

## **CURRENT SENIOR OF PHARMACEUTICAL INDUSTRY & ITS CHALLENGES**

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### **INTRODUCTION**

#### **THE PHARMACEUTICAL INDUSTRY**

The Pharmaceutical industry discovers, develops, produces, and markets drugs or pharmaceutical drugs for use as medications. Pharmaceutical companies may deal in generic or brand medications and medical devices. They are subject to a variety of laws and regulations that govern the patenting, testing, safety, efficacy and marketing of drugs.

#### **MID-1800S – 1945: FROM BOTANICALS TO THE FIRST SYNTHETIC DRUGS**

The modern pharmaceutical industry traces its roots to two sources. The first of these were local apothecaries that expanded from their traditional role distributing botanical drugs such as morphine and quinine to wholesale manufacture in the mid 1800s. Rational drug discovery from plants started particularly with the isolation of morphine, analgesic and sleep-inducing agent from opium, by the German apothecary assistant Friedrich Sertürner, who named the compound after the Greek god of dreams, Morpheus. Multinational corporations including Merck, Hoffman-La Roche, Burroughs-Wellcome (now part of Glaxo Smith Kline), Abbott Laboratories, Eli Lilly and Upjohn (now part of Pfizer) began as local apothecary shops in the mid-1800s. By the late 1880s, German dye manufacturers had perfected the purification of individual organic compounds from coal tar and other mineral sources and had also established rudimentary methods in organic chemical synthesis. The development of synthetic chemical methods allowed scientists to systematically vary the structure of chemical substances, and growth in the emerging science of pharmacology expanded their ability to evaluate the biological effects of these structural changes.

#### **THE PHARMACEUTICAL INDUSTRY IN INDIA**

The Pharmaceutical industry in India ranks 3rd in the world terms of volume and 14th in terms of value. According to Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, the total turnover of India's pharmaceuticals

industry between 2008 and September 2009 was US\$21.04 billion. Hyderabad, Mumbai, Bangalore and Ahmedabad are the major pharmaceutical hubs of India. The domestic market was worth US\$13.8 billion in 2013.

The government started to encourage the growth of drug manufacturing by Indian companies in the early 1960s, and with the Patents Act in 1970. However, economic liberalization in 90s by the former Prime Minister P.V. Narasimha Rao and the then Finance Minister, Dr. Manmohan Singh enabled the industry to become what it is today. This patent act removed composition patents from food and drugs, and though it kept process patents, these were shortened to a period of five to seven years.

The Lack of patent protection made the Indian market undesirable to the multinational companies that had dominated the market. Whilst the multinationals streamed out, Indian companies carved a niche in both the Indian and world markets with their expertise in reverse-engineering new processes for manufacturing drugs at low costs. Although some of the larger companies have taken baby steps towards drug innovation, the industry as a whole has been following this business model until the present.

India's biopharmaceutical industry clocked a 17 percent growth with revenues of Rs.137 billion (\$3 billion) in the 2009-10 financial year over the previous fiscal. Bio-pharma was the biggest contributor generating 60 percent of the industry's growth at Rs.8,829 crore, followed by bio-services at Rs.2,639 crore and bio-agri at Rs.1,936 crore

#### **REGULATED DRUG MANUFACTURING IN INDIA:**

Drug business is highly regulated for manufacturing and testing of drugs. There are good Manufacturing practices guideline and schedule M. requirement for plant and equipment. Ministry of health & family welfare amended schedule "M" of Drugs & cosmetic Rules 1945, which specified "Good Manufacturing Practices" to be followed by drug Manufacturers so that a finished formulation is of highest quality and is effective and safe till expired. There are

pharmacopoeias like I.P, B.P, and U.S.P. etc which gives monographs for drugs, packing materials and drug dosage forms. Drug manufacturers have to comply with the specification given in pharmacopeia monographs, if they are Official

Opponents of widespread use of generics point out that they are tested on only a few young, healthy individuals, compared with the large numbers of patients who participate in clinical trials of the original drug. According to guidelines from the World Health Organization, 18 to 24 healthy adult volunteers are considered sufficient for a bioequivalence study. The number of participants may be greater, however, if absorption or clearance of the drug is highly variable. What's more, the people who volunteer for generic drug studies cannot smoke or take concurrent medication. To exclude the possibility that food co-administration affects the generic medication being studied, the food & drug authority further recommends bioequivalence testing of oral formulations on volunteers eating standardized meals. These criteria help minimize the magnitude of inter-subject variability and reduce the possibility of bias which could be caused by the disease process, concurrent conditions, or medication interaction, rather than by formulation differences.

**Safety and Efficacy:** Our literature search yielded little evidence that generic drugs are less safe or less effective than their brand-name equivalents. The meta-analysis, for example, included 47 studies (38 of 47 were Randomized Control Trials) covering 9 subclasses of cardiovascular medications. In trials involving beta-blockers, diuretics, calcium channel blockers, antiplatelet agents, statins, angiotensin-converting enzyme inhibitors, and alpha-blockers, no evidence of superiority of brand-name drugs versus generics was found.

**Cost:** Generic drugs typically cost 30% to 60% less than their brand-name counterparts, and widespread use of generics has the potential to reduce the price of other brand-name drugs by creating more competition.

**Another plus:** Patients taking generic drugs appear to be more willing to continue therapy than those taking brand-name medications. Lower co-pays are a key factor. In 1 recent study of patients with hypercholesterolemia or diabetes, those taking generics had greater adherence compared with patients receiving brand-name drugs.

**Quality:** It is important to note that many generic medications are produced under the license of the manufacturer of the original brand-name product, with the lower-cost equivalent often introduced after the drug's patent has expired. Even

when different manufacturers produce the branded product and the generic, strict standards exist to guarantee the quality of generic drugs.

## **PHARMACEUTICAL COMPANY BUSINESS STRATEGIES**

What's the secret behind these successes? For one, the company operates in niche formulations (chronic) segments such as psychiatry, cardiovascular, gastroenterology and neurology. While most of the top Indian companies have focused on antibiotics and anti-infectives (acute), Sun Pharma focused on therapeutic areas such as depression, hypertension and cancer. The company has introduced the entire range of products and has gained leadership position in each of these areas. Being a specialty company insulates Sun Pharma from the industry growth. The first quarter results for FY02 explain this to some extent. While the industry was affected to a large extent by a slowdown in the domestic formulations market, Sun Pharma logged a growth of 26% in revenues. Over the years Sun has also used the strategy of acquisitions and mergers to grow quickly. It acquired Knoll Pharma's bulk drug facility, Gujarat Lyka Organics, 51.5% in M. J. Pharma, merged TamilNadu Dadha Pharma & Milmet Labs and acquired Natco's brands. Post Merger with TamilNadu Dadha Pharma the company gained presence in gynecology and oncology segments. One of the constants of pharmaceutical company strategy over the past decade has been increasing scale.

## **FUTURE CHALLENGES**

The pharmaceutical industry is a rising and prosperous sector in the developing country like India. The following future challenges can be noted as under:

- The population is increasing. The urban sector is bringing rural people in cities who are becoming health conscious and they require more health information as well as effective drugs.
- The health information network must be mass based so that the cities can get correct information.
- The branded drugs are established in these market and generic drugs have to face tough competition by branded drugs.
- The pharmaceutical industry has to face challenges from Naturopathy, Ayurveda, Homeopathy. The Allopath is challenged by Naturopathy. People are using these medicines being less harmful.

- The yoga meditation and other methods of spiritual awakening are also used .
- The pharmaceutical industry has to conduct research to resolve the crisis effectively based on new challenges.
- The new modes and methods based on ICTs are required. The websites, blogs as well as what's up and pod...techniques must be developed to inform the concerned

### THE CONCEPT OF GENERIC MEDICINE

The marketing of generic medicine is the subject and the conceptual frame has been explained in this part of the research work in a systematic manner.

Since many decades the importance of generic prescribing emphasized, mainly to reduce the cost of medicine. Thus it is clear that low and cheaper price is the important character of generic drugs and these drugs can be popular in the developing countries on these factors.

Once the patents expired, the drug is available in the open market for manufacture and sales for other companies. At this stage, the drug is referred as a generic medicine.. The popularity of such drugs can be marked at all levels because these drugs then become available to all at low price in the market.

Further there are two concepts to be understood here, one is generic v/s non proprietary name or generic name. It is clear that the generic drug is not a branded drug and it has tremendous value for a common man because the generic drug is easily available at low price.

Since generic product innovator is bioequivalent for the product, it is possible for a brand name product replacement by generic product. This substitution increases its value in the market. The branded drugs are costly and they are not affordable to common man but generic drugs are easily available at low price.

Generic drugs are generally much cheaper than their branded counterparts for a number of reasons. The pricing depends on many factors and these reasons can be very well explained on various grounds and factors in this study.

The generic products are sold at very low costs compared economical to innovator's products." The low price is based on many factors. These products are simple, easily available and they are not marketed like branded drugs. Hence they are chapter and low priced.

### MARKETING ACTIVITIES OF GENERIC MEDICINES

While many pharmaceutical companies have successfully deployed a plethora of strategies to target the various customer types, recent business and customer trends are creating new challenges and opportunities for increasing profitability. In the pharmaceutical and healthcare industries, a complex web of decision-makers determines the nature of the transaction (prescription) for which direct customer of pharma industry (doctor) is responsible. Essentially, the end-user (patient) consumes a product and pays the cost. Use of medical representatives for marketing products to physicians and to exert some influence over others in the hierarchy of decision makers has been a time-tested tradition. Typically, sales force expense comprises an estimated 15 percent to 20 percent of annual product revenues, the largest line item on the balance sheet. Despite this other expense, the industry is still plagued with some very serious strategic and operational level issues. From organizational perspective the most prominent performance related issues are enlisted below:

- a) Increased competition and shortened window of opportunity.
- b) Low level of customer knowledge (Doctors, Retailers, Wholesalers).

### CURRENT MARKETING STRATEGIES FOR GENERIC MEDICINE:

- The process of generic drugs depends on how they are provided by companies. They are not effectively marketed in the in the competitive market of branded medicines, which provide benefits to the doctors as well as distributors.
- The kickbacks are very less for the MRs and doctors don't take much interest in the marketing of generic drugs.
- The generic medicines don't have much popularity in comparison to branded drugs. Hence they always remain secondary and they are not marketed properly.
- The generic drugs don't have a proper publicity or media planning. Hence don't come in lime light.

## RESEARCH METHODOLOGY

The present study has attempted to investigate the current senior of pharmaceutical industry & its challenges looking at the nature of the topic and its scope, the methodology of study has to combine the library research and the online. The library research was aimed at survey of literature, compilation of secondary sources of information and cutting out the theoretical information that could help in building up to conceptual foundation of the subject.

## OBJECTIVE OF THE STUDY

Following are the objective of this study

- I) To study new Marketing trends of pharmaceutical companies.
- II) To study emerging trends in Generic Medicine

## CONCLUSION

The Indian pharmaceutical companies are going for off patent medicine manufacturing and marking the medicine that will help them generate large generic volume, but majority of the generic medicine is exported around the world, because in India the practices of doctors to prescribe branded medicine is not allowing generic medicine to expand in the Indian market. India is large country and majority of population of middle class and poor class, many of patients could not afford the branded medicine due to high price. Thus our country needs off patent drugs, because the prices of the off patent drugs is 30 to 40 % lesser as compared to branded medicine thus the current trends of pharmaceutical industry is shifting towards generic medicine.

## REFERENCE

- [1]. Faris El-Dahiyat\* And Reem Kayyali, "Evaluating Patients' Perceptions Regarding Generic Medicines In Jordan", Paper Published In *Journal Of Pharmaceutical Policy And Practice* 2013, 6:3 Doi:10.1186/2052-3211-6-3, Published 13 June 2013
- [2]. Dr. Jignesh K Ved, Dr. Sagar S Jagtiani, Dr. Kunal A Chitnis, "Pharmaceutical Advertisements in Indian Scientific Journals: Analysis of Completeness of Information Content", *International Journal of Pharma Sciences and Research (IJPSR)*, Vol.1(9), 2010, pp 366-370.
- [3]. Destrina Grace Simanjuntak and Raymond R. Tjandrawinata, "M&A of Generic Pharmaceutical Companies Increases Productivity", Id=1946761.
- [4]. Dr G Bakthavathsalam, "Generic Drugs: Cost Effective Alternate To Branded Drugs", *Health Administrator Vol : Xix Number 1: 16-19*
- [5]. Kesselheim AS, Misono AS, Lee JL, Stedman MR, Brookhart MA, Choudhry NK, Shrank WH., "Clinical Equivalence Of Generic And Brand-Name Drugs Used In Cardiovascular Disease: A Systematic Review And Meta-Analysis." *JAMA*. 2008 Dec 3; 300(21):2514-26. Institute For Rational Pharmacotherapy, 3rd December 2009
- [6]. Dickov V., "Marketing channels on the pharmaceutical market. *Int J*" *Nov Drug Deliv Tech*. 2011; 1(4): 233-239.
- [7]. [www.wiki.com](http://www.wiki.com)
- [8]. [www.timeofindia.com](http://www.timeofindia.com)
- [9]. AjoyBera and Ashish Mukherjee "The Importance Of Generic Drugs In India" *IJPCBS* 2012, 2(4), 575-587 aurabh Kumar Saxena "A Review Of Marketing Strategies Work By Different Pharmaceutical Companies"