GROWTH OF PHARMACEUTICAL COMPANY IN BANGLADESH.



This report presented in partial fulfillment of the requirements for the degree of Bachelor of Pharmacy

Submitted By

Md. Muyeen Nadin
ID: 111-29-294
Batch: 5th; Section: B
Department of Pharmacy
Daffodil International University

Supervised by

Md. Al-Faruk
Senior Lecturer
Dept. of pharmacy
Faculty of Allied Health Science
Daffodil International University

FACULTY OF ALLIED HEALTH SCIENCE DAFFODIL INTERNATIONAL UNIVERSITY DHAKA, BANGLADESH May 2015

APPROVAL

This Project, growth of pharmaceutical company in Bangladesh submitted by 111-29-294 to the Department of Pharmacy, Daffodil International University, has been accepted as satisfactory for the partial fulfillment of the requirements for the degree of Bachelor of Pharmacy and approved as to its style and contents.

BOARD OF EXAMINERS

Md. Arifur Rahman Assistant Professor and Head Department of Pharmacy Faculty of Allied Health Science DaffodilI International University

Internal Examiner-1

Internal Examiner-2

External Examiner

ii

DECLARATION

I hereby declare that, this project report is done by me under the supervision of Md.AL-Faruk,

Sr.Lecturer Department of Pharmacy, Daffodil International University, in partial fulfillment of the

requirements for the degree of Bachelor of Pharmacy. I am declaring that this Project is my original

work. I also declare that neither this project nor any part thereof has been submitted elsewhere for

the award of Bachelor or any degree.

Supervised By

MD.AL-FARUK

Senior Lecturer, Department of Pharmacy

Faculty of Allied Health Science

Daffodil International University

Submitted By

Md. Muyeen Nadim

ID: 111-29-294

Department of Pharmacy

Daffodil International University

Acknowledgement

All praise is for almighty Allah and also my parents who has given me ability to complete my B.Pharm project work and the opportunity to study in this subject.

I am proud fully indebted to Md.AL-Faruk Sr. Lecturer, Department of Pharmacy, Daffodil International University, for his ingenious supervision, valuable criticism, active encouragement, cordial operating along with unique direction of every Day work. I wish to convey my thanks and heartiest regard to him for providing important data and extended cooperation.

I feel proud to express my heartiest gratitude to my reverend teacher Assistant Professor, Md. Arifur Rahman, Head, Department of Pharmacy, Daffodil International University, for his mastermind direction, dexterous management, adept analysis, keen interest, optimistic counseling and unremitting backup.

I wish to convey my thanks and heartiest regard to Professor, Dr. Md. Selim Reza, Advisor, Department of Pharmacy, Daffodil International University.

It is also great pleasure for me to offer my indebtedness to all my respected teacher of Department of Pharmacy, Daffodil International University for extending their helping hands and affectionate attitude whenever I needed.

I would like extend my thanks to the office staff of Department of Pharmacy, Daffodil International University.

Cordial thanks to my family and friend and to all well wisher for their wholehearted inspiration and open-ended support throughout the period of the project of the research work.

Dedicated to.... My beloved parents and my supervisor Md. Al-Faruk.

Abstract

Pharmaceutical is the core of Bangladesh's Healthcare sector, and serves as one of the most important manufacturing industry. With a history since 1950s, the industry has now turned one of the most successful pharmaceuticals manufacturing industry among the developing countries. Presently, the industry meets 97% of local demand and exports to more than 80 countries. The industry has been experiencing robust growth over the last few years. A local industry supporting drug policy and effective regulatory framework, along with TRIPS relaxations are the key reasons for success of the industry. While the industry is achieving self-sufficiency, it yet procures 70% of raw materials from abroad. But developments are already taking place, with a number of firms now manufacturing raw materials locally. In addition, an API project has already been undertaken to accelerate the vertical integration within the industry. The industry has been expanding locally and internationally. Local market grew at 23% in 2010, while import reached USD 50 Million landmark. A number of firms got accreditations from USA, UK, Australia etc. developed markets, and are underway toward expansion into the developed markets. Locally, firms are preparing themselves for post 2016 scenario, when TRIPS will be implemented. Almost all the firms are upgrading their facilities and taking up precautions for post 2016 scenario, while aggressively expanding in both local and export markets. While TRIPS and import dependence on raw materials put challenges to the growing sector, prospect of the sector depends largely on the interactions among the players, regulatory bodies and the govt., whether they can meet up the requisites to continue growth of the sector while facing the challenge.

Table of contents

| Content Page No. |
|--|
| Chapter-1 |
| 1.1 Introduction02 |
| 1.2 Pharmaceutical companies in Bangladesh02 |
| 1.3 Growth of pharmaceutical company in Bangladesh02 |
| 1.4 Top 10 Pharmaceutical Company in Bangladesh 201503 |
| 1.5 Top listed pharmaceutical companies03 |
| 1.6 Growth potential of the domestic drug market10 |
| 1.7 Market Share Concentration |
| CHAPTER-2 |
| 2.1 Drug Regulatory Authorities in Bangladesh15 |
| 2.2 Key points of National Drug Policy of 198215 |
| 2.3 The Bangladesh Association of Pharmaceutical Industries – BAPI16 |
| 2.4 Control of Price |
| 2.5 Situation of Bangladesh Pharmaceutical Industry and Regulation16 |
| 2.6 Situation of Bangladesh Patent law and Pharmaceutical patent16 |
| 2.7 Analysis of pharmaceutical industry in Bangladesh17 |
| CHAPTER-3 |
| 3.1 Investment analysis of pharmaceutical industry in bangladesh20 |
| 3.2 Current Scenario of Bangladesh Pharma market |

| 3.3 Bangladesh Patent Law | 21 |
|--|----|
| 3.4 Business analysis of pharmaceutical firms in Bangladesh | 22 |
| 3.5 Literature review. | 22 |
| 3.6: Objective of the study | 23 |
| 3.7 Methodology of the study | 23 |
| CHAPTER-4 | |
| 4.1Discussions | 25 |
| 4.2 Foreign Competitions | 30 |
| 4.3 Research and Development | 31 |
| 4.4 Problems and Prospects | 32 |
| 4.5 Government incentive for supply of raw materials | 34 |
| 4.6 Export Policy of Bangladesh | 38 |
| 4.7 Implementation Strategy | 39 |
| 4.8 Application and Scope | 40 |
| 4.9 Challenges and Recommendations for Exporting Pharmaceutical Products | 40 |
| 4.10 Export channels | 42 |
| 4.11 Product specification, quality and output | 44 |
| 4.12 Import of pharmaceuticals | 45 |
| CHAPTER-5 | |
| Conclusion | 50 |
| CHAPTER-6 References | 52 |

CHAPTER-1

1.1Introduction

The pharmaceutical market in Bangladesh remains tiny compared to the population size because of the lack of spending power of the population. Pharmaceutical spending is also amongst the lowest in the world in per capita terms. Healthcare expenditures consist of only 3.4% of GDP. However, the increased awareness of healthcare and the government's increased expenditure in this sector is causing the demand to increase in this sector. In addition to the demand of therapeutic drugs, the demand for "wellness" drugs such as vitamins and minerals are increasing gradually and the future growth of the sector lies in it. Surprisingly, the pharmaceutical sector, which is widely regarded as a "hi-tech" industry, is the most developed among the manufacturing industries in Bangladesh. Roughly 250 companies are operating in the market. According to IMS, a US-based market research firm, the retail market size is estimated to be around BDT 55 billion, which grew by 16.8% in 2009. The market size in 2008 was BDT 47 billion with a growth of 6.9%. The actual size of the market may vary slightly since IMS does not include the rural market in their survey. However, the deviation is estimated to be not more than 5-10% in either direction. Unfortunately, there is no solid information source in Bangladesh other than IMS. The retail market is about 90% of the total market. In that respect, the total market size is more than BDT 60 billion.

1.2 Pharmaceutical companies in Bangladesh

In Bangladesh Pharmaceutical sector is one of the most developed hi tech sector which is contributing in the country's economy. After the promulgation of Drug Control Ordinance - 1982, the development of this sector was accelerated. The professional knowledge, thoughts and innovative ideas of the pharmacists working in this sector are the key factors for this developments. Due to recent development of this sector we are exporting medicines to global market including European market. This sector is also providing 95% of the total medicine requirement of the local market. Leading Pharmaceutical Companies are expanding their business with the aim to expand export market. Recently few new industries have been established with hi tech equipments and professionals which will enhance the strength of this sector.

1.3 Growth of pharmaceutical company in 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.

1.4 Top 10 Pharmaceutical Company in Bangladesh 2015

- BEXIMCO
- SQUARE
- INCEPTA PHARMA
- OPSONIN PHARMA
- RENATA
- ESKAYEF
- ACME
- ACI
- ARISTOPHARMA
- SANOFI AVENTIS

1.5 Top listed pharmaceutical companies

Beximco Pharmaceuticals

Beximco Pharmaceuticals Ltd (BPL) also known as Beximco Pharma, is a pharmaceutical company in Bangladesh. It is part of the Beximco Group of Companies. Beximco Pharmaceuticals Ltd. is a leading manufacturer of pharmaceutical formulations and Active Pharmaceutical Ingredients (APIs) in Bangladesh. It is the flagship company of Beximco Group, the largest private sector industrial conglomerate in Bangladesh. Beximco Pharma's state-of-the-art manufacturing facilities are certified by global regulatory bodies of Australia, European Union, Gulf nations, Brazil, among others. The company is consistently building upon its portfolio and currently producing more than 500 products in different dosage forms covering broader therapeutic categories which include antibiotics, gastro-intestinals, respiratory, analgesics, cardiovascular, anti-diabetics, etc, among many others.

- 2 Manufacturing Capabilities
- 2.1 Oral Solid Dosage
- 2.2 Metered Dose Inhaler
- 2.3 Ophthalmic

2.4 Intravenous Fluid

2.5 Liquid and Semisolid.

| | 2009A | 2010E | 2011E |
|--------------------------------|--------|-------|-------|
| Revenue (MM BDT) | 4868 | 5951 | 7205 |
| Operating Income(MM BDT) | 1001 | 1224 | 1482 |
| Operating Margin | 21% | 21% | 21% |
| Net Income (MM BDT) | 625 | 764 | 925 |
| NET Margin | 13% | 13% | 13% |
| 5 Year Revenue Growth(CAGR) | 15% | | |
| Capex (MM BDT) | 1332 | 486 | 460 |
| Debt/Equity | 34% | 29% | 24% |
| No. of Shares(MM) | 151.1% | 209.8 | 209.8 |
| Diluted EPS (BDT) | 2.98 | 3.64 | 4.41 |
| Dividend(BDT) | 0.00 | 1.10 | 1.20 |
| Current Price (BDT) | 146 | | |
| Target | 175 | | |

| price(BDT) | | |
|------------|-----|--|
| Return | 20% | |

Square Pharmaceuticals

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. 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 .Square Pharmaceuticals Ltd. is now on its way to becoming a high performance global player.

| | 2009A | 2010E | 2011E | 2012E | 2013E |
|--------------------------------|--------|--------|--------|--------|--------|
| Revenue(MM BDT) | 11826 | 13026 | 15099 | 17287 | 22003 |
| Operating Income(MM BDT) | 2929 | 3149 | 3537 | 3945 | 4960 |
| Operating Margin | 25% | 24% | 23% | 23% | 23% |
| Net Income (MM BDT) | 2116 | 2644 | 3306 | 4132 | 5165 |
| Net Margin | 18% | 17% | 16% | 16% | 16% |
| 5 Year Revenue Growth (CAGR) | 13% | | | | |
| Capex(MM BDT) | 2049 | 1386 | 1398 | 1426 | 1451 |
| Debt/Equity | 23% | 20% | 18% | 16% | 14% |
| No. of Shares(MM) | 12.1 | 15.1 | 15.1 | 15.1 | 15.1 |
| Dilutes EPS(BDT) | 140.19 | 175.24 | 219.05 | 273.82 | 342.27 |
| Dividend(BDT) | 40.00 | 50.00 | 60.00 | 70.00 | 80.00 |
| Current price(BDT) | 3722 | | | | |
| Target Price(BDT) | 7000 | | | | |
| CAGR Return(Up to end of 2013) | 23% | | | | |

Figure: Square Pharmaceutical snapshot

Incepta Pharmaceuticals

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 aware 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.

Opsonin pharma

Opsonin Pharma Limited is a pharmaceutical company in Bangladesh which was established in 1956. As per the IMS Health(Intercontinental Marketing Services, Health) report, Opsonin Pharma Limited is the 4th largest pharmaceutical company in Bangladesh in-terms of sales. As per the data of 4P Marketing Consultancy, Bangladesh Opsonin Pharma Limited holds the second position among all the pharmaceutical companies in Bangladesh in terms of prescription.

Products

- 1. Abdorin (Dicycloverine)
- 2. Acerux (Acyclovir)
- 3. Advel (Ibuprofen)
- 4. Algisum (Potassium Bicarbonate +Sodium Alginate)
- 5. Almitan (Almotriptan)
- 6. Alprax (Alprazolam).

Renata pharmaceutical

- * Renata is the market leader in agrochemical business.
- ❖ Strong growth history; in the last five years, revenue grew by a 23% CAGR whereas net profit grew by 31%. Even if gross profit margin remained the same, the company has consistently reduced its operating costs, thus improving the bottom line.
- ❖ The company achieved a return on equity of over 25% on average in the past five years. 2009 seems to be on the same track.

© Daffodil International University

- Renata boasts of the highest gross profit margin (almost 50%) among the local manufacturers.
- ❖ In 3Q09, Renata declared EPS of BDT 325.94 posting a 43.55% bottom line growth QoQ; reduction of operating expenses improved bottom line.
- Renata has a Modest dividend payment; dividend yield in 2008 was about 1%.
- ❖ A high retention rate is justified as the company consistently makes huge capital expenditures, financed by internal cash. This state is supposed to continue in the near future.
- ❖ Manageable leverage; D/E is about 50%. The entire debt is short-term.
- Renata has good management, disciplined growth and low leverage, and appears to be an attractive company. However, liquidity of shares is a big concern.

| | 2009A | 2010E | 2011E |
|---|--------|--------|--------|
| Revenue(MM BDT) | 4103 | 5128 | 6154 |
| Operating Income(MM BDT) | 1020 | 1179 | 1415 |
| Operating Margin | 25% | 23% | 23% |
| Netincome(MM BDT) | 660 | 783 | 952 |
| Net Margin | 16% | 15% | 15% |
| 5 Year Revenue Growth(CAGR)Capex (MM BDT) | 23% | | |
| Debt/Equity | 103 | 110 | 117 |
| No of Shares(MM) | 0% | 0% | 0% |
| Diluted EPS(BDT) | 1.4 | 1.8 | 1.8 |
| Dividend (BDT) | 456.52 | 541.58 | 658.19 |
| Current Price (BDT) | 60.00 | 65.00 | 80.00 |
| Target Price(BDT) | 12750 | | |
| Return | 19% | | |

Figure: Renata Limited Snapshot.

Eskayef pharmaceutical

Eskayef Bangladesh Ltd is one of the largest and fastest expanding pharmaceutical companies in Bangladesh. The company, which has its headquarters in Dhaka (the capital of Bangladesh), is also known as SK+F and is a part of the Transcom Group. Eskayef Bangladesh Limited was born from the old facilities of SmithKline & French in Bangladesh when the company was restructured to form GlaxoSmithKline in 2000. The company is involved in the manufacture and distribution of a diverse range of pharmaceutical products and therapeutic drugs. The company also has interests in the production of veterinary drugs and animal nutrition products. Annual sales are approximately Taka 2bn (€200m, £140m). The company started its production of pharmaceuticals with the manufacture of generic products for the domestic market but has since moved into bulk products and the veterinary market. Eskayef Bangladesh currently manufactures and markets 28 different animal health products in 57 different dosage forms.

Acme pharmaceutical

The Acme Laboratories Ltd. is one of the leading and diversified global conglomerates in Bangladesh, with offices in all major cities, employing over 6000+ employees and dedicated to bringing the highest quality products and services to our customers.

Acme vision

To ensure health, vigor and happiness for all.

Acme's Mission

Our holistic approach is to ensure health, vigor & happiness for all by manufacturing medicines of the highest quality at affordable prices and expanding in the local and global market. We view ourselves as partners with healthcare professionals, all other customers, our employees, and harmonize with environmental issues.

ACI pharmaceutical

- ❖ Advanced Chemical Industries (ACI) Limited is one of the most recognized pharmaceutical companies in Bangladesh.
- ❖ ACI currently lies at eighth spot in the local market.
- ❖ The company has expanded its business beyond pharmaceuticals encompassing agro-chemical, animal health, agro-machinery, consumer brands and retail chains. Since the company has been expanding its business horizon rather aggressively for the last few years, ACI has found itself in a cash crunch, which ultimately led the company to resort to a fair bit of leverage.
- ❖ However, ACI has recently issued a zero-coupon bond to improve their cash position.
- ❖ Despite cash constraint, ACI is one of the more consistent dividend paying companies in the local market.
- ❖ Although the core pharma segment and agribusiness segment are making respectable profits, consumer brands and other segments are not yet fully profitable. If and when these segments become profitable, the bottom line will see significant improvement.
- ❖ Although we believe ACI is a good company, we are still not totally convinced that they are a good option to invest at the moment.

| | 2009A | 2010E | 2011E |
|---------------------------|-------|-------|-------|
| Revenue (MM BDT) | 12300 | 13530 | 14883 |
| Operating Income (MM BDT) | 775 | 853 | 938 |

| Operating Margin | 6% | 6% | 6% |
|------------------------------|-------|-------|-------|
| Net Income (MM BDT) | 553 | 608 | 669 |
| Net Margin | 4% | 4% | 4% |
| 5-Year Revenue Growth (CAGR) | 39% | | |
| Capex (MM BDT) | 571 | 400 | 300 |
| Debt/Equity | 36% | 30% | 20% |
| No. of Shares (MM) | 19.4 | 19.4 | 19.4 |
| EPS (BDT) | 28.48 | 31.32 | 34.46 |
| Dividend (BDT) | 10.50 | 10.50 | 10.50 |
| Current Price (BDT) | 398 | | |
| Target Price (BDT) | 450 | | |
| Return | 13% | | |
| | | | |

Figure: ACI Limited Snapshot.

Aristopharma pharmaceutical

Aristopharma ltd. is a leading pharmaceutical company in Bangladesh. The company started its journey in 1986 with the honest promise of providing quality medicines at affordable prices to countrymen. Its state-of-the-art manufacturing plant, located at Shampur-Kadamtali I/A, 10 km from central Dhaka, is equipped with highly sophisticated and advanced facilities. The facility is planned and designed to meet the local as

© Daffodil International University

well as international demand both qualitatively and quantitatively. Aristopharma manufactures medicines of wide range of therapeutic classes like antiulcerants, antibiotics, NSAIDs, antipyretics, vitamins & minerals, laxatives, cardiovasculars, antidiabetics, steroids, antispasmodics, antihistamines, antipsychotics, antiemetics, antiseptics and many more. It started manufacturing sterile ophthalmic products in 2002 and presently is maintaining no. 1 position in ophthalmic market in Bangladesh. Aristopharma's 2nd plant with 66,000 sq.ft. floor area was built in 2010 beside the existing plant to manufacture hi-tech products like inhalers, lyophilized injections, pre-filled syringes, suppositories, insulin & others bio-tech products.

Sanofia aventis

Sanofia Aventis is a French multinational pharmaceutical company headquartered in Paris, France, as of 2013 the world's fifth-largest byprescription sales. [2] The company was formed as Sanofi-Aventis in 2004 by the merger of Aventis and Sanofi-Synthélabo, which were each the product of several previous mergers. It changed its name to Sanofi in May 2011. Sanofi engages in the research and development, manufacturing and marketing of pharmaceutical drugs principally in the prescription market, but the firm also develops over-the-counter medication. The company covers seven major therapeutic areas:cardiovascular, central nervous system, diabetes, internal medicine, oncology, thrombosis and vaccines.

1.6 Growth potential of the domestic drug market

In order to get a sense of what might potentially be the size of the drug market let us consider a simple model. Here we assume that the economy will have an average GDP growth of 6%. The economy will witness an uptrend in healthcare expenditure because of the growing health consciousness and the increased demand for "wellness" drugs as well as government expenditure. This means that drug and non-drug healthcare expenditure will increase at about the same pace. So, we also assume that the percentage spent on drug as part of total healthcare expenditure will remain similar current level, which is about 28%. These simple assumptions present an impressive growth upside of 83.6% by 2015 with a 6 year CAGR of 10.7%. Recent growth figures have proved to be better than the projection, which demonstrates that the growth prospect of the sector is justified.

| | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
|---------------------------------------|---------|---------|---------|---------|---------|---------|---------|
| GDP (MM BDT) | 6149432 | 6518398 | 6909502 | 7324072 | 7763516 | 8229327 | 8723087 |
| Healthcare Expenditure % of GDP | 3.4% | 3.8% | 3.8% | 4.0% | 4.2% | 4.3% | 4.4% |

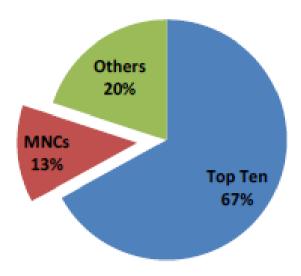
| Healthcare Expenditure (MM BDT) | 209081 | 234662 | 262561 | 292963 | 326068 | 353861 | 383816 |
|---------------------------------------|--------|--------|--------|--------|--------|--------|--------|
| Drug/Medicine Sales (MM BDT) | 60000 | 67341 | 75347 | 84072 | 93572 | 101548 | 110144 |
| Average GDP Growth Rate | 6.0% | | | | | | |
| Growth Upside | 83.6% | | | | | | |
| CAGR | 10.7% | | | | | | |

Table 3: Growth potential for domestic drug market.

Source: Bangladesh Bank, WHO, IMS Health and analyst's estimate.

Domestically, Bangladeshi companies including the locally based MNCs produce 95%-97% of the drugs and the rest are imported. Although about 250 pharmaceutical companies are registered in Bangladesh, less than 100 are actively producing drugs. The domestic market is highly concentrated and competitive. However, the local manufacturers dominate the industry as they enjoy approximately 87% of market share, while multinationals hold a 13% share. Another notable feature of this sector is the concentration of sales among a very small number of top companies. The top 10 players control around two-third of the market share while the top 15 companies cover 77% of the market. In comparison, the top ten Japanese firms generated approximately 45% of the domestic industry revenue, while the top ten UK firms generated approximately 50%, and the top ten German firms generated approximately 60%. Square Pharmaceuticals is the stand out market leader with a market share of 19.3% which posted domestic revenue of BDT 11.2 billion in the last four quarters (Apr 09 - Mar 10). Their nearest competitors are Incepta Pharmaceuticals and Beximco Pharmaceuticals with market shares of 8.5% and 7.6%.

1.7Market share concentration



Source: BAPI and newspaper reports

| Top Companies | Revenue April 09 - March 10 (MM BDT) | Market Share | Revenue 2009 (MM BDT) | Market Share |
|----------------------------|--|--------------|--------------------------|--------------|
| Square Pharmaceuticals | 11,158 | 19.3% | 10,701 | 19.5% |
| Incepta Pharmaceuticals | 4,919 | 8.5% | 4,524 | 8.2% |
| Beximco Pharmaceuticals | 4,415 | 7.6% | 4,239 | 7.7% |
| Opsonin Pharmaceuticals | 2,817 | 4.9% | 2,614 | 4.8% |
| Eskayef Pharmaceuticals | 2,788 | 4.8% | 2,520 | 4.6% |
| Acme Laboratories | 2,717 | 4.7% | 2,640 | 4.8% |

©Daffodil International University

| | | | | <u> </u> |
|--------------------|--------|--------|--------|----------|
| Renata Limited | 2,623 | 4.5% | 2,495 | 4.5% |
| Renata Elimied | 2,023 | 4.570 | 2,493 | 4.570 |
| ACI Limited | 2,466 | 4.3% | 2,460 | 4.5% |
| Aristopharma | 2,355 | 4.1% | 2,240 | 4.1% |
| Drug International | 2,283 | 3.9% | 2,132 | 3.9% |
| Sanofi-Aventis | 1,700 | 2.9% | 1,634 | 3.0% |
| GlaxoSmithKline | 1,266 | 2.2% | 1,229 | 2.2% |
| Novo Nordisk | 1,005 | 1.7% | 878 | 1.6% |
| Sandoz | 936 | 1.6% | 908 | 1.7% |
| Novartis | 675 | 1.2% | 558 | 1.0% |
| Others | 13,691 | 23.7% | 13,158 | 24.0% |
| Total | 57,815 | 100.0% | 54,929 | 100.0% |
| | | | | |

Source: BAPI and newspaper reports.

respectively. Incepta and Beximco had BDT 4.9 billion and BDT 4.4 billion in domestic sales for the last four quarters. Although a number of MNCs are operational in Bangladesh market, no MNCs are in the top ten in terms of domestic sales. Because Bangladesh API capacity is insignificant, pharmaceutical companies import approximately 80% of their APIs. Fifteen to twenty Bangladeshi firms are involved in the manufacture of about twenty APIs, but they usually run the relatively easier final chemical synthesis stage with API intermediaries, instead of the complete chemical synthesis. The other 1,000 required APIs are imported. Approximately 75-80% of the imported APIs are generic.

© Daffodil International University

CHAPTER-2

2.1 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.

2.2 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.

2.3 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.

2.4 Control of price

150 drugs were defined as essential drugs. For those, level prices are fixed for the finished drugs as well as for their corresponding raw materials. No manufacturer can set maximum retail prices for their goods beyond that limit. Changes in these level prices are decided by the Drug Control Committee. Since 1993, the number of price-controlled drugs has been reduced to 117 primary health care drugs. However, currently there are 209 drugs on the essential drugs list. For drugs that do not fall into this "Controlled Category", the manufacturer can set their own price, which must, however, be approved by the Drug Control Committee. This resulted in withdrawal of many foreign companies from the market in which they had had a share of around 70% in 1970, and strong growth in local production. This also created a boon for local pharmaceutical manufacturers. According to the Directorate of Drug Administration records, in the year 2002, all the essential drugs were produced locally and about 45% of the local drugs production concerned essential drugs. Locally produced drugs amount to over 80% of the market share and meet over 90% of the local drug demand. There are over 200 licensed pharmaceutical factories in the country, six of them are owned by multinational companies producing about 13% of the local production. 85% of the raw materials used in the local production are imported. Only about 1 % of the locally produced drugs is exported.

2.5 Situation of Bangladesh pharmaceutical industry and regulation

Before 1982, 80% of local pharmaceutical sales controlled by the MNCs and drug price was very high. In 1982 Drug Control Ordinance prohibited imports of products that are manufactured in Bangladesh restricted registration of drugs. A list of essential drugs introduced for price control by the government. It is within the government's purview to refuse the registration of any pharmaceuticals that are regarded as too expensive or unaffordable. Now 97% of local drugs needs supplied by the local pharmaceutical industry and 3% imported.

2.6 Situation of Bangladesh Patent law and Pharmaceutical patent

- ❖ There have been disputes among the scholars in Bangladesh about the patentability of pharmaceutical products under the *Patents and Designs Act 1911*.
- ❖ In the absence of a clear legislative provision or any court ruling on the distinction between processes and products both pharmaceutical products and processes are patentable under the *Patents and Designs Act* 1911.

- ❖ In 2008 the Department of Patents, Designs and Trademarks suspended the patenting of pharmaceuticals in Bangladesh until 1 January 2016 in accordance with the Doha waiver for LDCs.
- ❖ Prior to the suspension, the available information indicates that between 1998-2007 patent application and patents granted in Bangladesh increased two times than earlier and 90 percent of those patents owned by multinational corporations.
- ❖ In 2007, the Department of Patents, Designs and Trademarks registered 269 foreign patent applications of which 50 percent related to multinational pharmaceutical formulas.

2.7 Analysis of pharmaceutical industry in Bangladesh

In Bangladesh Pharmaceutical sector is one of the most developed hi tech sector which is contributing in the country's economy. After the promulgation of Drug Control Ordinance - 1982, the development of this sector was accelerated. The professional knowledge, thoughts and innovative ideas of the pharmacists working in this sector are the key factors for this development. Due to recent development of this sector we are exporting medicines to global market including European market. This sector is also providing 95% of the total medicine requirement of the local market. Leading Pharmaceutical Companies are expanding their business with the aim to expand export market. Recently few new industries have been established with hi tech equipments and professionals which will enhance the strength of this sector. There are several sectors on which Bangladesh can be proud of and undoubtedly the pharmaceutical sector is one of these sectors, rather it is the sector, which is the second-largest contributor to the government exchequer. There are about 231 companies in this sector and the approximate total market size is about Taka 76,500 million per year of which about 94% of the total requirement of medicines is created by the local companies and the rest 6% is imported. The imported drugs mainly comprise of the cancer drugs, vaccines for viral diseases, hormones etc. Bangladesh Pharmaceutical Industry is now heading towards self-sufficiency in meeting the local demand. The industry is the second highest contributor to the national exchequer after garments, and it is the largest white-collar intensive employment sector of the country. There are about 460 generics registered in Bangladesh. Out of these 460 generics, 120 are in the controlled category i.e. in the essential drug list. The remaining 340 generics are in the decontrolled category, The total number of brands /items that are registered in Bangladesh is currently estimated to be 5,300, while the total number of dosage forms and strengths are 8,300. 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 75%, while the MNCs are having a market share of 25%. During the last two decades the pharmaceutical industry of Bangladesh has been taken a newer height. Besides meeting the 94% need of local demand we are exporting the medicines into 77 countries. This sector contributes a lot into the national economy by exporting raw materials and finished goods. Bangladesh is ready to enter the Highly Regulated Market. For this reason different pharmaceutical companies are investing to build high tech pharmaceutical industries. Some renowned companies have already entered the Highly Regulated Market and got the UK MHRA, EU, Philippines, TGA Australia and GCC approval and some are in the process to get the USFDA & UK MHRA approval. Through this accreditation these companies will be able to export medicine and through contract manufacturing agreement.

CHAPTER-3

3.1 Investment analysis of pharmaceutical industry in Bangladesh

Following the Drug (Control) Ordinance of 1982, some of the local pharmaceutical companies improved range and quality of their products considerably. The national companies account for more than 65% of the pharmaceutical business in Bangladesh. However, among the top 20 companies of Bangladesh 6 are multinationals. Almost all the life saving imported products and new innovative molecules are channelled into and marketed in Bangladesh through these companies. Multinational and large national companies generally follow current good manufacturing practices (cGMP) including rigorous quality control of their products. The Drug Act of 1940 and its rules formed the basis of the country's drug legislation. Unani, ayurvedic, homeopathic and biochemic medicines were exempted from control under the legislation. The pharmaceutical industry was dominated by the foreign companies at that time. Even in the allopathic market there were extemporaneous preparations dispensed from retail pharmacies. The pharmaceutical industry, however, like all other sectors in Bangladesh, was much neglected during Pakistan regime. Most multinational companies had their production facilities in West Pakistan. With the emergence of Bangladesh in 1971, the country inherited a poor base of pharmaceutical industry. For several years after liberation, the government could not increase budgetary allocations for the health sector. Millions of people had little access to essential life saving medicines. With the promulgation of the Drug (Control) Ordinance of 1982 many medicinal products considered harmful, useless or unnecessary got removed from the market allowing availability of essential drugs to increase at all levels of the healthcare system. Increased competition helped maintain prices of selected essential drugs at the minimum and affordable level. In 1981, there were 166 licensed pharmaceutical manufacturers in the country, but local production was dominated by eight multinational companies (MNCs) which manufactured about 75% of the products. There were 25 medium sized local companies which manufactured 15% of the products and the remaining 10% were produced by other 133 small local companies. All these companies were mainly engaged in formulation out of imported raw materials involving an expenditure of Tk 600 million in foreign exchange. In spite of having 166 local pharmaceutical production units, the country had to spend nearly Tk 300 million on importing finished medicinal products. A positive impact of the Drug (Control) Ordinance of 1982 was that the limited available foreign currency was exclusively utilised for import of pharmaceutical raw materials and finished drugs, which are not produced in the country. The value of locally produced medicines rose from Tk 1.1 billion in 1981 to Tk 16.9 billion in 1999. At present, 95% of the total demand of medicinal products is met by local production. Local companies (LCs) increased their share from 25% to 70% on total annual production between 1981 and 2000. In 2000, there were 210 licensed allopathic drug-manufacturing units in the country, out of which only 173 were on active production; others were either closed down on their own or suspended by the licensing authority for drugs due to non compliance to GMP or drug laws. They 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. Anti-infective is the largest therapeutic class of locally produced medicinal products, distantly followed by antacids and anti-ulcerants.

3.2 Current Scenario of Bangladesh pharma market

In Bangladesh the pharmaceutical sector is one of the most developed hi-tech sectors within the country's economy. 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 these developments. Due to recent development of this sector it is exporting medicines to global market including European market. This sector is also providing 97% of the total medicine requirement of the local market. Leading pharmaceutical companies are expanding their business with the aim to expand export market. Recently few new industries have been established with high tech equipments and professionals which will enhance the strength of this sector. According to Bangladesh Pharmaceuticals and Healthcare Report Q1 2011, Bangladesh medicine sales reached Tk 7,000 crore in 2010. Business Monitor International in its latest report (Q1 2011) said Bangladesh has moved up one place to occupy the 14th position in 17 regional markets surveyed in BMIs Pharmaceutical & Healthcare Business Environment Ratings for the Asia region. Globally, Bangladesh occupies 67th position in BMIs 83 market-strong pharmaceutical universe.

3.3 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.

Differences between industries should be considered in context of patent reform

The long development cycle for and heavy regulation patented pharmaceuticals distinguishes such products from short development cycle unregulated products. Reform proposals should consider the impact on pharmaceutical innovation. Pharmaceutical is one of the higest priority sectors in Bangladesh. There are more than 230 small,medium,large and multinational companies operating in the country producing around 97% of the total demand (Bangladesh Bureau of Statistics(BBS),Annual Bulletin-2008). The sector is the second highest contributor to the national ex-chequer after tobacco and it is the largest white-collar intensive employment sector in Bangladesh.95% of the total demand of Bangladesh is being met by local manufacturing (Ministry of health of Bangladesh half yearly assessment report published in 2007). The remaining 5% basically constitute import of mutch specialized products like

© Daffodil International University

vaccines ,anti-cancer products and hormone drugs (Bangladesh Pharmacy Council(BPC),Annual Report 2009). The country can continue to produce patented products until 2016as per trade related intellectual property rights(TRIPS).

Limitation of the study

Lack of available previous research works in this area for designing the study. Time and cost is also a considerable limitation. The category of the product of the pharmaceutical organijation was not same. So it was difficult to compare among their performance.

Growth of pharmaceutical sector of Bangladesh

The pharmaceutical industry is one of the most developed industrial sectors of Bangladesh. There are approximately 250 companies active in the market at the moment. This rapidly growing industry contributes almost 1% of the GDP and is currently the third largest tax paying sector in the country. USA-based research firm IMS had stated in 2009 that the retail pharmaceutical market value in Bangladesh is around BDT 55 billion. The annual average growth rate of pharmaceuticals has hit double digit since 2009. The pharmaceutical sector of Bangladesh has achieved a great reputation worldwide for its quality products. This can be seen by the increasing number of export orders the companies are getting from foreign buyers. Back in the 1980s, only a couple of companies exported pharmaceutical products to only Myanmar, Sri Lanka and Nepal. Now this sector is exporting products in 52 different countries. These products include high tech medicines such as inhalers, suppositories, infusions and injectable. A massive opportunity opened up for Bangladesh after WTO/TRIPs 'Patent Law' was implied which has made it possible for Bangladeshi pharmaceutical companies to export patented drugs until January 2016.

3.4 Business analysis of pharmaceutical firms in Bangladesh

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 (http://banglapedia). After the promulgation of Drug Control Ordinance-1982, the development of pharmaceuticals industry has accelerated. The skills and knowledge of the professionals and innovative ideas of the people involved in this industry are the key factors for these developments. Due to recent development of this sector, the country is exporting medicines to global market including European countries and on the top of it, the industry has been supplying about 95 percent of the domestic demand for medicine.

3.5 Literature review

At the global level, highly valuable studies are available on pharmaceuticals industry and related sectors. Specific studies on Bangladesh pharmaceuticals industry are limited. Infrastructure development and the deployment of trained manpower are now perceived as two of the essential prerequisites for the implementation of national pharmaceutical policies (Jayasuriya, 1991). Pharmaceuticals have greatly

© Daffodil International University

improved health in developing countries, but many people in developing countries do not obtain even inexpensive pharmaceuticals and little pharmaceutical R&D is oriented towards products needed by developing countries, such as a malaria vaccine and access to existing products could be improved by facilitating differential pricing (Kremer, 2002). It is suggested that under conditions of rapidly changing demand (as found in pharmaceuticals), price-caps could be manipulated and using simulations.

3.6 Objective of the study

The objectives of the study are:

- To present the current scenario of pharmaceutical industry in Bangladesh.
- > To identify the problems and prospects in different areas of pharmaceutical industry.
- ➤ To suggest some policy guidelines for resolving these problems and to cope with the new regime of globalization.

3.7 Methodology of the study

This study has utilized both primary and secondary data. ten leading pharmaceutical firms have been selected for the study. Primary data have been collected from discussions with 110 concerned executives of different pharmaceutical companies, top level officials of different pharmaceutical companies, officials of the Directorate of Drug Administration (Government of Bangladesh) and interviewing the customers of the drugs. The study utilizes different secondary industry-related data on export, import, marketing, human resources, dumping etc. which are collected from the website, annual reports of different pharmaceutical firms important research papers, magazines, relevant books, newspapers, journals, and other relevant documents.

CHAPTER-4

4.1Discussions

Products

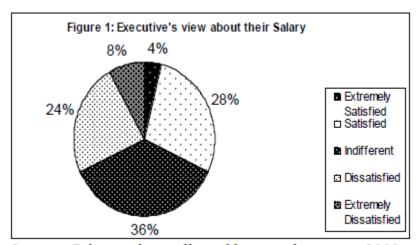
Up to year 2000, there were 210 licensed allopathic drug-manufacturers in the country; of them only 173 actively produced the medicines while others were either closed down on their personal problems or by the authority for drugs administration due to non-compliance of drug laws. The manufacturers are now producing near about 5,600 brands of medicines in different forms. For promoting these products, there are 1,495 wholesale and around 37,700 retail drug license holders in different areas of Bangladesh. Anti-infective is the largest therapeutic class of locally produced medicinal products, distantly followed by antacids and anti-ulcer ants. There are some other significant therapeutic classes including non-steroidal anti-inflammatory drug (NSAID), vitamins, central nervous system (CNS) and respiratory products. The local industry is extraordinarily increasing the production of basic chemicals. At present, there are 13 medicinal product manufacturing units, which also manufacture certain basic materials. These include paracetamol, ampicillin trihydrate, amoxycillin trihydrate, diclofenac sodium, aluminium hydroxide dried gel, dextrose monohydrate, hard gelatin capsule shell, chloroquine phosphate, propranolol hydrochloride, benzoyl metronidazole, sodium stibogluconate (stibatin) and pyrantel pamoate. However, most of these are restricted to the last stage of synthesis.

Marketing

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 these representatives.

26



Source: Primary data collected by sample survey, 2009

The researcher conducted a small survey over the field level executives, who are playing the prime role for marketing of the products of pharmaceutical companies. Here, the study finds that, only 32% employees are in satisfactory and extremely satisfactory level. So, how it is possible to expect, the executives will devote maximum effort for marketing their products. Most of the interviewees think that the sector should increase the benefits to the marketing executives with relevant effort.

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 storm 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.

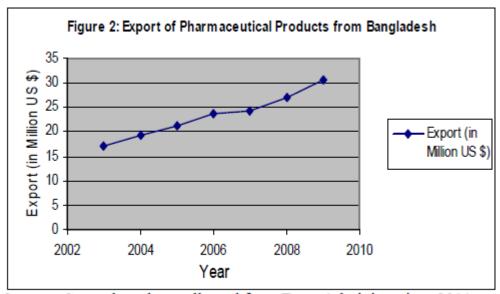
Training and development

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.

Exporting

Exports are goods and services produced by a firm in one country and then sent to another country (Rugman, 2004). To export products to developed markets, companies must bring their factories into conformance with GMP (Good Manufacturing Process) standards and by this process, the vast majority of Indian pharmaceutical exports went to other developing countries with similar disease profiles and disregard for patent protection (Smith, 2000). Export of pharmaceutical products of Bangladesh is still in infancy. But the rate of establishment of pharmaceuticals industries in private sector is increasing and they have already entered the export market with their finished products. In 2000, Bangladesh imported US\$84,000,000 worth of medicinal and pharmaceutical products and had negligible exports and some recent statements by industry representatives suggest that exports will increase in the near future (VanDuzer, 2003). Bangladesh is exporting their pharmaceuticals products to Vietnam, Singapore, Myanmar, Bhutan, Nepal, Sri Lanka, Pakistan, Yemen, Oman, Thailand, and some countries of Central Asia and Africa. It also has a large market in European countries.

28



Source: Secondary data collected from Drug Administration, 2011.

From the above figure, it can be concluded that the trend of export is upward. According to the drug administration; Bangladesh could not export the expected amount of pharmaceuticals products in the year 2007 due to some political problems. Drug administration hopes that the trend will continue in future.

Importing

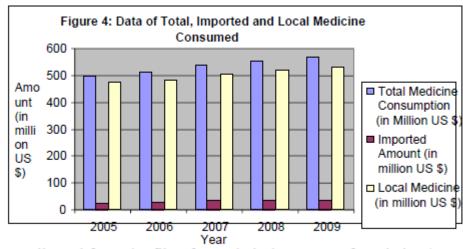
Importing is acquiring or purchasing the goods or products which have been made in another country (Skinner & Ivancevich, 2003). Bangladesh is importing the medicinal products from different countries, especially from India. Different organizations of this country are related to import the pharmaceuticals products and raw materials of pharmaceutical industries. Novo and Medintis are importing maximum amount of these types of products. Other organizations are engaging to import the pharmaceuticals products. They are-Sanofi, Aventis, Glaxo Smithkline, Sandoz, Novartis, Roche, Unimed, Servier etc.

TABLE 1 Yearly consumed cost of medicine and imported cost

| Year | Total Medicine Consumption (in Million US \$) | Imported Amount (in million US \$) | Local Medicine (in million US \$) |
|------|---|------------------------------------|-----------------------------------|
| 2005 | 498.5 | 23.43 | 475.07 |
| 2006 | 512.06 | 28.27 | 483.79 |
| 2007 | 536.42 | 34.8 | 501.62 |
| 2008 | 552.58 | 33.15 | 519.43 |
| 2009 | 567.3 | 35.78 | 531.52 |

Source: Data collected from the file of Bangladesh Bureau of Statistics (BBS), 2011

This chart explains that the consumption of medicine and imported amount of medicine is increasing year by year. In 2007, Bangladesh imported huge amount of medicine due to some political and social problems. The imported amount of 2008 is lower than the previous year. According to drug administration, the production was high in 2008. For this reason the imported amount was low and political unrest is the reason for increasing the imported amount and declining the exported amount in 2007.



Source: Data collected from the file of Bangladesh Bureau of Statistics (BBS), 2011

From the above figure, it can be easily found that the maximum demand of medicine is met by the product produced by our locally established organization (locally owned and multinational). The production and imported amount are both increasing. Leaders of the owner's association of drug administration think that the government should take measures to impose tariffs and taxes on import that may encourage local pharmaceutical companies.

4.2 Foreign Competitions

At the beginning the foreign pharmaceuticals were dominating the market in our country. Still now, Pharmaceuticals industries are facing foreign competition. But our industry is not afraid of this foreign competition. There are many multinational pharmaceutical organizations which have established their plants in Bangladesh and importing their raw materials from abroad. Among these competitors, Roche, Glaxo SmithKline, Novartis are leading. In export market, the Novartis is playing the dominant role.

Dumping

Dumping is a situation when in which a company sells its products for lower prices than the market price to capture the market share (Griffin & Pustay, 2001). From the top management of the pharmaceutical companies, we got to know that some Indian medicines are sold in the country market at a lower price than Bangladeshi medicines but the medicine of developed countries and their origin country are sold in a competitive price, even in higher price. This creates the barrier to capture the market share by Bangladeshi pharmaceutical industries.

Owners of the pharmaceutical companies think that the government should take actions to stop this practice.

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 |
| SK-F | 4 |

Source: Primary data collected by sample survey, 2010.

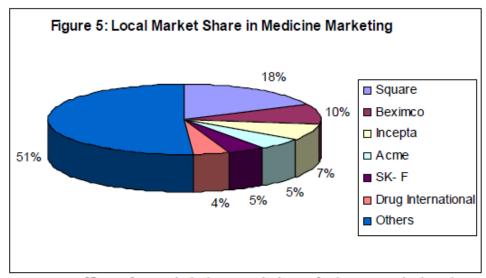
The above chart represents the scenario of customer choice toward the brand name. Most of the customers choose their medicine produced by square pharmaceuticals limited. According to the customer choice, no organization can play dominant role in the market.

4.3Research and Development

Research is defined as the systematic and objective process of gathering, recording, and analyzing data for aid in making decision and development (Zikmund, 2005). Every organization is related to research & development. The organization becomes backdated which is not related to update their product. 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 cooperative R&D partnerships with MNCs (Grace, 2004). 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 (Humer, 2005). The R& D team comprises of highly qualified and trained technical personnel continuously striving for product and process innovation and up gradation. 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.

Competitive Position

Pharmaceutical industry is facing competitive market domestically. Square, Beximco, Incepta, Acme, SK-F, Drug International, AristoPharma, ACI, are the competitors of one another in medicine market.



Source: Office of Bangladesh Association of Pharmaceutical Industry (BAPI), 2009.

To purchase the medicinal product is not depending on the customer choice. For this reason, the primary survey over the customer and the actual condition is different. From the above chart, this can be said that no organization can capture the maximum market share in medicine marketing. There is a tough competition among Square, Beximco, and Incepta.

4.4 Problems and Prospects

Problems of Marketing

- ➤ Because of having no sufficient incentives in comparison with their effort, the turnover rate of medical representatives is very high.
- Most of the time costs of marketing hardly affect the price of the medicine.
- > Professionalism in marketing is not achieved yet in Bangladesh like other developing countries.
- Lack of proper governmental laws and this implementation the law by the drug administration.
- ➤ Unstable political situation and different types of violence.
- ➤ Effect of globalization that has increased the competition.
- > Smuggled production counterfeit, that's coming from the neighbor countries.

Prospects of Marketing

- ➤ Marketing system is improving in this sector and proper marketing may help a firm to achieve the aim.
- For free and fair competitions marketing can play a major role.
- ➤ Marketing can be regarded one of the most important weapons to face the challenges of open market economy.

Problems of Foreign Competition

- Foreign competitors have more equipment, technology and plant facilities than that of locally owned firms.
- Foreign competitors have their own local market so that they can absorb some losses here.
- Foreign competitors get government help in some cases.

Prospects of Foreign Competition

- Foreign competitions made the country firms more eligible to face challenges that arose after the year 2005.
- ➤ Pharmaceuticals industries will become more efficient in producing medicine which may save our lives.
- > The local firms will not face any rigorous problem in foreign countries as they are accustomed in competition with foreign firms.

Problems of Export

- ➤ Unstable political situation is one of the vital reasons for not achieving the expectation in export.
- Problems of port (both sea and air) hinder the timely export.
- ➤ Irresponsibility of customs officers is a regular phenomenon which results in increase on the price and cost of medicine.
- > Sometimes competition tends to follow unfair promotional activities.
- > Still now, the products of the pharmaceuticals industries of Bangladesh are not world class.

Prospects of export

- ➤ Competition is increasing the quality of medicinal products.
- For surviving in the future, competitive environment is necessary.
- ➤ Competition reduces monopolistic attitude of the firms. As a result, the customers will be benefited by getting quality products.
- ➤ Export brings foreign currencies for the country which is helpful for the reserve of the country.

Problems of Customer Choices

- ➤ One main problem is in producing rare drugs foreign companies are ahead of us in terms of quality, experience and market share.
- ➤ Most of the time, to purchase the medicinal products is not depending on the customer choice.

> Customers buy their product according to the prescription of doctors.

Prospects of Customer Choices

- ➤ By increasing quality, more customers as well as market share can be absorbed.
- ➤ By producing rare drugs at home, the country can save its foreign exchange.
- ➤ By extensive promotional activity, customer choice can be driven.

Problems of Power Development

- Like other industries, there is a crucial problem faced by the pharmaceutical industries that is power generation problem. They are not getting power according to their demand.
- ➤ Lack of opportunity to supply the emergency power to smooth continuation of production in pharmaceutical sector.

Prospects of Power Development

- ➤ By following all the rules and innovating alternative power supply source, this sector is entering the competitive market.
- > Pharmaceuticals may open a big door of prospect in the foreign market.

4.5 Government incentive for supply of raw materials

Recently, the government introduced flat rate of import duty of 5% on import of raw materials 12. The pharmaceutical product produced from the imported raw materials for ultimate export enjoy duty draw back facilities. Locally produced raw materials produced enjoy the "value added tax" exemption benefit if the products are exported. So far there is no special cash incentive for export production. But government is being persuaded by the industry repre4sentitative s to declare cash incentive. For fi8nished goods suggested rate o9f cash incentive is 20% while for raw materials to be used for export of 30%. In the year 2007-2008 no cash incentive have been announced for t5he pharmaceuticals sectors, though of the export products of Bangladesh enjoy a certain percentage of cash incentives to remain in competition in the international markets.

❖ Packaging and packaging materials

Packaging materials used in the local pharmaceutical industries include aluminum foil (blister and strip)Alu Alu foil ,rubber stropper, flip-off sealprinting materials,plastic cap,injectable,tear-off seal,tube,PVC, PVDC, level,bottle(white and colour) plastic container, paper cartoon packets etc. Almost every packaging materials is locally available except aluminum foil ,alu-alu foil,PVC, PVDC, color bottles,etcwhich are imported from countries like Korea, Dubai,India ,China and so on. It is expected that a number of packaging industries will appear in near future as backward and forward linkages to support pharmaceutical sector.

❖ Manpower in the pharmaceutical sector

In Bangladesh there exist a pool of qualified professionals and expert engaged in the pharmaceutical industry sector.15-16 leading companies including new entrants have their regular product delopment research. Every company hires a number of pharmacists, Zoologists and Chemists who obtained higher education from the local university followed by advanced degrees from developed countries. There are about 34000 pharmacists in the country, about 100000 people are involved in manufacturing ,over all 350000 people are involved directly or indirectly in pharmaceuticals sector of Bangladesh. Technologies are adopted in Bangladesh were introduced by the multinationals which have been steadily replicated by the local professionals. Now, this sector hires the higest number of professionally brilliant people in the country. Manpower and experts are available in this sector. Both public and private institutions are in existrance to train pharmacy people. There is one pharmacy association. Pharmacists council of Bangladesh 13, Doctors Association of Bangladesh are working directly or indirectly to improve the sector. The Dhaka Chamber of Commerce and industry (DCCI) is the largest chamber of the country acting as one of the patronize of the sector. There is also pool of experts who are good in sales and marketing in both local and international level. Moreover the supplires of pharmaceutical items regularly provide demonstration on technology and technical know hoh to the local staff for their self-development.

Availability of required utility services

All required utility facilities and services like water ,gas,electricity etc are available.Except interruption in power supply ,there is no problem in carrying out regular and smooth production of the pharmaceutical industries. As substitute of power, the government waived import duty from industrial generator. Presently power generation capacity has also increased and private sector power production has been encouraged and 15 years tax exemption from income of power project is allowed.

Commonly used quality equipment are given below

- Gas Chromatography
- High Pressure Liquid Chromatography
- InfraRred Spectrophotometer
- UV-visible Spectrophotometer
- Memo Titrator
- HP Meter
- Dissolution tester
- Microbiology Laboratory that consists of
- Incubator, sterilizer, Autoclave, Colony
- Counter, Practical counter, Glass weares
- Conical flask, Pipette, Measuring cleve
- Burette etc

The role of federal research and development

The federal government spent more than \$25 billion on health-related R&D in 2005. Only some of that spend-ing is explicitly related to the development of new pharmaceuticals. However, much of it is devoted to basic research on the mechanisms of disease, which underpins the pharmaceutical industry's search for new drugs. The primary rationale for the government to play a role in basic research is that private companies perform too little such research themselves (relative to what is best for society). In general, the information generated by basic research can be readily replicated at low cost. Thus, many of the benefits of that research accrue not to the company that performs it but to the public and to other firms. With pharmaceuticals, those spillover benefits can be significant because the development of new drugs depends on scientific advances. Federal funding of basic research directly stimulates the drug industry's spending on applied research and development by making scientific discoveries that expand the industry's opportunities for R&D.

***** 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 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.

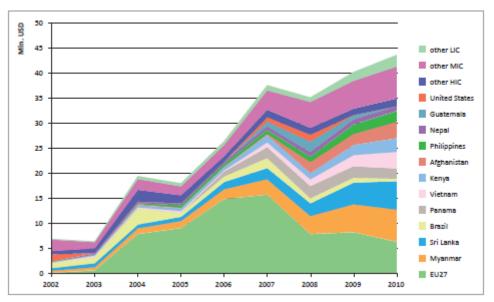


Figure: Bangladesh pharmaceutical exports, by destination, 2002-10 (in 1000 USD)

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. 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 | |

4.6 Export Policy of Bangladesh

- * Encouraging labor-intensive (especially female labor) export-oriented production;
- ❖ Ensuring availability of raw materials for manufacturing export goods.
- Increasing productivity and diversity of products;
- ❖ Improving the quality of products; encouraging the use of modern, appropriate and environment-friendly technology, producing high-end products, and improving the design of the products;
- **Solution** Enhancing efficiency and dynamism by using e-Commerce and e-Governance;
- ❖ Initiating new strategies for the expansion of the markets for export products, making proper utilization of computer technology and encouraging all modern technologies including e-Commerce;
- ❖ Assisting the development of necessary infrastructure, particularly for backward and forward linkages in order to encourage the production of exportable goods;
- ❖ Providing all-out support to new exporters as well as to existing exporters;

- ❖ Assisting the development of a skilled labor-force through proper training for managing international trade; and
- Providing adequate guidance to trade bodies, business organizations, business people and related individuals in understanding the changing international trading system, etc.

4.7 Implementation strategy

- ❖ Providing assistance to producers and exporters in collecting market intelligence information on the demands for commodities abroad, expanding markets, attaining competitive and higher price, etc.
- Extending support to export facilitating agencies by introducing automation and e-Governance for enhancing work-efficiency and ensuring transparency and accountability;
- ❖ Providing assistance for updating and modernizing the over all trade system by ensuring the best use of all modern technologies including e-Commerce for making the export products more competitive through reducing cost of business, increasing production, expanding market and shortening lead time;
- ❖ Disseminating latest information to the exporters on export markets and technology to facilitate diversification of exports;
- Creating training opportunities and establishing sector-specific training institutes for workers, staff and management personnel to increase productivity;
- ❖ Encouraging promotion of export through increased institutional facilities including trading and export houses;
- ❖ Providing assistance in establishing internationally accredited certification system to ensure the quality of the products;
- ❖ Encouraging the establishment of product-wise design centers for improvement of product designs;
- * Assisting producers in using modern technology for production;
- ❖ Providing supports to the exporters to get acquainted with the working procedures of significantly successful exporting countries;
- Providing various financial and tax subsidies or incentives including low-interest loans to exporters;
- ❖ Reducing lead time in export by means of improvement of port management and infrastructure, simplification of procedures for releasing goods, and improvement of the transport system;
- Sending trade missions abroad and providing support to exporters to hold single country fairs abroad as well as to participate in different international trade fairs to familiarize and market the products;
- Taking all necessary initiatives for achieving duty-free market access to developed and developing countries including United States for expanding markets for Bangladeshi products and services abroad;
- ❖ Taking special initiatives to enhance exports of products and services to South Asia, Middle East and other Asian and African countries;
- ❖ Awarding CIP status and National Export Trophy every year to the best exporters of different sectors in recognition of producing new products, diversifying of products, enhancing exports, etc;

- * Reviewing country's export situation at least once annually and providing necessary directions by the "National Committee on Export";
- ❖ Monitoring and evaluating the progress of the implementation of the decisions of the "National Committee on Export, by the task force established for this purpose; and Identifying the problems related to export and recommending possible remedies by the Export Monitoring Committee headed by the Vice-Chairman of the Export Promotion Bureau.

4.8 Application and scope

- ❖ Unless otherwise stated, the Export Policy 2009-12 shall be applicable to exports of all types of goods and services from Bangladesh.
- ❖ The Export Policy 2009-12 shall be effective from the date of its publication in the Bangladesh Gazette, and shall remain in force until June 30, 2012. However, this Export Policy shall remain effective until the next Export Policy is issued.
- This policy shall be applicable to all places in Bangladesh except the Export Processing Zones (EPZs).
- ❖ Any tax/ tariff related decision declared in the National Budget or by the National Board of Revenue shall prevail over the Export Policy.
- ❖ Whatever is stated in this policy, any specific decision related to export issued by the government through any other order shall prevail over this policy even if the order is inconsistent with any section of this policy.
- ❖ The Government will review the Export Policy at least once a year, and make any modification, expansion or amendment, if necessary.

4.9 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:

* 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.

***** 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.

4.10 Export channels

Bangladesh government has adopted extensive policy packages for improving exports of pharmaceutical products. Private sector is also enthusiastic that export is possible to be improved in the coming years by utilizing the positive policy packages announced by the government. A large number of trade fair, seminars, dialogues ,negotiating meetings are being organized to explore to new export destinations. Asignificant number of new establishment and

BMRE activities are going on for direct exports. As about 85% of the inputs are the imported, the expoters are the same time impoters. There are some trading companies also who are bulk importing to facilitate small expoters. Some small companies are also willing to be part of the large companies to penetrationinto the export market.

Shipping

As the government is sincere to increase the exports of pharmaceutical products, the efficiency of port handling has been increased recently where exporters get priorities.

Packaging

Packaging is the process by which the pharmaceuticals are suitably placed so that they should retain their therapeutic effectiveness from the time of their packaging till they are consumed. It is the art and science which involves preparing the articles for transport, storage, display and use.

Selection of packaging material

The materials selected for packaging must have the following characteristics:

- 1. They must protect the preparation from environmental conditions.
- 2. They must not be reactive with the product,
- 3. They must not impart tastes or odours to the products,
- 4. They must be non-toxic,
- 5. They must be FDA (Food & Drug Administration) approved,
- 6. They must meet applicable tamper-resistance requirements
- 7. They must be adaptable to commonly employed high-speed packaging equipment. and
- 8. They must have reasonable cost in relation to the cost of the product.

Packaging materials

The following materials are used for the construction of containers and closures

- 1. *Glass:* -(i) Type-I Borosilicate glass (ii)Type-II Treated sodalime glass (iii)Type-III Regular soda-lime glass (iv)Type-NP General purpose soda lime glass (v)Coloured glass 2. Metals (i) Tin
- - (ii) Iron
 - (iii) Aluminium
 - (iv) Lead.

- 3. Plastics
- (a) Thermosetting resins:
- (i) Phenolics
- (ii) Urea
- (b) Thermoplastic resins:
- (i)Polyethylene
- (ii)Polypropylene
- (iii)Polyvinylchloride (PVC)
- (iv)Polystyrene
- (v)Polycarbonate
- (vi)Polyamide (Nylon)
- (vii)Acrylic multipolymers
- (viii)Polyethylene terephthalate (PET)
- 4. Rubber
- (i) Natural rubber
- (ii)Neoprene rubber
- (iii)Butyl rubber.

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.

4.11 Product specification, quality and output

Most regular companies strictly follow current Good Manufacturing Practice(cGMP). The National Drug Policy ,drawn in line with the recommendations of World Health Organization (WHO), guides the local industries. According to the policy, products like cough syrup, alkali syrup,gripe water,combination product had been banned for production and import. The Drug Policy has introduced a list of essential drugs in line with the essential product list of WHO. The Drug Control Committee approves new molecules ,if any after assessing therapeutic value ,safety and necessity of the product for the country. High-tech medicines like anti-cancer, anti-hypertension, anti diabetic ,etc., are permitted to import. After having satisfactory report on quality control facilities of acompany , the government issues or renews "drug manufacturing license" to a company which is renewable every 2 years upon satisfactory results of quality

control laboratry laboratry inspection. In order to get registration each product has to pass through a test for import or local production. Each and every product must have manufacturing and expiry date, batch number and price (Maximum Retailed Price) and other necessary labelling requirements. All leading companies are well equipped with all modern machinery and equipment.

Price, Distribution and Promotion:

Prices of products under controlled category are determined by the government. Manufacturing companies are allowed to propose the prices of the products that are under decontrolled category and the approvals of these proposed prices are given by the government. The local Drug Administration Authority strictly controls prices of products. Prices needed to be fixed by a company within the band announced by the government. The MRP should not exceed the double of the price of the basic ingredients i.e. if the price of Amoxicillin is US\$0.10, then MRP shall not be more than US\$0.20. In Bangladesh, promotion of pharmaceutical products in the mass media is strictly prohibited. Manufacturing companies can only promote their brands to the health professionals by personal selling, clinical meetings, seminars, symposia etc. According to the government regulation, the pharmacists/Chemists are entitled to get 16% retail margins on top of the trade prices of the products. Most of the leading pharmaceutical manufacturers have their own distribution network and ensure supply of products up to retail level. But the companies, who do not have their own distribution network, have to distribute their products through distributors/wholesalers. In that case, they usually fix the distributors margin as mutually agreed between them and distributors/wholesalers. With regards to raw material sourcing, the pharmaceutical manufacturers in Bangladesh procure raw materials from various countries namely USA, UK, France, Germany, Japan, Holland, Italy Denmark, China, Switzerland, Austria, Hungary, India, Ireland etc.

4.12 Import of pharmaceuticals

Yearly imports of pharmaceuticals

In Bangladesh, both finished productsand raw materials are imported every year from abroad in large quantity. More than 700 different types of finished products are being imported every year. A list of the permitted items that has been imported can be seen in the attachment 31. More than 750 numbers of basic raw materials including packaging materials are being impoted in Bangladesh for the use of the local pharmaceutical companies. Two categories of raw materials used and imported 1. Active ingredients/basic materials and 2. Excipients. Almost 85% of the raw materials are being imported. But the imported finished products is negligible i.e around 3% of the total consumption in the local market. Table below shows the statistics on import:

| Year | Imported | | |
|------|---------------|---------------------|-------------------|
| | Raw materials | Packaging materials | Finished products |
| 2000 | 118.09 | 22.91 | 4.41 |
| 2001 | 122.58 | 25.45 | 34.86 |
| 2002 | 125.49 | 14.31 | 45.42 |
| 2003 | 136.92 | 15.61 | 35.41 |
| 2004 | 91.94 | 8.06 | 31.66 |
| 2005 | 105.93 | 9.67 | 39.92 |
| 2006 | 99.03 | 9.39 | 39.31 |

Figure: Yearly import of pharmaceutical products (in million US\$)

Countries of import:

Pharmaceutical products including raw materials are being imported from Germany, Swetzerland, France, USA, Denmark, Cyprus, Ireland, United Kingdom, Hungry, Austria, Greece, Italy, Belgium, Netherland, Pakistan, Spain and other west European countries, Japan, Korea, Singapore, China, India and United Arab Emirates etc. 50% of the total raw materials are imported from China,20% from India and the rest 20% are imported from other countries. Anumber of packaging materials are used by the local companies; a portion of which are produced locally. Locally produced packaging materials include cartoon, product literature, white bottles, empty syringe/injectables, strip, cork, plastic containers, droppers, etc. Imported packaging materials are: aluminum foil, colour bottle, foil(blister and strip) alu-alu, rubber stopper, flip off seal, tear off seal, tube, PVC, PVDC, etc. 80% of the total packaging materials are producing locally including bottles, printing materials etc. But the country still depends on import for foils.

Projection of import of pharmaceuticals:

In view of socio-economic scenario and with the increase in the per capita income, literacy rate in the country and also due to increased concern about health of a certain group of people in the urban areas, it is assumed that total demand for all kinds of medicines and health care products will grow in Bangladesh in the near future. Simultaniously, with the increasing trend in the

export of pharmaceuticals, the demand for raw materials with increase substantially. However, taking into consideration of the past performance as well as introduction of new entrants in the sector, it is expected that the import will experience at an annual average growth rate of at least 10% in the next 4-5 years. This rate once the existing API projects are in commercial operation. Projected import of pharmaceuticals can be shown in table below:

| Products | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
|------------------|--------|--------|--------|--------|--------|--------|
| Raw materials | 162 | 178.22 | 196.02 | 215.62 | 237.18 | 260.9 |
| Formulations | 43.22 | 47.56 | 52.32 | 57.55 | 63.3 | 69.63 |
| Estimated Import | 205.24 | 225.76 | 248.33 | 273.17 | 300.48 | 330.53 |

Figure: Projected annual imports of pharmaceuticals products(value in US\$)

Apparent consumption of pharmaceuticals

The total consumption of raw materials of pharmaceuticals can be calculated from both the quantity produced for local market and the total annual import. Local consumption of pharmaceuticals can be estimated from the total production and total export. Total consumption is increasing every year; average growth rate is 10-12%. Consumption of medicine is also increasing at the same time import is also increasing. Since the volume of local consumption as well as import and production is increasing, the country has made significant progress in its export. So, total consumption of raw materials can also be assessed from the performance of the local production and export.

| Particulars | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 |
|-----------------------------|--------|--------|--------|--------|--------|--------|
| Total production(Estimated) | 401.78 | 555.01 | 590.08 | 685.15 | 804.61 | 711.98 |
| Total export | 5.98 | 7.83 | 10.93 | 26.1 | 25.54 | 39.71 |
| Total local consumption | 395.8 | 547.18 | 579.15 | 659.05 | 779.07 | 672.27 |

Figure: Local consumption of pharmaceuticals (Calendar Year).

***** Potential consumption of pharmaceuticals

Since there is an increasing trend in both local and export market, it is assumed that the potential demand for raw materials (Category wise raw materials potentiality)wii be increased at a significant volume in near future. On the top of that, new company have already production and another batch of new units is in the pipeline that will start production. So there is a good market potential for manufacturers and exporters of raw materials. Similarly, the potential demand for finished products in Bangladesh will also increase due to several valid reasons. Reasons are increased rate of literate persons tend to be more health conscious, elder people seeking higher life expectancy, increase in per capita income, improved life style, large groups of eduycated and increased awareness among mass people about newly invested drugs and medicines and so on. Finally the volume of import of both basic materials and hi-tech formulations used for serious diseases will be increased substantially. Annual average growth rate of local production is around 13%.

CHAPTER 5

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. 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.

CHAPTER-6

References

- 1. "BD firm plans to export version of Tamiflu". Daily Times. 2006-04-05. Retrieved 2008-03-08.
- 2. Jump up^ Reuters, Bangladesh Beximco exports drugs to Philippines
- 3. Eric Palmer and Carly Helfand for FiercePharma. March 4, 2014 The top 10 pharma companies by 2013 revenue
- 4. Jump up^ "Sanofi-Aventis to sign deal to build flu vaccine plant in China source". AFX News(Forbes). 23 November 2007. Retrieved 2009-04-19
- 5. Current scenario of Bangladesh Pharma market-Detail News-BDdrugs.com-First Online drug index of Bangladesh.BDdrugs.com.Retrieved2013-05-17._
- 6. Anamul and Zahedul, Business Analysis of Pharmaceutical Firms in Bangladesh, Volume VI, Number I, January-June, 2011
- 7. Drug Ordinance of Bangladesh, 1982
- 8. Pharmaceutical Opportunities in Bangladesh, UK Trade and Investment Chapter 14, The Pharmaceutical Sector in Bangladesh, World Bank Report, 2013www.dgda.gov.bd
- 9. Improving The Competitiveness of The Pharmaceutical Sector in Bangladesh, World Bank April 2007
- 10. Moklesur Rahman Sarker, Pharmacy Profession in Bangladesh, Future Prospects and Challenges.
- 11. Abbott T. A. (1995), "Price regulation in the pharmaceutical industry: Prescription or placebo?" Journal of Health Economics, Volume 14, Issue 5, December 1995,pp. 551-565.
- 12. Chowdhury, F., S. Gurinder, S. Raihanuddin, and S. Hasan Nasir. 2006. "A Strategy for Establishing the API Park." Interim Report. Bangladesh: Ministry of Industry.
- 13. .Bumpas J. (2007)Private Sector Approaches to Improving Bangladesh Drug Quality.
- 14. Chowdhury A.I., (2000), Consumer Behavior School of Business, Bangladesh Open University, pp. 1-13._
- 15. DeCenzo D.A., Robbins S.P. (2005) Human Resource Management Seventh Edition, John Wiley & Sons , Inc.pp.34-45._
- 16. DiMasi J.A.(2000), "New Drug Innovation and Pharmaceutical Industry Structure" "Trends in the output of Pharmaceutical Firms" Drug Information Journal, Vol. 34pp.1169-1194.
- 17. Gehl Sampath P (2007), "Intellectual Property and Innovation in Least Developed Countries": Pharmaceutical, Agro-Processing and Textiles and RMGin Bangladesh.