. 4 FUNCTIONS OF MEXICAN PHARMA INDUSTRY**

Pharmaceutical Company is made up of a number of functional divisions and each of these departments is responsible for one area of the activities. The departments of pharmaceutical company are followed as:

### **2. 4. 1 Research and Development**

Research departments are responsible for finding compounds which can be developed into new and better medicines. Development staff must then go through all the processes that are necessary to produce a new medicine from the original research idea.

### **2. 4. 2 Regulatory Affairs**

Regulatory department is responsible for liaising with regulatory authorities, with regard to approval of application and other type of license. They also submit annual reports and supplements to the regulatory agencies and have

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an advisory role with regard to providing information on country-specific regulations.

### **2. 4. 3 Quality assurance**

Quality Assurance is the most vital function of Total Quality Management (TQM) in pharmaceutical industry. Quality Assurance functions as the company's internal quality auditing and compliance. Generally, they are most involved in global issues and frequently conduct periodic GMP training to personnel at all levels of the organization. Also, Quality Assurance department act as arbitrator between the Quality Control functions and production departments.

### **2. 4. 4 Production**

Once the drug is approved by the regulatory board, the regulatory department will give the Master Formulation Record to the production department. The production department is involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and relabeling, to completion of the finished product.

### **2. 4. 5 Quality Control**

The term quality control refers to the sum of all procedures undertaken to ensure the identity and purity of a particular pharmaceutical or the process of Checking or testing, that specifications are met, or the regulatory process through which the industry measures actual quality performance, compares it with standards, and acts on the difference.



## **2. 4. 6 Sales and Marketing**

Every Pharmaceutical company will have their own marketing and sales strategies to introduce the drugs into the market. A drug company employee regularly visits physicians and office practices and apart from that, they will take care of retail, distributor and wholesale sales and provides information on the company's products-usually putting a negative 'spin' on competitors' products.

## **2. 5 BUSINESS ACTIVITIES OF PHARMA INDUATRY**

### **2. 5. 1 Registration**

The first decision point in the pharmaceutical chain is registration, which was originally introduced to protect patients from catastrophes like the thalidomide cases in the 1950s, and evaluates a drug' s efficacy against a specific disease and its possible side effects. The process regulates the labelling, marketing, usage, warning and prescription requirements for a drug. Registration procedures need to be transparent and applied uniformly, and should leave no room for individual discretion. The registration process should guarantee drug safety and efficacy.

### **2. 5. 2 Selection**

Drug selection processes should ensure that the most cost-effective and appropriate drugs for a population' s health needs are chosen fairly. The WHO Model List of Essential Medicines is a helpful framework in this regard for most developing countries because it establishes priority areas of treatment and covers the most common diseases. But this can open a new avenue for corruption since manufacturers have a strong interest in getting

their products selected as essential medicines. If institutions are weak and individuals have incentives to engage in corrupt activities, the selection process can be replete with kickbacks and payoffs so that drugs on a national drug list may not necessarily reflect appropriate and cost-effective drugs.

### **2. 5. 3 Procurement**

Procurement is the principal interface between the public system and drug suppliers, and its goal is to acquire the right quantity of drugs in the most cost-effective manner. This involves inventory management, aggregate purchasing, public bidding contests, technical analysis of offers, and proper allocation of resources, payments, receipts of drugs purchased and quality control checks.

### **2. 5. 3. Distribution**

Distribution in the pharmaceutical system ensures drugs are allocated, transported and stored appropriately at all points where they are to be dispensed. This involves central and regional warehouses, pharmacies and service floors. Information must flow easily through every level of the system to control inventory movements and deliveries. In addition, the system requires storage facilities, including refrigeration units, to guarantee the integrity of the drugs and good security to minimise the risk of theft. The electronic monitoring of transport vehicles and careful checking of delivery orders against inventories of products delivered are some of the methods that can reduce this likelihood.

## **2. 5. 4. Service delivery**

Service delivery involves the participation of physicians, pharmacists, nurses and other health care providers who diagnose patients and identify what drugs a patient should consume to treat a particular disease. This is the decision point at which patients should experience the benefits of the entire system. Here physicians prescribe, pharmacists dispense and nurses administer drugs to treat patients. Health providers ideally utilise evidence-based practice to provide effective therapy to their patients. The interface between the pharmaceutical industry and physicians is an area that is particularly susceptible to corruption, as service delivery can be influenced by the marketing practices of the pharmaceutical industry.