Report on

Pharmaceutical Sector of Bangladesh: Prospects and Challenges

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EMBA Program
Semester: Spring 2014
Course Title: Management of Organization
Course ID: MGT 701

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Executive Summary

The pharmaceutical industry is one of the most technologically advanced sectors currently in existence in Bangladesh. It has grown in the last two decades at a considerable rate. The skills and knowledge of the professionals and innovative ideas of the people involved in this industry are the key factors for these developments. About 300 pharmaceutical companies are operating at the moment. Only 3% of the drugs are imported, the remaining 97% come from local companies. Positive developments in the pharmaceutical sector have enabled Bangladesh to export medicine to global markets. By overcoming the underlying obstacles this sector can develop more and can be an effective exporting sector of Bangladesh.

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Introduction

There are several sectors in Bangladesh on which we can be proud of and undoubtedly the pharmaceutical sector is one of these sectors. It is one of Bangladesh's success stories and one of the most technologically advanced sectors currently in existence. This industry is matter of substantial pride to the country. Skillful attitudes, knowledge and innovative ideas from the professionals are the key reasons why this industry grew in the way it did.

The success story of Bangladesh pharmaceutical sector is very pleasant. It had to travel a long way to achieve the present prestigious position in domestic and international markets. By now, 97% of country's demand of medicines is produced locally mainly by national pharmaceutical companies. The pharmaceutical sector of Bangladesh is expanding rapidly and some companies have already certified by different international regulatory authorities like UK-MHRA, Australia-TGA, EU, etc. for quality management and quality products manufacturing. Moreover, few companies are on the road to achieve US-FDA approval. According to the information of the Director General of Drug Administration of Bangladesh (DGDA), there are 263 Allopathic drug manufacturing companies in Bangladesh; 209 of which are functional, 29 companies are non-functional and 25 companies are suspended in status. Pharmaceutical export is contributing to the GDP of the country and every year this contribution is positively growing In the meantime, Pharma sector has become the 2nd largest potential sector in Bangladesh to earn foreign currency. At present, about 30 pharmaceutical companies have started their export activities.
Many smaller companies are on the verge of entering highly regulated overseas markets. Bearing in mind its successful past endeavors, the industry has the ability to establish itself in mass exportation.

In this report the current scenario of pharmaceutical industries of Bangladesh has been presented along with an analysis of its prospects and challenges.

Global Pharmaceutical Industries

The main aim of Pharmaceutical companies is to work for the betterment of heath and care of the individuals and they strive a lot to give their best. Their products not only comprises of drugs that help in curing diseases but also contains numerous nutritional supplements and with the means of trading these products are sent in all over the world.

Pharmaceutical Industries: The pharmaceutical industry develops, produces, and markets drugs or pharmaceuticals licensed for use as medications. Pharmaceutical companies are allowed to deal in generic or brand medications and medical devices. They are subject to a variety of laws and regulations regarding the patenting, testing and ensuring safety and efficacy and marketing of drugs. The pharmaceutical industry is comprised of companies that make, patent and sell drugs that have therapeutic effect. The majority of leading pharmaceutical companies also work in Consumer Health, Animal Health, Nutritional Products or Medical Devices / Diagnostics business segments

Generic Medicine: Generic means a medicine based on an active substance that is out of patent and which is marketed under a different name from that of the original branded medicine.

Global Pharmaceutical Market: The global pharmaceutical market is highly competitive and entry is difficult due to a combination of strict regulations and the need for extensive research and development, involving time-consuming clinical trials. In addition, high research and development costs, lengthy clinical trial processes, expiring patents and difficulty in gaining product approval from the appropriate regulatory bodies all mean that companies must produce blockbuster drugs and continue to do so to remain in good standing.

Spending on generic drugs is driving most of the growth in the leading emerging markets, which will contribute to the increase in the share of generic spending. Branded products accounted for nearly two-thirds of global pharmaceutical spending in 2011. However, as patents expire in developed markets, that share is expected to decline.
The growth is coming mainly from market expansion in the leading emerging countries and from generics.

Top Global Pharmaceutical Companies:

With the advent of modern technologies, innovative and latest methods are adopted for the production of best drugs and therefore pharmaceutical industry is also expanding day by day, with a great competition every company is struggling very hard to prove itself best. Here is the list of top 10 best pharmaceutical companies in 2014 that are renowned for their work in all over the world.

Top 10 best pharmaceutical companies in 2014:

i. Pfizer
ii. Novartis
iii. Hoffmann-La Roche
iv. Johnson & Johnson
v. Merck & Co
vi. GlaxoSmithKline
vii. Sanofi
viii. Eli Lilly
ix. AstraZeneca
x. Abbott Laboratories

Picture: Top two Global Pharmaceutical Companies

Highlights of Global Pharmaceutical Market:

- The global pharmaceutical market will reach nearly USD 1200 million by 2016.
- The revenues from generics in 2016 are expected to reach USD 400–430 billion, approximately 70% of which will be outside developed markets.
- Global generic spending is expected to increase from USD 242 billion to USD 400–430 billion by 2016, of which USD 224–244 billion of the increase is from low-cost generics in emerging markets.
- Global brand spending is forecast to increase from USD 596 billion in 2011 to USD 615–645 billion in 2016.
- In addition, the highest growth in this market is observed in Asia-Pacific.
- Leading emerging countries will account for 28% of global spending on pharmaceuticals by 2015, compared to 12% in 2005.
- Over the next five years growth rate for emerging markets - 15 % to 20%, for matured markets – 6% to 10%
- Blockbuster drugs ($150 billion) to lose patents between 2010 and 2017.
- Cardiovascular and CNS are the two largest market segments, constituting nearly 38% of the global generic pharmaceutical market together.
- However, therapeutic segments such as Respiratory, CNS and Oncology are likely to witness significantly high growth rates, attracting the attention of market participants.
- On the contrary, segments such as Diabetes and Genitourinary/ hormonal drugs are expected to decline by the 2017.

Research and Development

The research and development (R&D, also called research and technical development or research and technological development, RTD in Europe) is a specific group of activities within a business.

Models of R & D: The activities that are classified as R&D differ from company to company, but there are two primary models.

- In one model, the primary function of an R&D group is to develop new products
- In the other model, the primary function of an R&D group is to discover and create new knowledge about scientific and technological topics for the purpose of uncovering and enabling development of valuable new products, processes, and services.

Under both models, R&D differs from the vast majority of a company's activities which are intended to yield nearly immediate profit or immediate improvements in operations and involve little uncertainty as to the return on investment (ROI). The first model of R&D is generally staffed by engineers while the second model may be staffed with industrial scientists. R&D activities are carried out by corporate (businesses) or governmental entities.

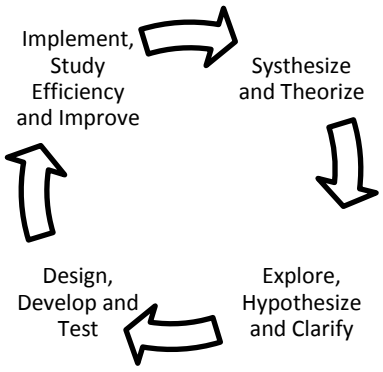

Figure: Cycle of Research and Development

Drug Discovery and Drug Development

Drug Discovery: Drug discovery is the process by which potential drugs are discovered or designed. In the past most drugs have been discovered either by isolating the active ingredient from traditional remedies or by serendipitous discovery. Modern biotechnology often focuses on understanding the metabolic pathways related to a disease state or pathogen, and manipulating these pathways using molecular biology or biochemistry. A great deal of early-stage drug discovery has traditionally been carried out by universities and research institutions.

Drug Development: Drug development refers to activities undertaken after a compound is identified as a potential drug in order to establish its suitability as a medication. Objectives of drug development are to determine appropriate formulation and dosing, as well as to establish safety. Research in these areas generally includes a combination of in vitro studies, in vivo studies, and clinical trials. The amount of capital required for late stage development has made it a historical strength of the larger pharmaceutical companies.

In pharmaceutical sector, multinational corporations are more concerned about research and development than locally owned companies. The implication is that MNCs will need to find ways to increase their R&D productivity, and it also means that Indian and Chinese firms with relatively novel approaches to product and process development may find opportunities opening up for them, whether through go-it-alone strategies or through co-operative R&D partnerships with MNCs.

Pharmaceutical's R&D team is committed to the development and introduction of novel drugs and drugs delivery systems that make them a frontrunner in the Pharmaceuticals industries. But budget for the research and development is not sufficient for appropriately doing this task. Research & Development are the main reasons for the progressive consolidation of our industry & fifteen years ago, the ten largest companies commanded 25% of the global market; today their market share is over 50% for concerning R & D. The R& D team comprises of highly qualified and trained technical personnel continuously striving for product and process innovation and up gradation.

Often, large multinational corporations exhibit vertical integration, participating in a broad range of drug discovery and development, manufacturing and quality control, marketing, sales, and distribution. Smaller organizations, on the other hand, often focus on a specific aspect such as discovering drug candidates or developing formulations. Often, collaborative agreements between research organizations and large pharmaceutical companies are formed to explore the potential of new drug substances. More recently, multi-nationals are increasingly relying on contract research organizations to manage drug development.

Picture: Drug Discovery

The sincere and relentless effort of the R& D team has taken the company a step further through introduction of high tech Anti-AIDS and Anti-cancer products in the recent years. A good number of APLs are also in the development pipeline to ensure availability of raw materials in the post WTO era. With their continuous investment in R&D and cutting –edge technology, Pharmaceutical is moving forward to meet tomorrow‘s healthcare needs.

Key Points Regarding Drug Discovery and Development:

- It takes 10–15 years to develop a medicine or vaccine.
- The research-based pharmaceutical industry currently spends over USD 135 billion on R&D per year.
- In 2011, 35 new pharmaceuticals were launched, out of more than 3,200 compounds in development.
- In 2007–2011, the number of new chemical or biological entities launched on the world market fell to 149 from 196 a decade earlier.
- It costs an average of USD 1.38 billion to develop a single drug.
- In 2011, 5 of the 10 leading global R&D firms were pharmaceutical companies
- By the time a medicinal product reaches the market, an average of 12-13 years will have elapsed since the first synthesis of the new active substance.
- The cost of researching and developing a new chemical or biological entity was estimated at €1,172 million ($ 1,506 million in year 2011 dollars) in 2012

- On average, only one to two of every 10,000 substances synthesized in laboratories will successfully pass all stages of development required to become a marketable medicine.

International Drug Regulatory Authorities

A regulatory agency is a public authority or government agency responsible for exercising autonomous authority over some area of human activity in a regulatory or supervisory capacity. An independent regulatory agency is a regulatory agency that is independent from other branches or arms of the government.

Regulatory agencies deal in the area of administrative law—regulation or rulemaking. The existence of independent regulatory agencies is justified by the complexity of certain regulatory and supervisory tasks that require expertise, the need for rapid implementation of public authority in certain sectors, and the drawbacks of political interference. Some independent regulatory agencies perform investigations or audits, and some are authorized to fine the relevant parties and order certain measures.

Regulatory agencies are usually a part of the executive branch of the government, or they have statutory authority to perform their functions with oversight from the legislative branch. Their actions are generally open to legal review. Regulatory authorities are commonly set up to enforce standards and safety, or to oversee use of public goods and regulate commerce.

Some International Drug Regulatory Authorities are:

- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- European Medicines Agency (EMEA)
- Therapeutic Goods Administration (Australia) (TGA)
- U.S. Food and Drug Administration (FDA)
- Medicines and Healthcare products Regulatory Agency (MHRA)

Pharmaceutical Industry of Bangladesh

The pharmaceutical industry in Bangladesh is one of the most developed hi-tech sectors within the country's economy. In 2000, there were 210 licensed allopathic drug-manufacturing units in the country, out of which only 173 were in active production; others were either closed down on their own or suspended by the licensing authority for drugs due to non-compliance to good manufacturing practices or drug laws. Now about 300 pharmaceutical companies are operating at the moment. The industry manufactured about 5,600 brands of medicines in different dosage forms. There were, however, 1,495 wholesale drug license holders and about 37,700 retail drug license holders in Bangladesh.

After the promulgation of Drug Control Ordinance - 1982, the development of this sector was accelerated. The professional knowledge, thoughts and innovative ideas of the pharmaceutical professionals working in this sector are the key factors for this development. Due to recent development of this sector, the industry is exporting medicines to global markets, including the European market. This sector is also providing 97% of the total medicine requirement of the local market. Some of the companies produce insulin, hormones, and anticancer drugs, which were not previously produced in Bangladesh. Leading pharmaceutical companies are expanding their business with the aim to expand into the export market. Recently, a few new industries have been established with high tech equipment and professionals to enhance the strength of this sector.

History

The pharmaceutical sector is one of the thrust sectors in Bangladesh. Before Liberation, there was hardly any pharmaceutical enterprise in Bangladesh (then East Pakistan). After several years of liberation, the government could not increase (in relative terms) budgetary allocations for the improvement of health sector. At that time, most of the people had little access to the essential lifesaving medicines. This sector started to improve from 1980s. The pharmaceutical industry has grown in the last two decades at a considerable rate.

Right after liberation war three fourth of the pharmaceutical industries was dominated by multinational companies. The National Drug Policy (NDP) in 1982 and 2005 has major impact in the development and growth of the Bangladesh pharmaceutical industry.

The need for NDP was very evident. Almost all the multinational companies were producing simple and non-essential drugs in Bangladesh like vitamins mixture or cough syrups. They used to import their raw materials from abroad at high prices.

There was a need for vast quantity of essential, useful and economic drugs in Bangladesh. It was essential and important for Bangladesh to introduce a drug policy for the betterment of national health by availing international standard medicine in lower cost to Bangladeshi people. Precisely, multinational companies were prevented to reduce their unessential drugs production and discouraged to import raw material at high process.

Key points of National Drug Policy of 1982:

- To provide administrative and legislative support for ensuring quality of essential drugs which are relevant to the national health need.
- To reduce the price of medicine by ensuring the lowest competitive price.
- To eliminate non-essential medicine from the market.
- To promote production of local drug and raw materials.
- To develop proper drug monitoring and information system to prevent wasteful misuse and to ensure the proper utilization of the drugs.
- To ensure GMP and qualified pharmacist in manufacturing companies.

As NDP 1982 implemented, most multinational companies sold their business to local pharmaceutical. This fueled to the evolution of the local pharmaceutical sectors. According to the Directorate General of Drug Administration (DGDA) website, the value of the locally produced drug was 175 crore in 1981 that increased to 325 crore by 1985.

Essential Drugs' List: Under the Drug (Control) Ordinance 1982, the Government determines Maximum Retail Prices (MRP) of 117 essential drug chemical substances. This price

determination is only for the local producer companies and still now the multinational organizations are determining their price by their own way.

The Bangladesh Association of Pharmaceutical Industries – BAPI: BAPI, (Bangladesh Aushad Shilpa Samity in Bengali), established in 1972 with just 33 members, has been playing a very vital role for development of this sector. Today, BAPI is a very strong organization having as many as 144 companies as its members.

Drug Regulatory Authorities in Bangladesh

A regulatory agency is a public authority or government agency responsible for exercising autonomous authority over some area of human activity in a regulatory or supervisory capacity. An independent regulatory agency is a regulatory agency that is independent from other branches or arms of the government. Two organizations regulate drugs and pharmacies in Bangladesh, one governmental and one semi-government, which are:

- The Directorate General of Drug Administration (DGDA)
- The Pharmacy Council of Bangladesh (PCB)

The Directorate General of Drug Administration (DGDA): DGDA is the drug regulatory authority of Bangladesh, which is under the Ministry of Health and Family Welfare. DGDA regulates all activities related to import and export of raw materials, packaging materials, production, sale, pricing, licensing, registration, etc. of all kinds of medicine including those of Ayurvedic, Unani, and Herbal and Homoeopathic systems.

The Pharmacy Council of Bangladesh (PCB): PCB was established under the Pharmacy Ordinance in 1976 to control pharmacy practice in Bangladesh.

The Bangladesh Pharmaceutical Society is affiliated with international organizations International Pharmaceutical Federation and Commonwealth Pharmaceutical Association. The National Drug Policy (2005) states that the WHO's current Good Manufacturing Practices (GMP) should be strictly followed and that manufacturing units will be regularly inspected by the DDA. Other key features of regulation are restrictions on imported drugs; a ban on the

production in Bangladesh of around 1,700 drugs which are considered non-essential or harmful; and strict price controls, affecting some 117 principal medicines.

Local Market Overview

The Bangladesh pharmaceutical marketplace is predominantly a branded generic marketplace. Pharmaceutical firms in Bangladesh can either sell to the private sector pharmacies, to the government and its public health care facilities, or to international organizations operating in Bangladesh (e.g. UNICEF).

Bangladesh pharmaceutical industry is mainly dominated by domestic manufacturers. Of the total pharmaceutical market of Bangladesh, the local companies are enjoying a market share reaching around 97%, while the MNCs are having a poor market share. Out of the top ten pharmaceutical companies in Bangladesh, all are local pharmaceutical companies. The top two domestic manufacturers, namely Square and Incepta Pharma are having a combined market share of more than 30% of the total pharmaceutical market of the country.

Bangladesh Association of Pharmaceutical Industries (BAPI) was instituted in 1972, since then BAPI playing a pivotal role in shaping up the industry. Association's member include large, medium, small, national and foreign companies who together are responsible for manufacturing 97% of the country's pharmaceutical production.

Here are the names of the pharmaceutical companies of Bangladesh:

- Square Pharmaceuticals
- Incepta Pharmaceuticals
- Beximco Pharmaceuticals
- Opsonin Pharma
- Renata
- Eskayef Bangladesh
- ACI
- Acme Pharmaceutical
- Aristopharma

- Drug International
- Sanofi-Aventis Bangladesh Ltd
- GlaxoSmithKline(GSK) Bangladesh Limited
- Orion Pharma Ltd
- Novo Nordisk
- Healthcare Pharmaceuticals Limited
- General Pharmaceuticals Ltd
- Sandoz (generic pharmaceuticals division of Novartis)
- Popular Pharmaceuticals Ltd. (PPL)
- Novartis (Bangladesh) Limited
- IBN SINA Pharmaceutical Industry Ltd. (IPI)
- Nuvista Pharma Limited
- UniMed UniHealth Pharma Ltd
- Sun Pharmaceutical (Bangladesh) Ltd
- Globe Pharmaceuticals Ltd
- BIOPHARMA Ltd
- Roche Bangladesh Ltd
- Radiant Pharmaceuticals Ltd
- Pacific Pharmaceuticals Ltd
- Jayson Pharmaceuticals Ltd
- BEACON Pharmaceutical Limited
- Social Marketing Company (SMC)
- Orion Infusion Ltd
- Kemiko Pharmaceuticals Ltd
- NAVANA Pharmaceuticals Ltd
- Delta Pharma Ltd
- Servier Bangladesh
- SOMATEC Pharmaceuticals Ltd
- Rangs Pharmaceuticals Ltd
- Libra Pharmaceuticals Ltd
- ALCO Pharma Ltd

- Apex Pharma Ltd
- Pharmadesh Laboratories Ltd
- Silva Pharmaceuticals Ltd
- Medimpex Bangladesh
- Edruc Limited
- Ziska Pharmaceuticals Ltd
- White Horse Pharmaceuticals
- RAK Pharmaceuticals Pvt. Ltd
- Asiatic Laboratories Ltd

Market Flashback: Year 2012

- Square Pharmaceuticals retained the top position with its local sales figure reaching Tk 10.70 billion in 2012 in the country's Tk 55.0 billion pharmaceutical market followed by Incepta Pharmaceuticals.
- Incepta Pharma, established in 1999, stood at Tk 4.52 billion in 2009. Beximco Pharma's position in the country's top 10 pharmaceutical companies was the third in terms of sales. Its total sales were Tk 4.2 billion in 2009.
- Fourth position took by the ACME Laboratories and its sales were Tk 2.64 billion in 2009.
- Opsonin Pharma Ltd., established in 1956, ranked the fifth by local sales worth Tk 2.61 billion in 2009.
- Eskayef took the sixth position with sales of worth Tk 2.52 billion. Reneta Pharma sales were nearly Tk 2.50 billion in 2009 and took the seventh position.
- Eighth position took by the Advance Chemical Industries (ACI) with local sales worth Tk 2.46 billion.
- The sales of Aristopharma products were Tk 2.23 billion and Drug Internationals were Tk 2.13 billion. Respectively they took the 9th and 10th position in the local pharmaceutical market.
- Sanofi-Aventis ranked the top among the multinational pharmaceutical companies followed by GlaxoSmithKline. Sandoz took the third position.

Growth of Bangladesh's Pharmaceutical Market, 2007–12 (according to BAPI):

Year	Growth (%)
2012	26.2
2011	23.6
2010	23.8
2009	16.8
2008	6.9
2007	15.8

Sales of Square Pharmaceuticals, the market leader, were Tk 1,270 crore in 2010,Beximco grew faster than other companies at a staggering 33 percent in 2010 with Tk 523 crore sales. Incepta's sales and growth rate were Tk 665 crore and 31 percent respectively, followed by Acme's Tk 600 crore and 17 percent. Eskayef logged Tk 426 crore in sales and the growth rate was 27 percent, the third highest pace in the 2010. Zenith Pharmaceuticals, established in 1952, Zenith Pharmaceuticals Ltd is one of the sturdiest growing Pharmaceutical Company committed to produce medicine strictly under GMP compliance and extended its services to all the valued Customers. The company complies with GMP at its plant, where validation and documentation ensures the position in accordance to international standard.

GDP: Gross domestic product (GDP) is the market value of all officially recognized final goods and services produced within a country in a year, or other given period of time. GDP per capita is often considered an indicator of a country's standard of living.

GDP and Healthcare Expenditure in Bangladesh, 2005–10

Year	GDP (US$ billion)	Total healthcare expenditure (US$ billion)
2005	60.3	1.9
2006	61.9	2.1
2007	68.4	2.4
2008	79.6	2.7
2009	89.4	3.0
2010	100.3	3.5
Source: World Bank World Development Indicators.		

The total expenditure on healthcare as a percentage of the GDP was only 3.35% in 2009, according to a World Bank report published in 2010. The General government expenditure on healthcare as a percentage of total government expenditure was only 7.9% as of 2009 and the citizens pay most of their health care bills as the out-of-pocket expenditure as a percentage of private expenditure on health is 96.5%

Current Market Review

In Bangladesh, pharmaceutical is now one of the fastest growing sectors. In 2013, the total size of the pharmaceutical market of Bangladesh was estimated to be approximate Tk. 101 Billion. With an annual growth rate of about 8.12 %, Bangladesh Pharmaceutical Industry is now self-sufficient in meeting the local demand. Bangladesh pharmaceutical industry is a contributor to the national exchequer, and it is the largest white-collar intensive employment sector of the country.

According to IMS Report of 4th quarter of 2013 the current local pharmaceutical market scenario of Bangladesh is as follows:

- **Total Market:** 101,685,403,612 BDT
- **Annual Growth:** 8.12%

Here is a view of top ten pharmaceutical companies of Bangladesh with their market share and growth:

Square Pharmaceuticals retained the top position with its local sales figure reaching Tk 19.72 billion in 2013 in the country's Tk 101 billion pharmaceutical market followed by Incepta Pharmaceuticals. Its total sales were Tk 10 billion in 2013. Beximco Pharma's position in the country's top 10 pharmaceutical companies was the third in terms of sales. Fourth position took by the Opsonin Pharma Ltd., established in 1956. Renata took the fifth position. Sanofi-Aventis ranked the second among the multinational pharmaceutical companies followed by GlaxoSmithKline.

In the following table there is a list of top ten pharmaceuticals of Bangladesh,

Table: Top Ten Pharmaceuticals

Si. No.	Name of the Company	Market Size (BDT)	Market Share (%)	Growth (%)
1	Square	19,722,066,693	19.4	12.55
2	Incepta Pharma	10,184,993,624	10.02	11.84
3	Beximco	8,967,999,031	8.82	8.04
4	Opsonin Pharma	5,302,711,389	5.21	4.77
5	Renata	5,056,968,911	4.97	8.75
6	Eskayef	4,547,963,290	4.47	4.28
7	Aristopharma	4,382,948,837	4.31	11.37
8	A.C.I.	4,263,630,198	4.19	8.69
9	Acme	3,954,249,448	3.89	5.76
10	Drug International	3,924,562,931	3.86	10.51

Here is a brief description of top three leading companies of the country:

Square Pharmaceuticals Ltd.: It is a public limited pharmaceutical company based in Bangladesh. It is part of the SQUARE Group of Companies. The company was founded in 1958 by Samson H. Chowdhury along with three of his friends as a private firm.

Picture: Square Pharmaceuticals Limited

It went public in 1991 and is currently listed on the Dhaka Stock Exchange. Square Pharmaceuticals Ltd., the flagship company, is holding the strong leadership position in the pharmaceutical industry of Bangladesh since 1985 and it has been continuously in the 1st position among all national and multinational companies since 1985. Square Pharmaceuticals Ltd. is now on its way to becoming a high performance global player.

Incepta Pharmaceuticals Limited: This is a pharmaceutical company based in Dhaka, Bangladesh, which manufactures and markets medicinal drugs in a variety of therapeutic classes. Incepta Pharmaceuticals Ltd. is one of the leading pharmaceutical companies in Bangladesh established in 1999. The company has a very big manufacturing facility located at Zirabo, Savar, 35 kilometer away from the center of the capital city Dhaka. Since its inception Incepta has been launching new and innovative products. The company produces various types of dosage forms which include tablets, capsules, oral liquids, ampoules, dry powder vials, powder for suspension, nasal sprays, eye drops, creams, ointments, lotions, gels, prefilled syringes, liquid filled hard gelatin capsules, lyophilized injections, human vaccine etc. Beyond the manufacture of medications, Incepta also conducts research and development in order to fulfill unmet demand of the medical community. The company sells its products in Bangladesh and also started to begin exporting to both developed and developing countries around the world.

Beximco Pharmaceuticals Ltd: Beximco Pharma, is a part of the Beximco Group of Companies. Beximco Pharma was founded in 1976 and started operations in 1980, manufacturing products under the licenses of Bayer AG of Germany and Upjohn Inc. of USA. It has now grown to become a leading pharmaceutical company in Bangladesh, and it supplies more than 10% of country's total medicinal needs. Today Beximco Pharma manufactures and

markets its own branded generics for several diseases including AIDS, cancer, asthma, hypertension, and diabetes for both national and international markets. Beximco Pharma manufacturing facilities are spread across a 20-acre (81,000 m^2) site located in Tongi, Bangladesh. The facilities consist of a number of purpose-built plants, including a new Oral Solid Dosage (OSD) plant. The site includes manufacturing facilities as well as a research laboratory and a number of warehouses. The plant and machinery of the facilities were designed, produced and installed by partners from Germany, Switzerland, Sweden, Italy and the United Kingdom, amongst others.

Top Drug Groups

Proton-pump inhibitors (**PPIs**): These are a group of drugs whose main action is a pronounced and long-lasting reduction of gastric acid production. They are the most potent inhibitors of acid secretion available. The group followed and has largely superseded another group of pharmaceuticals with similar effects, but a different mode of action, called H_2-receptor antagonists. These drugs are among the most widely sold drugs in Bangladesh, and are generally considered effective.

These drugs are used in the treatment of many conditions, such as:

- Dyspepsia
- Peptic ulcer disease
- Gastroesophageal reflux disease (GERD or GORD)
- Laryngopharyngeal reflux
- Barrett's esophagus
- Eosinophilic esophagitis
- Stress gastritis prevention
- Gastrinomas and other conditions that cause hypersecretion of acid
- Zollinger-Ellison syndrome (often 2-3x the regular dose is required as compared to the other indications)

Specialty professional organizations recommend that people take the lowest effective dose possible to achieve the desired therapeutic result when using proton pump inhibitors to treat gastro esophageal reflux disease long-term.

Antibiotics: An antibiotic is an agent that either kills or inhibits the growth of a microorganism. These include, for example, the beta-lactam antibiotics, which include the penicillins, the cephalosporins, and the carbapenems, aminoglycosides, sulfonamides, the quinolones, and the oxazolidinones.

These drugs are used in the treatment of many conditions, such as:

- Bacterial infection
- Protozoan infection, e.g., metronidazole is effective against several parasitics
- Immunomodulation, e.g., tetracycline, which is effective in periodontal inflammation, and dapsone, which is effective in autoimmune diseases such as oral mucous membrane pemphigoid

These are also used in prevention of infection, like

- Surgical wound
- Dental antibiotic prophylaxis
- Conditions of neutropenia, e.g. cancer-related

Antipyretics: These are drugs that reduce fever. Antipyretics cause the hypothalamus to override an interleukin-induced increase in temperature. The body then works to lower the temperature, resulting in a reduction in fever. Most antipyretic medications have other purposes. The most common antipyretic in Bangladesh is Paracetamol. Non-steroidal anti-inflammatory drugs (NSAIDs) are antipyretic, anti-inflammatory, and pain relievers.

Many medications have antipyretic effects and thus are useful for fever but not heat illness, including:

- NSAIDs such as ibuprofen, naproxen, ketoprofen, and nimesulide.
- Aspirin, and related salicylates like choline salicylate, magnesium salicylate, and sodium salicylate.
- Paracetamol

In Bangladesh there has been huge demand for PPIs, antibiotics and anti-pyretics. Thus these drugs comprise the top ten pharmaceutical products for the country. The recent IMS data exhibits the top ten medicines for Bangladeshi market.

The top ten pharmaceutical brands of Bangladesh are:

Table: Top Ten Brands (December, 2013; IMS)

Si. No.	Brand Name	Drug Class	Name of the Company	Growth (%)
1	Seclo	Proton Pump Inhibitor	Square	35.05
2	Losectil	Proton Pump Inhibitor	Eskayef	-6.43
3	Maxpro	Proton Pump Inhibitor	Renata	22.41
4	Pantonix	Proton Pump Inhibitor	Incepta	13.11
5	Cef-3	Antibiotic	Square	13.92
6	Napa	Anti-pyretic	Beximco	4.34
7	Neotack	Anti-ulcerant	Square	3.58
8	Napa Extra	Anti-pyretic	Beximco	12.04
9	Sergel		Health Care	28.73
10	Zimax	Antibiotic	Square	-4.22

Multinational Pharmaceuticals in Bangladesh

The multinational pharmaceutical companies are working in Bangladesh from a very long time. Nowadays there are still some companies operating here. Here is a table containing top five multinational pharmaceutical companies of Bangladesh.

Table: Top Five MNCs

Sl. No.	Name of The Company	Market Size	Market Share (%)	Growth (%)
1	Novo Nordisk	2,083,257,490	2.05	-5.85
2	Sanofi Aventis	2,032,579,187	2.00	-6.38
3	Glaxosmithkline (GSK)	1,694,068,206	1.67	4.43
4	Novartis	1,373,449,983	1.35	9.16
5	Roche	709,712,519	0.70	8.66

Novo Nordisk: Novo Nordisk manufactures and markets pharmaceutical products and services and was created in 1989 through a merger of two Danish companies dating back to the 1920s. It produces, in particular, diabetes care equipment and medications. Novo Nordisk is also involved with haemostasis management, growth hormone therapy and hormone replacement therapy. Company headquarters are in Denmark, with production facilities in seven countries, and affiliates or offices in 76 countries. It employed approximately 29,000 people globally as of Q4 2009, and marketed its products in 179 countries. It is the largest publicly traded company in the Nordic countries by market capitalization. In January 2012, Novo Nordisk was named as the most sustainable company in the world by the business magazine Corporate Knights.

The company makes several drugs under various brand names. Some of them are Levemir, NovoLog, Novolin R, NovoSeven, and Victoza. The Novo Nordisk logo since the year after the company's foundation has been the Apis bull, one of the sacred animals of ancient Egypt.

Sanofi: It is a French multinational pharmaceutical company headquartered in Paris, France, the world's fourth-largest by prescription sales. Sanofi engages in the research and development,

manufacturing and marketing of pharmaceutical products for sale principally in the prescription market, but the firm also develops over-the-counter medication. The company covers 7 major therapeutic areas: cardiovascular, central nervous system, diabetes, internal medicine, oncology, thrombosis and vaccines (it is the world's largest producer of the latter through its subsidiary Sanofi Pasteur). Sanofi is a full member of the European Federation of Pharmaceutical Industries and Associations (EFPIA). The company was formed as Sanofi-Aventis in 2004 by the merger of Aventis and Sanofi-Synthélabo. It changed its name to Sanofi in May 2011. In January 2012, Sanofi announced that they will invest $125 million in Warp Drive Bio to support their cancer research program.

GlaxoSmithKline plc (**GSK**): GSK is a British multinational pharmaceutical, biologics, vaccines and consumer healthcare company headquartered in Brentford, London. It is the world's fourth-largest pharmaceutical company after Pfizer, Novartis and Sanofi, measured by 2009 prescription drug sales. The company was established in 2000 by the merger of Glaxo Wellcome plc (formed from the acquisition of Wellcome plc by Glaxo plc) and SmithKline Beecham plc (formed from the merger of Beecham plc and SmithKline Beckman Corporation, which in turn was formed by combining the Smith Kline French and Beckman companies).

GSK has a portfolio of products for major disease areas such as asthma, cancer, virus control, infections, mental health, diabetes and digestive conditions. It also has a large consumer healthcare division that produces oral healthcare and nutritional products, drinks and over-the-counter medicines, including Sensodyne, Boost and Horlicks. Andrew Witty has been the chief executive officer since May 2008.

Marketing Strategy of Pharmaceuticals in Bangladesh

Marketing is the process by which companies create value for customers and build strong customer relationships in order to capture value from customer in return (Kotler, 2005). Marketing is the backbone of all industries. Though pharmaceuticals produce life saving drugs, they also need marketing. But their marketing is to some extent different from other industries. Some major characteristics of marketing sector are given below:

- Their distributional channel includes invoice system, own distribution channel.

- Medical representatives are the key persons in marketing.
- For promotion, the groups such as doctors, surgeons are targeted.
- Major promotional strategies include printed promotional materials, physical sample, and clinical materials.
- Special incentives are given to the doctors. For example, the doctors are given honeymoon packages, the cost of which is borne by the pharmaceuticals.

The field level executives are playing the imperative role for marketing division. Basically, they have taken the responsibility to market the products of their companies. So, the success of a pharmaceutical industry intensively depends on the efficiency and effectiveness of the medical representatives. If an organization wants efficient employees in this section, he should to satisfy this representative.

Customer Choice

Customer is a person who buys the products as well as consumes the products and consumer only consumes the products (Chowdhury, 2000). Pharmaceutical industries are dealing with life saving drugs; here customer choice does not change so rapidly. People may prefer one brand to another. But the medicine may carry the same compound/ same ingredients.

Customer choice depends on the customers' reliance upon the company. For example, Beximco's Napa, and Glaxo's Parapirol carry the same compound and used for the same purpose. But, the customer purchases one of them. Customers usually prefer some foreign medicine in case of sensitive problem. However, our local pharmacies do not produce all the sensitive drugs, especially injections. This research also conducted a small survey over the customer of medicinal product and their choices. The sample was taken from different hospitals and pharmacy that came to buy the products.

Customer's Choice of Brand Name:

Brand Name	Respondent (in %)
Square	38
Beximco	24
Incepta	16
Glaxo SmithKline	8
Acme	6
SK-F	4
Others	4

Source: Primary data collected by sample survey, 2010.

The above chart represents the scenario of customer choice toward the brand name. Most of the customers choose their medicine produced by square pharmaceuticals limited. According to the customer choice, no organization can play dominant role in the market.

Drug Distribution

Bangladesh's drug distribution marketplace is composed of small independent pharmacies. This structure combined with an under-regulated industry, few firms manufacturing pharmaceuticals, and companies competing to sell branded generics based on brand names provides ample opportunity for the sale of low-quality drugs at higher prices. And this partly explains why the quality of drugs available for sale varies significantly in Bangladesh.

A visit to four pharmacies in Dhaka and ten pharmacies in the bordering Gazipur, Narayanganj, Keranigonj and Manikgonj districts reveal that pharmacies sell from 200-22,000 types of medicines each. Each type of medicine has one to twenty five possible brands. Large pharmacies reported buying medicines according to sales trends – e.g. what sells the most. Medium and small pharmacies reported being linked with a medical doctor and thus sales are usually skewed towards that medical professional's preferences. Most pharmacies are individual shops, though some chains are starting to develop, especially in urban areas. On average, each pharmacy visited has 10-50 pharmaceutical firms that supply them medicines on a daily basis.

For example, Beximco Pharmaceuticals has 1,200 people visiting pharmacies daily to take orders for drugs. None of the pharmacies visited will keep restocking any medicine that they consider a slow item. Small pharmacies report of keeping a medicine for a maximum period of six months. Although there are approximately 300,000 private pharmacies in Bangladesh, the government has only 26,000 pharmacies officially listed. The rest are illegal pharmacies as they have no license / licensed pharmacist on staff. Pharmacists have varying levels of education and many lack adequate training. For example, while the four large urban pharmacies visited each had one professional pharmacist (with four years of coursework), two of the medium-sized pharmacies visited had one person trained for one year along untrained coworkers working as pharmacists. Rural pharmacists can have high school graduates with approximately two weeks training. The Bangladesh Pharmacist Society is currently implementing the first phase of a three-phased program to improve the skills of pharmacists. The three-phased program should be complete in seven to eight years.

While about 95% of the consumers in big pharmacies visited purchase medicines with a prescription, as few as 50% of people in medium and small pharmacies visited have a prescription. If people don't have a prescription, they either come in and ask for a specific drug or come in and describe their ailment to the pharmacist who then makes a diagnosis and recommends a drug on the spot. Popular products include antibiotics of various levels, pain-killers, and gastric remedies. People purchase one to ten tablets or capsules at a time. The amount purchased depends more on the financial capacity of the consumer than on the required dose of medicine.

There are several brands of each drug on the market with variable levels of quality. In the urban areas, the pharmacies visited tended to sell the higher quality brands whereas in more rural areas, the pharmacies visited tended to sell lower quality, lower cost brands. The political sway of the district also influenced the selection of brands as pharmacies tended to have brands associated with people who had power in that district. Medium and small pharmacies reported stocking cheaper drugs as the consumers cannot purchase expensive medicines. Pharmacies further away from the center of the city also had increasingly more ayurvedic and herbal medicines.

Drug Quality of Bangladesh

For generic pharmaceutical products, quality is defined as the generic drug having the same active ingredients as the original formulation and being bioequivalent to the brand name counterpart with respect to pharmacokinetic and pharmacodynamic properties (equivalent absorption rates, elimination rates, and other in vivo effects). By extension, therefore, generics are assumed to be identical to the original product in dose, strength, route of administration, safety, efficacy and intended use.

While some Bangladeshi pharmaceutical products on the market are of world-class standards, others are less so. Medical professionals and pharmacists interviewed voiced strong opinions on the quality levels of different brands. Although further comprehensive and systematic analysis is required to assess Bangladesh's pharmaceutical quality, some anecdotal reports exist of lower quality drugs.

- The International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR, B) tested the zinc content in 20 zinc-syrup formulations marketed in Bangladesh. The samples were purchased from local pharmacies in Dhaka. Only two of the tested products contained zinc concentrations within 5% of the stated content. The rest contained zinc, just not enough. The problem could have originated from either poor manufacturing or poor product handling in the distribution channel, because zinc degrades if exposed to light.
- Of eleven drugs UNICEF sent for testing to a laboratory in Australia, two had substandard results. When the manufacturers were informed, one company immediately stopped production until it found the problem—a very good response. The other company however, refused to address the problem, claiming that the test was in error. UNICEF sent the drug for a second testing to a lab in Denmark where the drug was also found substandard. The company still refused to address the issue.

Some Bangladeshi firms have invested in quality raw materials, manufacturing processes and environment, and technical know-how. However, a "perverse incentive" exists against upgrading due to the weak regulatory structure. Firms that have invested minimally in quality continue to sell drugs alongside those that have invested substantially. Because of weak regulations, the

consumer cannot determine quality differences and select for purchase the superior product. As a result, firms that have invested in quality manufacturing and quality processes are in a sense penalized.

Medicine Exporting Scenario of Bangladesh

Bangladesh Pharmaceutical Industry exports active pharmaceutical ingredients (APIs) and a wide range of pharmaceutical products covering all major therapeutic classes and dosage forms to 79 countries. Beside regular forms like; Tablets, Capsules & Syrups, Bangladesh is also exporting high-tech specialized products like HFA Inhalers, CFC Inhalers, Suppositories, Nasal Sprays, Injectables, IV Infusions, etc. are also being exported from Bangladesh, and have been well accepted by the Medical Practitioners, Chemists, Patients and the Regulatory Bodies of all the importing nations. The packaging and the presentation of the products of Bangladesh are comparable to any international standard and have been accepted by them.

By the late 1980s, Bangladesh had become a drug exporting country. Bangladeshi pharmaceutical exports totaled US$48.3million in FY 2011/12, only 0.2 percent of total export earnings. The bulk of export earnings owe to Novartis/Sandoz. Exports comprise only around 8 percent of the total production of the local

Pharmaceutical Exports from Bangladesh, FY 2005/06 to FY 2011/12

Fiscal year	Exports (US$ million)	Share of total exports (%)
2005/06	27.5	0.3
2006/07	28.2	0.2
2007/08	43	0.3
2008/09	46	0.3
2009/10	41	0.3
2010/11	44	0.2
2011/12	48	0.2

Exports of pharmaceuticals from Bangladesh are still small in scale. However, they are increasing rapidly – at a compound annual growth rate of 26.1 percent between 2002 and 2010. Most of the growth is coming from exports to middle income countries and to nearby low income countries (Myanmar, Afghanistan, Nepal). While exports to the EU reached almost 15m USD in 2007, they have fallen off since. In addition, a significant amount of Bangladesh's reported exports to the EU is for anti-Malaria drugs, the import of which is not confirmed by EU reported data. Most likely, this reflects purchases of European aid agencies destined for third countries. Most exports are to markets where pharmaceuticals are unregulated to medium regulated. Even relatively lightly regulated markets can be challenging to access, with significant delays to obtaining approval. For instance, industry stakeholders highlighted that getting market approval in Myanmar can take up to five years.

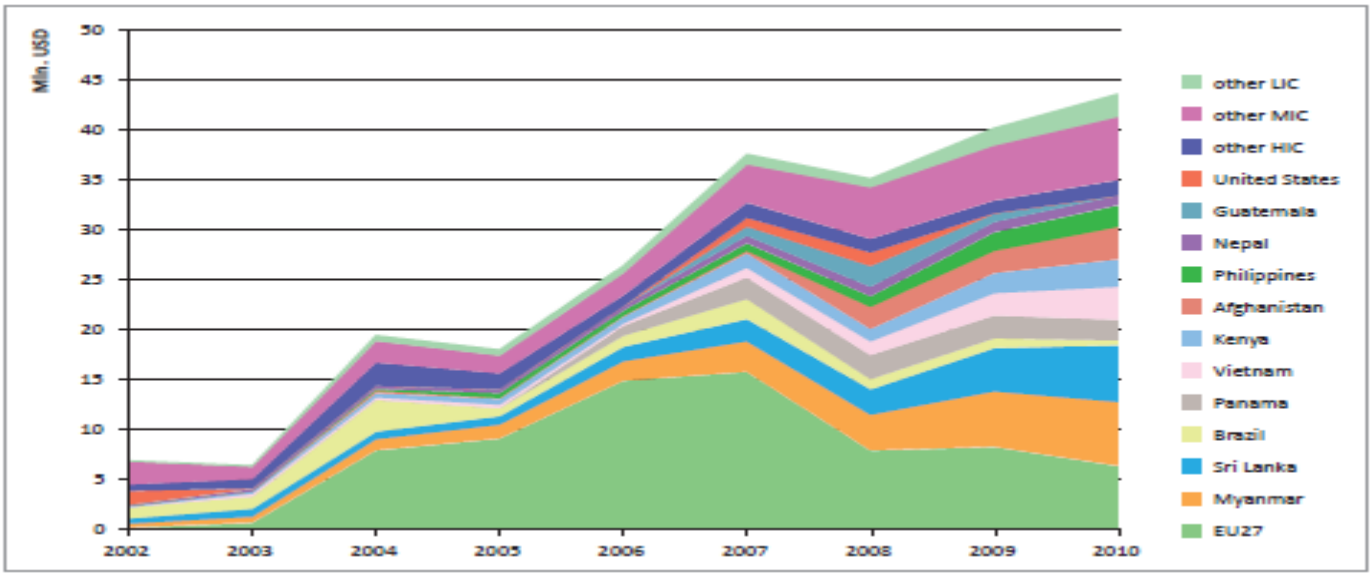

Figure: Bangladesh pharmaceutical exports, by destination, 2002-10 (in 1000 USD)

This pattern of exports reflects the low price positioning of Bangladesh's pharmaceutical exporters. Low prices are more important to prescribers and consumers in low and middle income countries than in high income countries. The lack of developed country regulatory approval for most of Bangladesh's pharmaceutical exports is a greater barrier to market access in high income regulated markets than in low income unregulated or lightly regulated markets.

Competition in global pharmaceutical markets is overwhelmingly dominated by exports from high income countries. However, if export markets are weighted by the significance they have for Bangladesh's exports, India, China, and other Middle Income Countries emerge as accounting for a substantially higher share. This reflects the fact that pharmaceutical exporters from these countries tend to target markets similar to those currently served by the industry in Bangladesh, with a similar market positioning based on low prices.

Rising competition and large scale exports (India: 6.1 bln USD, China: 4.5 bln. USD in 2010 (COMTRADE)) from these countries therefore poses a more significant threat to the industry in Bangladesh than competition from high income country producers. At the same time, the growth and transformation of the pharmaceutical industries in China and in particular India bears some interesting lessons for Bangladesh which will be discussed later in the report.

According to report from DGDA, in 2014 Medicine has been exported to the following countries by the following companies:

SL	Company Name	Country Name	Export Amount
1	ACI Limited	Albania	10,000.00
2	ACI Limited	Australia	80,000.00
3	Acme Laboratories Ltd.	Brazil	25,000.00
4	Acme Specialized Pharmaceuticals Ltd.	Afghanistan	1,515.00
5	Acme Specialized Pharmaceuticals Ltd.	Albania	1,546.00
6	Acme Specialized Pharmaceuticals Ltd.	Australia	5,025.00
7	Advent Pharma Ltd.	Afghanistan	150,000.00

The WTO and TRIPS

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the World Trade Organization (WTO) that sets down minimum standards for many forms of intellectual property (IP) regulation as applied to nationals of other WTO Members.

The TRIPS agreement introduced intellectual property law into the international trading system for the first time and remains the most comprehensive international agreement on intellectual property to date. In 2001, developing countries, concerned that developed countries were insisting on an overly narrow reading of TRIPS, initiated a round of talks that resulted in the Doha Declaration. The Doha declaration is a WTO statement that clarifies the scope of TRIPS, stating for example that TRIPS can and should be interpreted in light of the goal "to promote access to medicines for all."

Specifically, TRIPS requires WTO members to provide copyright rights, covering content producers including performers, producers of sound recordings and broadcasting organizations; geographical indications, including appellations of origin; industrial designs; integrated circuit layout-designs; patents; new plant varieties; trademarks; trade dress; and undisclosed or confidential information. TRIPS also specifies enforcement procedures, remedies, and dispute resolution procedures. Protection and enforcement of all intellectual property rights shall meet the objectives to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

According to the WTO's TRIPS (Trade Related Aspects on Intellectual Property), all signatory parties are bound to implement 20 year product patent protection for pharmaceutical products into their domestic legislation. TRIPS is not a uniform law, but a framework that sets minimum standards for intellectual property protection. Countries must then design legislation to meet its requirements, but there is still significant flexibility. Countries were given the following transition periods:

January 2000: By this date, all developing countries who had patent protection had to bring their patent law into compliance with TRIPS standards (Article 65.2). Countries who did not have patent protection in place had to create a "mailbox" to receive patent applications. During the mailbox period, the country must grant exclusive marketing rights for those products for where patents have been filed in the mailbox, marketing approval had been obtained in the country, and the said product had previously been patented in another country (Article 70.8 and 70.9). Thirteen countries notified the WTO of their use of this transition period, but a number of these countries implemented full TRIPS patent protection before the 2005 deadline. As of 2003, 6 members were still using the transition period – Cuba, Egypt, India, Pakistan, Qatar, and United Arab Emirates.

January 2005: As of this date, all WTO countries, except the 49 Least Developed Countries (LDCs), had to ensure that their national laws fully conformed to the provisions of the TRIPS Agreement. If a pharmaceutical firm did not file a patent for a product before January 1995, it would remain in the public domain. If a pharmaceutical product was involved in the mailbox program, the country must grant exclusive marketing rights until the application is processed or five years has elapsed, whichever comes first. Although a substantial change happened when the developing countries started to process the mailbox patents in January 2005, in effect, patent protection will phase in over time as new drugs are developed and replace older drugs. Slowly the market composition will migrate towards more and more patented drugs and fewer and fewer generic drugs.

January 2016: The 49 LDCs are not obliged to legislate product patent rights until 2016. Until then, LDCs can provide no patent protection at all, patent protection that is less than required by TRIPS or patent protection equal to or greater than TRIPS. Many LDC countries have implemented full TRIPS patent protection or expanded TRIPS-plus patent protection in advance of the 2016 deadline. Activists say this is due to pressure from multinational pharmaceutical companies or developed country governments while MNCs say that IP laws are individual to each country and may reflect other trade and policy priorities.

TRIPS significantly changed the international pharmaceutical world as, before the start of the TRIPS negotiations, more than 50 countries did not grant pharmaceutical product patent protection at all and some excluded process patents as well.

Many developing countries are challenged to implement TRIPS due to a lack of technical expertise to effectively implement TRIPS flexibilities; bilateral and other pressures not to use TRIPS and to adopt TRIPS-plus standards; difficulty in regulating anti-competitive practices; abuse of intellectual property rights; and difficulty in assessing pricing and patent status information. The US government spends approximately $1 billion to maintain its patent office, a sum few other countries can afford. Furthermore, much of the international assistance for TRIPS implementation has been focused on enforcing patent-holder rights instead of taking advantage of the flexibilities TRIPS offers.

TRIPS Implications for Bangladesh

TRIPS provide Bangladesh pharmaceutical firms with patent-free production rights domestically until 2016 and limited exporting advantage. Domestically, as long as Bangladesh has to import APIs however, they will have to buy these from firms which are compliant with TRIPS laws and hence will have to incorporate the higher royalty patent price for these.

TRIPS also allow Bangladesh to export drugs patent free. The advantages that TRIPS does offer is somewhat offset by the pace and ferociousness of the Indian and Chinese generic market, where companies can produce drugs, even including the patent costs, at an enormously competitive rate. An analysis of the potential export market under TRIPS, shown below, reveals that the opportunities are also limited. Until 2016, Bangladesh may:

Export to any country if the drug is not under patent. For example, most drugs on WHO's Model List of Essential Drugs are not patented as affordability is one of the criteria used in designating medicines as "essential."

Export to another LDC or non-WTO country that has not implemented product patent protection. However, today, virtually all the LDC WTO members provide TRIPS patent

protection. A 2001 IPR Commission study revealed that only 2 African LDCs had yet to provide for intellectual property protection, one of which is not yet a WTO member. In Asia, Myanmar – currently engaged in the WTO accession process – is perhaps the only country that has yet to put in place a patent protection regime.[i] Article 65.5 of TRIPS says that any country availing itself of a transitional period flexibility shall not change their laws to result in a lesser degree of consistency with TRIPS.

Export to a country where the patent holder has not filed for patent protection for this drug. As companies do not file patents in all countries, there are gaps in patent coverage that can be exploited. Companies tend not to file patents in countries where sales and profit prospects are low or where there is no meaningful judicial patent protection.

Be the first one to market when a patented drug goes off patent. As previously discussed, there is great profit potential for the first generic firm to get approval for a product. The Bolar Exception of TRIPS allows any country in the world to start working on a drug before patent expiry. Thus, Bangladesh's patent-free LDC status does not offer any competitive advantages in this arena and Bangladesh will have to compete head to head in this very fierce and competitive market.

Export to a country that has issued a compulsory license for the drug and awarded the production contract to Bangladesh. Article 31 of TRIPS grants governments the right to issue a compulsory license for public health purposes. A compulsory license is where the government overrides a patent and grants another entity the right to produce the patented product. The 6 December 2005 Decision gives countries who do not have adequate manufacturing capacity (and all LDCs are given this status) the right to import the drug for which it issues a compulsory license. Thirty three developed countries have declared they will not use this TRIPS flexibility to import and eleven countries announced they would not use it unless it was a national emergency.

Although Canada, Japan, the US, and the UK all have issued domestic compulsory licenses for pharmaceuticals, very few developing countries have. Potential reasons include legal battles with a developed country can be quite expensive and time-consuming; governments must

balance fully exploiting TRIPS flexibilities with upsetting MNCs, who often do business with domestic firms for outsourcing or manufacturing; and the US can apply Section 301 of the Trade Act to threaten retaliation with trade sanctions if they consider a country to have "non compliance with adequate standards of intellectual property."[ii] In a case being watched around the globe, Thailand issued a compulsory licenses for Merck's Efavirenz, an HIV/AIDS drug, in November 2006 and has since become a maelstrom of international pharmaceutical legal dispute. Pre-2005, there were many countries which could fulfill a compulsory license exporting request as many countries were manufacturing patented drugs off-patent.

As of 2005, Bangladesh will be one of the few places in the world where firms are legally producing patented drugs off-patent. As of 2005, India and China, the world's largest suppliers of generic drugs, will no longer be able to engage in this process for any drug patented after 2005. Considering that firms require two to three years to reverse engineer and start producing a specific drug in a quality manner, this means that when a compulsory license is issued for any drug patented after 2005, Bangladesh will have an enormous head start. However, TRIPS has clearly stated that export for compulsory licensing is intended for health policy, not industrial policy.

Therefore, TRIPS flexibilities offer some domestic advantages and limited export potential. In the long term, Bangladesh will have to rely on standard business practices of producing the highest quality product at the lowest price to compete on the international market.

Bangladesh Patent Law

Bangladesh's patent law is based on the Patent and Designs Act of 1911 and the Patents and Designs Rules of 1933. The law grants both process and product patent rights for pharmaceutical products. They have issued approximately 40 drug formula patents. The Patent office issues approximately 300 patents per year, 90% of which are held by MNCs.

The patent law in Bangladesh is not consistent with the TRIPs in many ways. The most basic of these is that Bangladesh does not have to enact patent legislation of any kind until 2016. The Department of Patent, Designs and Trademarks within the Ministry of Industries is preparing a

Draft Patent Act 2006. This draft law, prepared with the assistance of World Intellectual Property Organization (WIPO) excludes pharmaceutical patents, and includes the Bolar. Provision and parallel importation. The current 1911 law already provided for compulsory licenses but the flexibility has never been used.

A recent Dutch study of the patent law situation concluded that the current draft law still needs work. The study also concluded that the draft law is not likely to be passed by the current Caretaker government in the foreseeable future. Thus, the study recommends implementing a small piece of legislation that just declares TRIPS to be applicable in Bangladesh.

Pharmaceutical Export of Bangladesh After 2016

As a member country of LDC, Bangladesh is enjoying waiver from patent law enforcement which will continue up to 2016. By virtue of this opportunity, our companies can manufacture patented drugs without giving any payment for patent right, thus it is now possible for us to produce any patented drugs at very low price and can export to other countries. For this reason, a Bangladeshi company would offer export price to an LDC much lower than could do a company from India, China or other countries where patent right implemented. In this sense, Bangladesh is passing a golden time for export of patented drugs in other LDCs.

Yet, our export price is not as lower as it would be compared to India and China, because we are not yet independent to our raw materials and other materials required for the production of a finished medicine. Still, we have to import more than 95% of active ingredients and excipients of medicines. This is still a great drawback for the achievement of our pharmaceutical export. If patent right is enforced in Bangladesh after 2016, the production cost of medicines will remarkably be increased, thus it would not be possible for us to compete with the offer price of India and China, thus our export market drastically will be reduced, because the pharma market in LDCs will be opened for all and we will have toface great challenges for our existence in global market. But fortunately, if the patent waiver is extended for another 10 years, we can really enjoy the taste of patent exemption at thattime because our pharma sector will be almost self-reliable within that period.

Challenges and Recommendations for Exporting Pharmaceutical Products

Policies related to pharmaceutical sectors need to be in the right direction to keep on encouraging this potential sector. The challenges hardening the way are ought to be identified and necessary initiatives should be taken to help the sector emerge as a very thriving one tapping the vast international market and earning bounties in foreign currencies.

Here is a description regarding the challenges in exporting of pharmaceutical products:

API/Raw Material Production Plant: The major advancement of Bangladesh pharmaceutical sector has been occurred only in the production of finished products. Manufacturing of pharmaceutical products are vastly dependent on imported raw materials, as almost 90% of raw materials are now being imported. This dependency on imported raw materials is resulting in increased production cost of the finished products. Ultimately the competition to offer export prize is becoming tougher, which is one of the major challenges of pharmaceutical sector of Bangladesh. Setting up of a standardized Active Pharmaceutical Ingredient (API) plant is very essential. Local production of raw materials will greatly contribute to pharmaceutical export to extend export volume, and also can potentially contribute to the country's economy.

Some APIs are now produced within the country, and the range is increasing. The government and industry are jointly planning the development of an "API Park" at Bausia, about 40km from Dhaka, to concentrate API process development and production in a single location. Services and infrastructure (such as an incinerator and an effluent treatment plant), can be shared. Approximately 40 pharmaceutical businesses are likely to establish API production in the Park. There were hopes that the API Park can become operational in 2012.

API Park

Name of the project: API (Active Pharmaceutical Ingredient) Industrial Park Project

Project Implementation Period: January 2008 to December 2012

Location of the project: Bausai, Upazila-Gazaria, Dist: Munshigonj (37 Kms. aways from Dhaka by Dhaka-Chittaging highway)

Estimated cost of the project: Gob 23350.00 lac

Enterepreneurs equity 2500.00 lac

Total: 25850.00 lac ADP (2011-12) Taka 5200.00 Lac

Objectives of the project:

- To establish an environmentally suitable industrial park to produce Active Pharmaceutical Ingredients.
- To attain self-sufficiency in producing Active Pharmaceutical Ingredients, import substitution and saving foreign currency.
- To create employment through industrialization

Bioequivalence Test Facility: Bioequivalence study of a product is a must for the registration of that product in many of the moderately regulated and regulated countries of the world. There is no standard facility for bioequivalence study in Bangladesh. In order to register a product, a pharmaceutical company has to carry out this test in foreign country by spending of a huge charge. For this reason, many pharmaceutical manufacturers don't show interest to register their products in foreign countries that require Bioequivalence study. It is relevant here to mention that BAPI and pharmaceutical exporters first felt the necessity of having Bioequivalence test facility in our country and they proposed and demanded to set up a modern Bioequivalence test center to the govt. for the promotion of pharmaceutical export.

Modern Drug Testing Laboratory: A major limitation of drug control authority of Bangladesh that also affects pharmaceutical export is unavailability of a modern, well equipped drug testing laboratory (DTL) with the engagement of sufficient and skilled pharmaceutical scientists. Due to lack of this, our drug control authority cannot monitor the quality of drugs manufactured by different pharmaceutical companies in Bangladesh. Moreover, foreign buyers and regulatory authorities raise question about the status of our drug testing laboratory, the central quality monitoring facilities of drug authority of Bangladesh.

Custom Harassment in Sending Drug Sample: Considerable hazards or bureaucratic obstacles are confronted by the local pharmaceutical companies in sending samples abroad, to station or

appoint representatives in foreign countries, in sending money for the purpose and doing other promotional activities. The customs authority of Bangladesh imposes restrictions in sending drug samples to the importing countries. Restrictions are being made on giving permission to send drug samples and also limiting the quantity of samples to be sent.

The regulatory authorities of Bangladesh: The documents provided by the Drug Administration of Bangladesh are not impressive; represent the poor status of drug regulatory authority of Bangladesh to the business community and to the regulatory authorities of importing countries. Besides, the website of DGDA is still lacking lot of necessary and up to date information, required and inspected by the business partners and regulatory authorities of importing countries.

Regulated Markets: To register pharmaceutical products in regulated markets it requires highly standardized documents. There are regulations directed by the regulatory authorities of United States of America, European Union, Australia and Japan along with other highly regulated and semi regulated countries. To meet all their requirements sophisticated and accredited manufacturing plant, standardized manufacturing process, proper quality control and above all highly skilled professionals are required. It is tough to meet all the requirements by small pharmaceutical companies of Bangladesh.

Medicine export should be emphasized to LDCs than any other countries: Some companies are aggressive to enter the highly regulated overseas markets, such as, USA, Australia, Europe, Canada, France, and Golf countries. But the practical observation is that getting export status to those countries requires huge investment in the manufacturing plant to achieve certification from different international drug regulatory authorities, highly sophisticated documentation, and huge initial capital investment. Actually the export volume to the highly regulated countries will not be easily feasible; rather we can perform pretty well and can potentially increase our export if the exporters become more attentive to LDCs. Among 50 LDCs, only Bangladesh has its strong fundamental and modern manufacturing base, hence we can easily share the drug market of rest of the LDCs. So, considering the practical situation, the LDCs should be the targeted markets of our pharmaceuticals, of course, side by side, moderately regulated and highly regulated

markets may be explored gradually. However, we can establish joint-venture, tool manufacturing, and contract- manufacturing business with the companies of developed countries, not only for exporting medicines.

Establishing Export cell by the govt./private Consultancy firms may promote Pharma export: Government can establish specialized Export Cell to promote exports of pharmaceuticals to grab and capitalize the huge export opportunities in LDCs. Some private Consultancy firms having experience and expertise in drug export professionally can be engaged to assist the pharmaceutical companies who do not have the technical and expertise know-how to go through the entire process of export, or have lacking in documentation skills or even do not have the skilled man power to deal with the drug export. Thus, Consultancy firms can play a significant role to explore export to maximum countries, accelerate export activities, and to reduce the overall cost of export. Even some small companies having International Marketing Department (IMD) can explore the benefits of outsourcing by hiring Export Consultants to reduce its overhead expenditure and make a comparative study of cost-benefit ration to justify having IMD.

Important Departments of Management of Pharmaceuticals

Human Resources:

Human resources are people recruited in the organization and treated as the prime mover and an important element for success of any organization (DeCenzo & Robbins, 2005). The sector consistently creates job opportunities, especially for highly qualified people. Pharmaceutical companies are either directly or indirectly contributing largely towards raising the standard of healthcare and standard of living by enabling local healthcare personnel to gain access to newer products and also to latest drug information.

Like other industries, pharmaceutical industry also believes that the human resources are most valuable asset for the organization. Pharmaceutical industry is making considerable investments in attracting and developing competent professional human resources. Pharmaceuticals not only foster entrepreneurship, but also consciously encourage entrepreneurship in their organizational

environment. This leads to innovation and creativity transformed into new products, services and new ways of doing things. To get most effort strom human resources, pharmaceutical industries implement programs like decentralization, job enrichment and job rotation. The extent of empowerment enjoyed by people at various levels of the organization enables each employee from the very bottom to the top, to contribute to the overall momentum of the companies.

Data from the Labor Force Survey of 2005/6 showed employment of 64,000 in the pharmaceutical sector of Bangladesh, of whom 3,000 were female. There has been strong growth in employment, driven mainly by growing domestic market sales, but also by significant growth in exports.

Training and Development:

Training refers to instruction provided for a current job and has a rather narrow focus and should provide skills that will benefit the organization rather quickly. Development, on the other hand, has a broader scope and may not be focused on either the present or future job but more on the organization's general long-term needs (Anthony et al, 2003). Pharmaceutical industries are continuously striving to explore the necessary competences of the employees, especially the marketing executives to face the challenges of the competitive environment. They arrange different types of learning programs which are enforcing as a motivation too to upgrade necessary knowledge and skills of their employees. By interviewing the employees of different pharmaceuticals the researcher comes to know that they participated in various training programs that include: Pharmaceutical marketing situation beyond 2005, Company formation, regulatory compliance and company meeting, Industrial control and mechatronics, Continuous improvement and changing behavior, Presentation skills, General guidelines of Standard Operating Procedure (SOP), Sanitation, hygiene and environment control, Maintenance of equipments, calibration and validation, Industrial automation, etc.

Conclusion

The pharmaceutical sector has already been declared as the thrust sector by the government of Bangladesh. Bangladesh has built a strong baseline and going towards the self-sufficiency for the production of medicine. Meanwhile, some companies have started to produce vaccine, insulin, anticancer drugs, etc. Our pharmaceutical industries are successful in domestic market. Now, it's the time to grow our international market because we passing golden time getting the opportunity of patent exemption by the TRIPS until 2016. Besides the above discussing points, providing cash incentive by the govt. to the medicine exporters, like RMG may encourage pharmaceutical exporters. International fair arrangement by Export Promotion Bureau (EPB) is a very effective way to search buyers and to establish business in a new country. A lot of initiative have been taken by BAPI in different times, such as, high level pharmaceuticals delegation team visited foreign countries to explore export initiated by BAPI. This organization also upheld the demand and urged to the government and other concerning authorities for API Park, Bioequivalence test laboratory, Central drug testing laboratory, cash incentives, problems in remit transfer and sample sending etc. But many issues are yet to resolve. We have already wasted our valuable time and still losing to build our infrastructure for export. We should complete our infrastructure as soon as possible because TRIPs patent protection may be adopted to us after 2016. The government should really be attentive to remove all the obstacles and solve all the problems to see pharmaceutical sector as a vital player in international market.

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