

# Example of pharmacy industry and products case study

[Business](#), [Company](#)



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## Introduction

Pharmaceutical industry has existed for many years and plays an integral role in the economic development. The industry develops, process, manufactures, and markets various drugs and other pharmaceutical products, which are used for medication purposes. In essence, the industry does not only deal with processing, marketing, and development of drugs and pharmaceutical products, but renders quality medical services and champions the discovery of generic and brand drugs. In most cases, pharmaceutical industries are subjected to stringent laws, policies, and regulations, which provide an elaborate and effective framework of operation in and within the industry (Tharp, 2003). Pharmaceutical companies are required to adhere to the laws, regulations, policies, and practices, which guide their operations to guarantee safety, efficacy, and effectiveness of drugs and medical services. In a similar vein, pharmaceutical industries are supposed to consider patent laws and testing to ensure that they do not

contravene and jeopardize their operations as required by the law.

Like any other industry, pharmaceutical companies operate in dynamic and unprecedented business environment that is marked with change in consumers' behavior, technology, and price fluctuations. However, the industry has remained competitive and relevant in its operation by processing, developing, discovering, and marketing effective drugs for curing and treating various illnesses; an idea that improves healthcare sector.

Although pharmaceutical companies develop, process, and market drugs and licensed pharmaceuticals, they are different in many ways. First, they are differentiated in terms of prescription drugs and Over The Counter Drugs demoted as OTC. Prescription drugs are taken under the prescription of a medical doctor and exclusively sold in recognized and licensed pharmacies. Consequently, over the counter drugs are exclusively used for self-medication purposes and available in drugs stores and pharmacies (Food and Drug Administration, 2010). The second distinction is premised on originality of pharmaceutical products, which are divided into generic and original brands. In essence, patent laws protect original brands whereas generic products share similar aspects and chemical formula with the existing drugs. The paper explores market size and major players, research and development and regulations governing pharmaceutical industry.

## **Market size and major players**

In the last few years, pharmaceutical industry has experienced significant growth and developed in terms of market size, profit margin, and structural changes and trends. Currently, the global pharmaceutical market records an

approximate \$300 billion annually. A recent report released by World Health Organization (2009) indicates that the industry would record \$400 billion by the end of 2015; an idea that would boost the industry's operation and efficiency. This tremendous change in global market is attributed to several factors including advancement in technology in health care sector, expansion of market niche in developing and developed countries, and emphasis in research and development. Technology advancement has increased sales of prescription drugs in most developed countries, especially in America. In 2006, the American government enacted Drug Improvement and Modernization Act that has increased usage of pharmaceutical products among elderly and aged persons hence increasing the sales volume of the industry.

Pharmaceutical industry is competitive and shows a high level of concentration and dominance among fifteen multinational companies, which control more than one third of the global market. Most of these multinational companies record a profit margin of 30% and a sales volume of \$10 billion annually. Three-quarters of these multinational companies are based in America and the rest are located in Europe, but they have not diversified in their operations (Tharp, 2003). In other words, most of these pharmaceutical companies either develop and process pharmaceutical products or manufactures other health care products. South America, North America, Japan, and Germany (Europe) are the leading countries in terms of capital spending in the industry since they account for more than eighty-five percent of the global market.

Globalization has played a vital role in pharmaceutical industry as it has

expanded market space through acquisition, merger, joint ventures, and co-marketing strategies. Globalization allows multinational pharmaceutical industries denoted as “ Big Pharma” to indulge in research and development thus helping these companies become relevant and competitive in the long-term. Merger, acquisition, and joint ventures help companies share knowledge, skills, and risks involved in the business. For instance, the acquisition of Pharmacia by Pfizer and Guidant by Johnson& Johnson in 2004 helped these American based companies to expand their market niche and solidify their expertise and competences. Globalization has also helped pharmaceutical industries to share research findings and skills thus fuelling innovation and discovery of new pharmaceuticals and drugs (Biopharmaceutical industry contributions to state and U. S. economics, 2004). Based on these assertions, globalization has played a crucial role in transforming the industry.

## **Research and development**

Pharmaceutical companies have invested heavily in research and development because it promotes discovery of new drugs. It has been established that drug development process coupled with research and development is an expensive exercise because not all compounds identified as drugs are approved and confirmed safe for human consumption by the various regulation bodies. This infers that pharmaceutical companies use a large amount of money in research and development and should make profits for the industry to survive and remain competitive.

In most cases, pharmaceutical companies are supposed to finance and settle

cost involved in research and development. They are supposed to calculate the opportunity cost and risk involved in developing, processing, and marketing a new drug before commencing the process. However, the government provides research grants to enable these companies to conduct their research effectively and in a cost-effective manner. Additionally, has subsidized equipments and resources required in research and development process to reduce operation cost of these companies.

Research and development is more important than marketing and sales in a pharmaceutical industry. Great risks and cost is involved in developing, processing and marketing a drug, not only compounds used in drug processing become approved drug viable for human consumption and sale. Pharmaceutical companies take approximately 10-15 years before recovering their previous cost developmental cost. This means that a company should invest heavily in research and development so that to process a drug that will generate adequate revenues and cover previous failures.

## **Regulation**

Drug approval process is legal and regulatory exercise that accords an individual, innovator, or an organization the permission to launch and market a drug (Martinez, 2007). In essence, this process entails several stages, which an individual should follow. They are: Application to perform clinical trials, executing/conducting clinical trials, and application to market authorization of the drug and post-marketing researches. Before applying for an application to conduct clinical trials, the innovator conducts non-clinical

studies to ascertain efficacy and safety of the drug. After conducting non-clinical trials, the applicant applies for an application to conduct clinical trials (Phases 1-4). Clinical studies are carried out to ensure efficacy and safety of the drugs and optimize the dosage of the drug in the human body. After completing clinical studies, the innovator applies for an application to market authorization of the drug and post market research to the relevant body for drug approval. An authorization body approves a drug if the drug is safe for human consumption and has desirable effects compared to adverse effects. However, regulations pertaining to drug approval differ from one state to the other.

## **Conclusion**

Pharmaceutical industry has existed for many years and contributes in national, regional, and global economic development. The industry process, manufacture, develops, and market pharmaceutical products and renders medical services. Normally, pharmaceutical companies are supposed to adhere to patent laws, regulations, and policies during their operations and ensure safety and efficacy of the drug. The industry records more than \$300 billion annually; with majority of multinational companies recording revenue of more than \$10 billion yearly. The leading multinational companies are located in America and Europe; with South and North America, Japan, and Germany ranked the leading countries in capital and spending. Globalization has promoted acquisition, merger, joint ventures, and co-marketing in the industry. Research and development is an important component in pharmaceutical industry because it promotes discovery of new drugs. The

government provides federal research grants and subsidizes in tax credit to help pharmaceutical industries conduct research and development. Drug approval process entails three key steps namely; an application to perform clinical trials, executing/conducting clinical trials, and application to market authorization of the drug and post-marketing researches.

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