

A Report on Pharmaceutical Industry of Bangladesh

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1. Introduction

The pharmaceutical sector is one of these sectors which Bangladesh can be proud of. 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 30,000 million per year of which about 98% of the total requirement of medicines is created by the local companies and the rest 2% is imported. The imported drugs mainly comprise of the cancer drugs, vaccines for viral diseases, hormones etc.

In fact, the real growth of local pharmaceutical industries started after the "Drug Control Act" was promulgated in 1982 in Bangladesh to restrict massive import of drugs and to encourage local manufacturing of the same. A lot of multinational companies (MNCs) became unhappy for this development.

2. Historical Background of Pharmaceutical Industry

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 life- saving medicines.

Characteristic:

- ❖ This sector started to improve from 1980s. The pharmaceutical industry has grown in the last two decades at a considerable rate.
- 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 98 per cent of the domestic demand for medicines.

3. Market Overview

At present, Bangladesh's pharmaceutical industry is effectively exporting their products to 87 countries. Bangladesh's pharmaceutical products in every way, meet international standard.

Actual growth of pharmaceutical industry in the country started in 1982, when the Drug Control Ordinance was promulgated. The restriction of disproportionate import of drugs encouraged local companies to increase production of their own products. Although this displeased the multinational companies those were importing medicines to Bangladesh, the regulation accelerated growth of local companies.

Skillful attitudes, knowledge and innovative ideas from the professionals were the key reasons why this industry grew in the way it did. After 1990s, some of the companies started producing insulin, hormones and cancer combating drugs those were not previously produced in the country. Many smaller companies are on the verge of entering highly regulated overseas markets.

Although Bangladesh's pharmaceutical sector is developing at a persistent rate, they have to strive to endure this speed. The future of the industry surely is very bright. However, in order to enhance their global and local image, the industry must overcome every future obstacle and preserve their position in the top list.

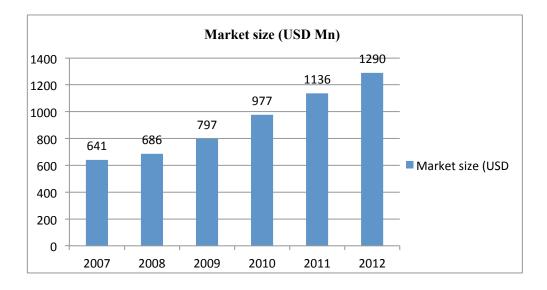
4. Market size:

- In 2012, the total size of the pharma market of Bangladesh was estimated to be Tk. 100 Billion.
- Annual growth rate of about 15%, Bangladesh Pharmaceutical Industry is now heading towards selfsufficiency in meeting the local demand.
- Bangladesh pharmaceutical industry is the second highest contributor to the national exchequer after garments.
- It is the largest white-collar intensive employment sector of the country.
- There are about 450 generics registered in Bangladesh. Out of these 450 generics, 117 are in the controlled category i.e. in the essential drug list. The remaining 333 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 80%, while the MNCs are having a market share of 20%.Out of the top ten pharmaceutical companies in Bangladesh; eight are local pharmaceutical companies, while only two are MNCs. The top two domestic manufacturers, namely Square and Beximco Pharma are having a combined market share of about 25% of the total pharmaceutical market of the country.

The Bangladesh Association of Pharmaceutical Industries – 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 listed at Annexure-I) as its members.



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	INDUSTRY AT A GLANCE			
Industry Size - 2012	(BDT	API & Raw Materials	21	
Bn)				
Domestic Market	94.04	Finished Formulations	267	
Export	5.40	Industry Depth		
Export Destination (Countries)	87	API	41	
Industry Growth	(%)	Branded Generics	8000	
2012 Growth	11.90%	Brands	22913	
CAGR (2008-2012)	17.10%	Market	Structure	
		Concentrated		
Market Leader		Share	Market	
SQUAREPHARMA	18.63%	Top 5	46.25%	
		Top 10	68.21%	

Source: Export Promotion Bureau of Bangladesh, 2013.

5. Raw Material & Machinery Sourcing

Bangladesh imports 80 per cent of its pharmaceutical raw materials. A good number of skilled professionals from home and abroad are expected to join the industry to enrich its human resource pool. The pharmaceutical manufacturers in Bangladesh procure raw materials from various countries namely USA, UK, France, Germany, Japan, Netherland, Italy, Denmark, China, Switzerland, Austria, Hungary, India, Ireland etc.



Most of the machinery comes from Germany and China. Some of the bigger companies are using machinery from

UK.

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.

<u>The Pharmacy Council of Bangladesh (PCB)</u>: 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 Common wealth 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.

6. Local Market Overview

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



- Bangladesh pharmaceutical industry is mainly dominated by domestic manufacturers. Of the total pharmaceutical market of Bangladesh, the local companies are enjoying a market share reaching around 98%, while the MNCs are having a poor market share.
- Out of the top ten pharmaceutical companies in Bangladesh, all are local pharmaceutical companies. The
 top two domestic manufacturers, namely Square and Incepta Pharma are having a combined market share of
 more than 30% of the total pharmaceutical market of the country.
- Bangladesh Association of Pharmaceutical Industries (BAPI) was instituted in 1972, since then BAPI playing a pivotal role in shaping up the industry. Association's member include large, medium, small, national and foreign companies who together are responsible for manufacturing the country's pharmaceutical production.

Here are the names of the market players of pharmaceutical companies of Bangladesh:

- 1) Square Pharmaceuticals
- 2) Incepta Pharmaceuticals
- 3) Beximco Pharmaceuticals
- 4) Opsonin Pharma
- 5) Renata
- 6) Eskayef Bangladesh
- 7) ACI
- 8) Acme Pharmaceutical
- 9) Aristopharma Drug International
- 10) Sanofi-Aventis Bangladesh Ltd
- 11) GlaxoSmithKline(GSK) Bangladesh Limited
- 12) Orion Pharma Ltd
- 13) Novo Nordisk
- 14) Healthcare Pharmaceuticals Limited
- 15) General Pharmaceuticals Ltd
- Sandoz (generic pharmaceuticals division of Novartis)
- 17) Popular Pharmaceuticals Ltd. (PPL)

- 18) Novartis (Bangladesh) Limited
- 19) IBN SINA Pharmaceutical Industry Ltd. (IPI)
- 20) Nuvista Pharma Limited
- 21) UniMed UniHealth Pharma Ltd
- 22) Sun Pharmaceutical (Bangladesh) Ltd
- 23) Globe Pharmaceuticals Ltd
- 24) BIOPHARMA Ltd
- 25) Roche Bangladesh Ltd
- 26) Radiant Pharmaceuticals Ltd
- 27) Pacific Pharmaceuticals Ltd
- 28) Jayson Pharmaceuticals Ltd
- 29) BEACON Pharmaceutical Limited
- 30) Social Marketing Company (SMC)
- 31) Orion Infusion Ltd
- 32) Kemiko Pharmaceuticals Ltd
- 33) NAVANA Pharmaceuticals Ltd
- 34) Delta Pharma Ltd
- 35) Servier Bangladesh
- 36) SOMATEC Pharmaceuticals Ltd



37) Rangs Pharmaceuticals Ltd

39) ALCO Pharma Ltd

38) Libra Pharmaceuticals Ltd

7. Job Opportunities

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

8. Market Flashback: Year 2012

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

9. Current Market Review



In Bangladesh, pharmaceutical is now one of the fastest growing sectors. In 2013, the total size of the pharmaceutical market of Bangladesh was estimated to be approximate Tk. 101 Billion. With an annual growth rate of about 15 %, Bangladesh Pharmaceutical Industry is now self- sufficient in meeting the local demand. Bangladesh pharmaceutical industry is a contributor to the national exchequer, and it is the largest white-collar intensive employment sector of the country.

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

Total Market: 101,685,403,612 BDT

Annual Growth: 15%

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

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

Source: Export Promotion Bureau of Bangladesh, 2013.

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

Table: 1. Top Ten Brands (December, 2013; IMS)



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

10. Multinational Pharmaceuticals in Bangladesh

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

Table: 2. Top Five MNCs

S/l	Name of The Company	Market Size	Market	Growth (%)
			Share (%)	
1	Novo Nordisk	2,083,257,490	2.05	-5.85
2	Sanofi Aventis	2,032,579,187	2	-6.38



3	Glaxosmithkline (GSK)	1,694,068,206	1.67	4.43
4	Novartis	1,373,449,983	1.35	9.16
5	Roche	709,712,519	0.7	8.66

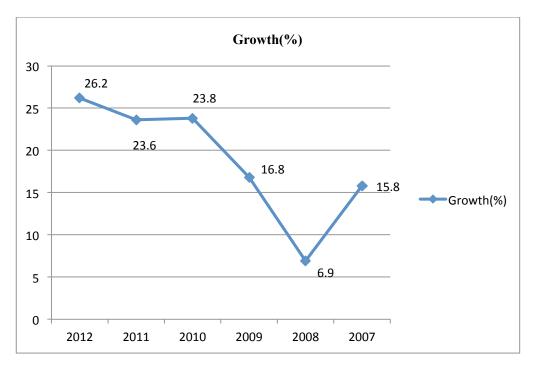
11. Growth of pharmaceutical Industry in Bangladesh

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

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

Source: BAPI, 2013





12. Drug Quality of Bangladesh

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

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

The International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR, B) tested the zinc content in 20 zinc-syrup formulations marketed in Bangladesh. The samples were purchased from local pharmacies in Dhaka. Only two of the tested products contained zinc concentrations within 5% of the stated content. The rest contained zinc, just not enough. The problem could have originated from either poor manufacturing or poor product handling in the distribution channel, because zinc degrades if exposed to light.

Of eleven drugs UNICEF sent for testing to a laboratory in Australia, two had substandard results. When the manufacturers were informed, one company immediately stopped production until it found the problem—a very good response. The other company however, refused to address the problem, claiming that the test was in error. UNICEF sent the drug for a second testing to a lab in Denmark where the drug was also found substandard. The company still refused to address the issue.

Some Bangladeshi firms have invested in quality raw materials, manufacturing processes and environment, and technical know-how. However, a "perverse incentive" exists against upgrading due to the weak regulatory structure. Firms that have invested minimally in quality continue to sell drugs alongside those that have invested substantially. Because of weak regulations, the consumer cannot determine quality differences and select for purchase the superior product. As a result, firms that have invested in quality manufacturing and quality processes are in a sense penalized.

13. 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, Injectable, 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.

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

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		

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2008/09	46	0.3
2009/10	41	0.3
2010/11	44	0.2
2011/12	48	0.2

Source: BAPI, 2013

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.

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

14. Investment opportunity

During last couple of years a good number of investments have taken place in the pharmaceutical sector in the form of facility expansion/upgrading and new entrants. It is estimated that a total investment of US\$ 300 million has been made in this sector in last few years. Bangladesh is also a large market for Active Pharmaceutical Ingredients (API) and intermediates. Although Bangladesh is meeting 98% of the countries demand by local production it still depends largely on imported bulk drugs. Around 80% of Bangladesh's total need of API is being met through imports.

Japanese NIPRO Corporation gets into Bangladeshi drug market:

World renowned medical, pharmaceuticals and life-saving healthcare company NIPRO Corporation Japan embarks upon its business in Bangladesh with a vision to manufacture high- tech appliances for health sector and help produce quality drugs in an increasingly dynamic pharmaceutical market. Japanese NIPRO Corporation and Bangladeshi JMI Group will merge in a 51:49 per cent share company taking the name NIPRO JMI Pharma with the Japanese counterpart investing US\$ 23 million (Tk 1.7 billion).

Source: Financial Express (VOL 20 NO 354 REGD NO DA 1589 | Dhaka, Wednesday March 14 2012)

15. Future opportunities

Healthy growth is encouraging the pharmaceutical manufacturers towards research and development for newer generics of quality drugs at affordable prices. The latest addition in this segment is the introduction of human vaccines, which were previously imported products. Now we are capable of meeting 100 % of the local demand and also exporting even to stringently regulated countries of the world.

Moreover, a high-tech insulin manufacturing plant has started operation to meet the country's growing demand. The pharmaceutical industry is trying to export to 120 countries. The pharmaceutical sector is the highest contributor to the national exchequer, along with being the largest white-collar employment sector of the country.

The pharmaceutical companies are now on the verge of entering highly regulated markets like

- > USA,
- > EU,

- > Australia and
- > GCC countries, and
- ➤ Have already obtained accreditation from USFDA, UKMHRA, TGA and GCC.

In addition to export there is a great opportunity for contract manufacturing and compulsory licensing within the LDC's of the Asia-Pacific and Africa regions.

The most important factors are drugs quality control and quality assurance from the manufacturer. The DGDRA Bangladesh is playing the key role in inspecting the WHO GMP and SOP of the pharmaceutical manufactures and enrolling the certifications for subsequent two years validity from the date of inspection.

The creation of Active Pharmaceutical Ingredient (API) is one of the most significant parts of the pharmaceutical industry as a whole. The government has taken substantial initiatives to establish this industrial park at Gazaria; Munshiganj by 2013. It would be a giant step in strengthening the pharma industry as at the moment 80% of raw materials are being imported from India/China.

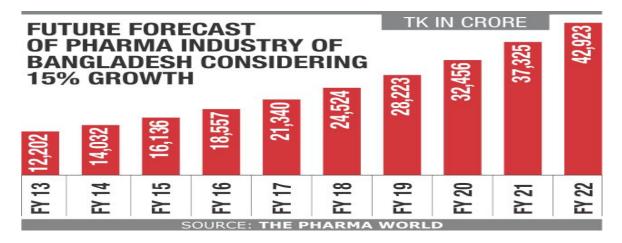
Bangladesh has a long way to go though there is huge potential in pharmaceutical manufacturing and international marketing.

The Bangladesh pharmaceutical sector has an opportunity to establish itself as a high volume export-oriented industry close to RMG sector.

16. Pharmaceutical Export of Bangladesh after 2016

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





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

17. Conclusion

The pharmaceutical sector has already been declared as the thrust sector by the government of Bangladesh. Bangladesh has built a strong baseline and going towards the self-sufficiency for the production of medicine. Meanwhile, some companies have started to produce vaccine, insulin, anticancer drugs, etc. Our pharmaceutical industries are successful in domestic market. Now, it's the time to grow our international market because we passing golden time getting the opportunity of patent exemption by the TRIPS until 2016. Besides the above discussing points, providing cash incentive by the govt. to the medicine exporters, like RMG may encourage pharmaceutical exporters. International fair arrangement by Export Promotion Bureau (EPB) is a very effective way to search buyers and to establish business in a new country. A lot of initiative have been taken by BAPI in different times, such as, high level pharmaceuticals delegation team visited

foreign countries to explore export initiated by BAPI. This organization also upheld the demand and urged to the government and other concerning authorities for API Park, Bioequivalence test laboratory, Central drug testing laboratory, cash incentives, problems in remit transfer and sample sending etc. But many issues are yet to resolve. We have already wasted our valuable time and still losing to build our infrastructure for export. We should complete our infrastructure as soon as possible because TRIPs patent protection may be adapted 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.