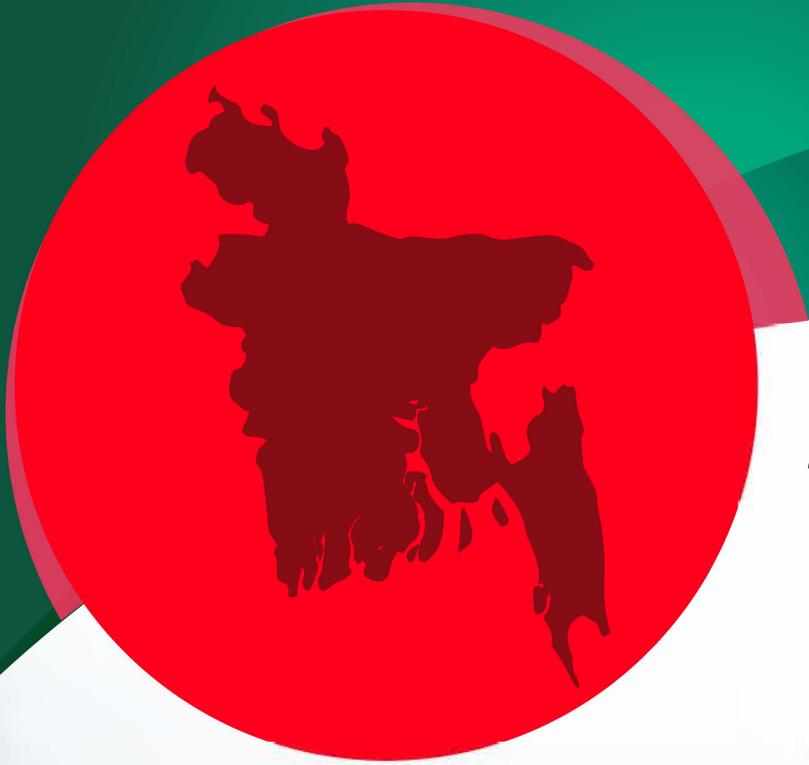


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Opportunities and Challenges of the Pharmaceutical Sector in Bangladesh

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Abstract

Pharmaceutical sector is one of the most developed sectors in Bangladesh contributing to the country's economy. With an annual turnover of around BDT 840 million (as on 2011), this is one of the fastest growing sectors in the country. Among the 49 least developed countries (LDCs), Bangladesh is the only country that is nearly self-sufficient in producing pharmaceutical products. This sector started flourishing after the 70's and its growth rate is remarkable. As a least developed country, Bangladesh is getting the benefit of producing and marketing drugs in TRIPs-related patent regimes. As this period is going to expire in 2016, a serious threat is looming for Bangladesh. The study used primary survey data collected from fifty one participants related to the pharmaceutical industry (physicians, manufacturers, pharmacists, sales persons and other stake-holders). Secondary data available from websites, books, newspaper and journals have also been used. This paper highlights the present scenario of the pharmaceutical industry in Bangladesh, emerging opportunities and the probable challenges it faces. The findings are expected to help potential investors and stake-holders of the pharmaceutical companies in Bangladesh.

1 Introduction

Pharmaceutical sector is one of the most developed and self-sufficient industries in Bangladesh, maintaining double-digit growth rate over the last few years. The industry tends to experience fairly steady demand and is less sensitive to changes in the business cycle because of the nature of its end-products. Companies in the sector are mainly affected by competitive market shares, diversified product lines, new product innovation, cost efficiency, pace of approvals from internationally recognized authorities, and the strength of research and development. With a history since 1950s, the industry has become one of the most successful manufacturing industries in the developing countries (Attaran 2004, Azad 2009, Chowdhury 2010, Nazmul, Mazharul and Anzir 2011, Nimalathasan 2009, Sampath 2008, Shafiuzzaman 2002).

Pharmaceutical industry in Bangladesh is contributing around 1% of GDP. There are 265 licensed pharmaceutical companies in Bangladesh among which 150 are actively in operation. The sector is highly concentrated as the top 20 companies constitute 85% of the total market. The pharmaceutical companies focus mainly on branded generic final formulations, produced from imported APIs (Active Pharmaceutical Ingredients). Generic drug is a product that is comparable to brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use

(<http://en.wikipedia.org>). About 85% of the drugs sold in Bangladesh are generic drugs and the rest are patented drugs.

Bangladesh manufactures roughly 1,300 generic drugs of various registered brands. These generic drugs have different dosage forms and strengths. The wide range of generic drugs includes anti-ulcerants, fluoro-quinolones, anti-rheumatic non-steroid drugs, non-narcotic analgesics and so on. The industry now caters to 97 percent of the country's pharmaceutical needs. The remaining 3 percent includes insulin, vaccines and high-end anti-cancer drugs, the production of which is capital intensive and therefore not economically feasible for Bangladesh.

2 Objectives of the Study

The objectives of this research are as follows:

1. To provide a comprehensive overview of the pharmaceutical sector in Bangladesh.
2. To assess the market share of top pharmaceutical companies, their cost structures and profit margin.
3. To discuss TRIPs and its implication for Bangladesh.
4. To evaluate the opportunities and prospects of the pharmaceutical sector.
5. To study the challenges pharmaceutical companies are presently facing.

6. To recommend probable solutions to overcome the challenges.

3 Scope

The scope of the study is mainly concerned with the domestic pharmaceutical companies in Bangladesh. There are 265 such pharmaceutical companies listed with the Directorate of Drug Administration (DDA). To obtain the overall picture about the sector, these 265 companies were considered. Some multinational companies currently operating in Bangladesh were also taken into consideration. However, the main focus was on the top ten companies about which detailed information was collected and analysis performed.

4 Methodology of the Study

The research design adopted is descriptive in nature and involved data collection about the characteristics of the pharmaceutical market, competitors, as well as the different manufacturers. Primary data was collected directly and from telephone interview with fifty one officials and stakeholders engaged in the top ten pharmaceutical companies. While interviewing, both structured as well as un-structured questionnaire have been used. Secondary information was gathered from websites, newspaper articles, journals and annual reports of different pharmaceutical companies. Online sources have also been used to carry out the study.

5 Limitations

Every research study encounters some obstacles and constraints. These obstacles can be addressed in future studies related to this work. This study has the following limitations:

1. Many of the pharmaceutical company professionals could not provide data due to company rules.
2. Other than the listed companies, the price sensitive information like total sales, gross profit, and net profit were not available. It would have been better if exact sales, operating expense, profit margin of the companies could be compared.

6 Market Size and Growth

Shown in Figure 1 and Table 1, the retail market size of pharmaceutical companies has reached BDT 840 billion as on 2011 according to Integrated Marketing Services Ltd. (IMS) report 2012. The report further indicated that net turnover achieved 23.6% growth in 2011, following 23.8% and 16.8% growth in 2010 and 2009 respectively.

High growth in the last three years indicates a positive outlook for this sector. Although the IMS does not include the rural market in this survey, the actual size will vary slightly. It was estimated that the retail market represents 90% of the total market.

7 Major Players in the Pharmaceutical Sector

According to the data (Table 1), Square Pharmaceuticals is the market leader in the pharmaceutical sector holding 18.7% (as on 2011 data) of the market share, followed by Incepta Pharmaceuticals (9.3% market share), Beximco Pharmaceuticals (8.8% market share), Opsonin Pharma (5.1% market share) and Renata (4.9% market share). The top 5 pharmaceutical companies held 46.8% market share in 2011 among which three are listed with the Dhaka Stock Exchange (DSE) and the Chittagong Stock Exchange (CSE). Table 1 shows the market size, market share and growth of the top pharmaceutical companies:

8 Cost Structure and Margins of the Pharmaceutical Companies

Production cost is around 45%–55% for the pharmaceutical companies depending on the products they produce which results in 55% to 45% in gross profit margin for most of the companies (Figure 2). As nearly 70% of the raw materials (API) are imported from outside the country, this accounts for most of the cost. The rest are conversion and other supporting costs. Operating cost is roughly 24% of sales for the top pharmaceutical companies. The tax rate for the pharmaceutical companies is 37.5%, but it is 27.5% for the listed companies. Listed companies further enjoy 10% rebate for paying out more than 20% dividend. Operating margin is hovering around 15%–25% and the net profit margin is around 15% for the top pharmaceutical companies. However, average net profit margin is roughly 7% for other small companies in the sector. Figure 2 shows the financial indicators in details.

9 Trade Related Intellectual Property Rights (TRIPs)

Intellectual property rights were brought into the GATT/WTO framework for the first time in the Uruguay Round of negotiations (Yusuf, 2006). The TRIPs agreement permits Bangladesh to reverse-engineer patented generic pharmaceutical products to sell locally and export to markets around the world. Article 66 provides Least Developed Countries (LDCs) with breathing space before introducing full product patent protection. Bangladesh

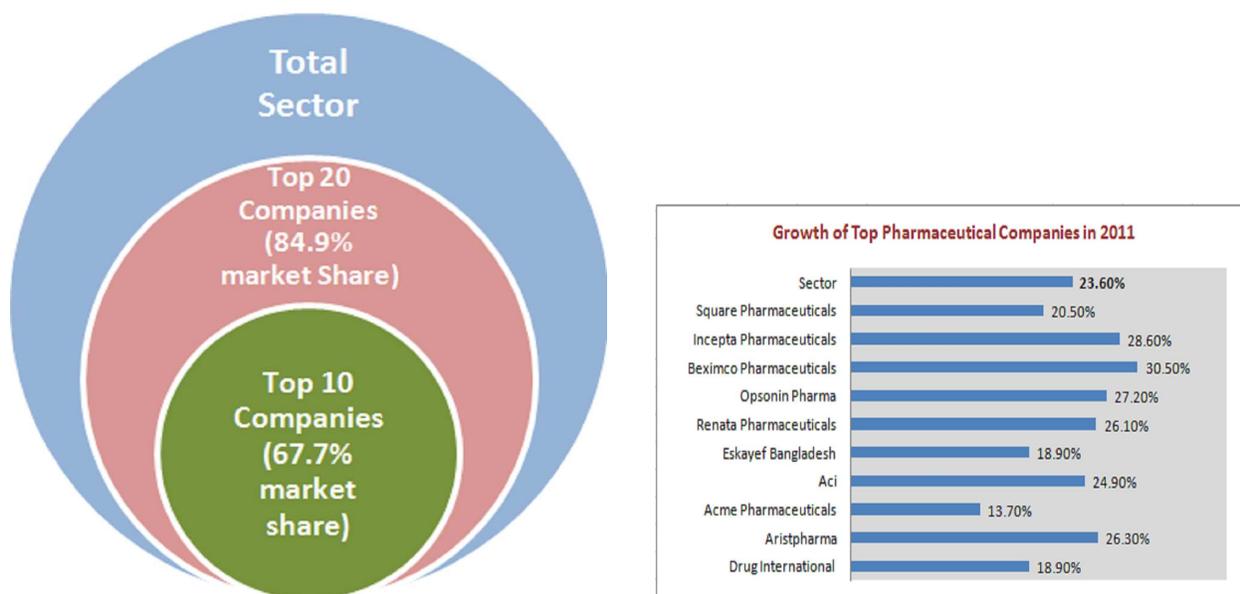


Figure 1: Market size and growth

Table 1: Market share of the top pharmaceutical companies

Company	Market Size (BDT million)	Growth in 2011 (%)	Market Share in 2011 (%)	Market Share in 2010 (%)
Square Pharmaceuticals	15,725.8	20.5	18.7	19.2
Incepta Pharmaceuticals	7,851.5	28.6	9.3	9.0
Beximco Pharmaceuticals	7,415.0	30.5	8.8	8.4
OpsoninPharma	4,275.4	27.2	5.1	4.9
Renata Pharmaceuticals	4,076.8	26.1	4.9	4.8
Eskayef Bangladesh	3,980.3	18.9	4.7	4.9
ACI	3,578.2	24.9	4.3	4.2
Acme Laboratories	3,500.7	13.7	4.2	4.5
Aristo Pharma	3,412.8	26.3	4.1	4.0
Drug International	3,070.2	18.9	3.7	3.8
Top 10 Companies	56,886.5	23.6	67.7	67.7
Top 20 Companies	71,382.5	24.1	84.9	84.6
Other Companies	12,661.6	20.7	15.1	15.4
Total Sector	84,044.1	23.6		

Source: World bank, Top pharmaceutical company websites, IMS report

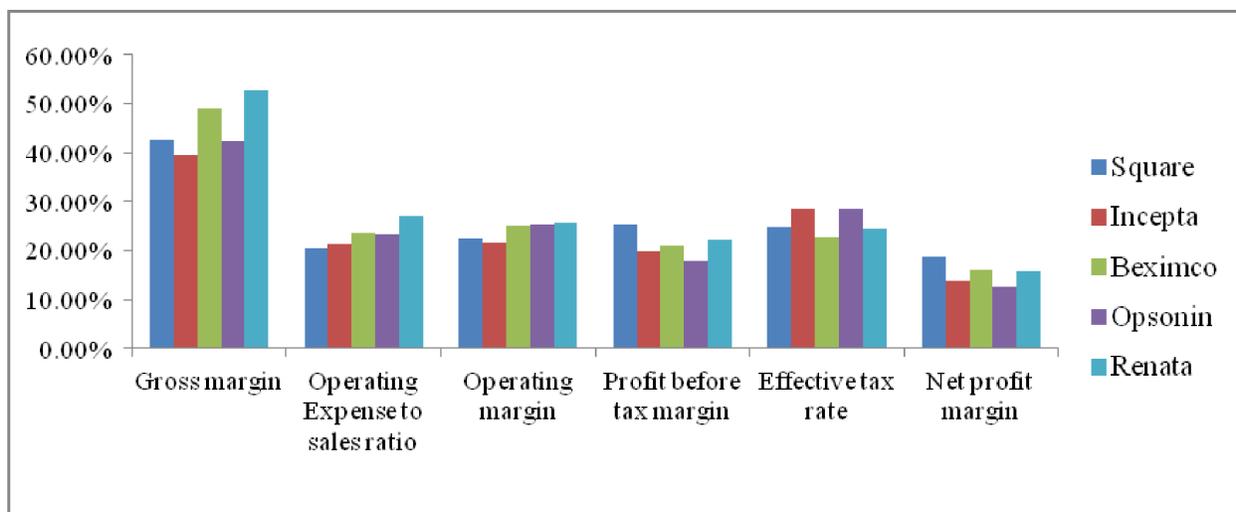


Figure 2: Financial indicators of the top five pharmaceutical companies

is therefore exempt until 2015 from patent protection on reverse-engineered generic products destined for the local market.

Bangladesh also enjoys some advantages from TRIPs in exporting pharmaceutical goods:

- Bangladesh can export generic drugs to markets where the patent owner has not filed for protection (Most drugs on *WHO's Model List of Essential Drugs* are not patented).
- Bangladesh can export to other LDCs or non-WTO members which have not implemented product patent protection, for example Myanmar.
- Bangladesh can also export to a country which has issued a compulsory drug license and awarded the production contract to Bangladesh.

The cost of importing APIs will most likely rise as TRIPs phases in. In case the TRIPs agreement is not extended beyond 2015, the local manufacturer will face a number of constraints:

- Import costs of patented APIs are likely to increase.
- The cost of manufacturing patented drugs will also increase as the companies are likely to pay royalty to the original manufacturer.
- Export of patented products will become costly.

10 Strategies for the Future (After 2015)

The strategies after TRIPs waiver period may be classified into micro and macro approaches. The strategies may seem a bit costly at the beginning but it is designed to benefit the sector as a whole.

Micro approaches: The micro approach focuses on the industries within the geographic boundary of Bangladesh. The strategies are designed to ensure strengthening of management of pharmaceutical operations and decreasing the equity disparity arising out of implementation of TRIPs.

Macro Approach: The macro approach is based on strategies that can be undertaken by utilizing the strengths of the regional countries, especially the developing countries. It may be mentioned that the only way to fight the competition from the developed world is by uniting the developing world to address the needs of the pharmaceutical sector.

However, it is expected that WTO will consider extending the TRIPs waiver period an additional 10 years. The WTO Director General, Pascal Lamy, while visiting Beximco Pharmaceuticals on April 1, 2012 commented, "WTO will examine whether Bangladesh needs a waiver as the country is graduating out of the LDC status. Bangladesh's economy is growing more than the world average and so far the country is on the right track. Still the waiver period may be extended on the ground of public health and technology transfer issues." (www.thefinancialexpress-bd.com, 2012)

11 Opportunities of the Bangladesh Pharmaceutical Industry

The pharmaceutical sector in Bangladesh has immense potential and can grow more rapidly in the coming years. There are a number of factors which are contributing to this phenomenal growth as shown in Table 2.

Population growth rate: Bangladesh's population growth has been on a steady increase since its birth. A direct correlation has been observed between the country's pharmaceutical sector and the population growth. Holding other variables constant, pharmaceutical market is expected to witness a steady growth with the population growth rate. The large population base of Bangladesh makes it an attractive market for Pharmaceuticals sector players.

Health consciousness among people: Health consciousness among people has improved significantly in the last few years. Government of Bangladesh, as well as the NGOs has taken a commendable initiative to increase awareness among people in the rural areas. These initiatives are contributing positively to the pharmaceutical sector.

Per capita income: Per capita income is an indicator of the standard of living of a country. Bangladesh's real GDP is growing at around 6.2% over the last decade and per capita income is increasing at 11.3%. With improved living standard, per capita expense in health care is also increasing. This is contributing positively to the growth of the pharmaceutical sector.

Life expectancy, child mortality rate, and prevalence of chronic disease: Over the past few years Bangladesh's health status has improved substantially as child mortality rates have decreased and life expectancy has increased. But prevalence of chronic diseases is growing at a staggering rate due to increased levels of hypertension, diabetes, and obesity. Now-a-days, the percentage of total mortalities from communicable diseases and maternal/prenatal conditions has decreased, while mortalities from chronic diseases have increased. This creates greater dependence on the pharmaceutical products.

Emergence of a number of private healthcare services: A number of top class hospitals have started their operations in Bangladesh. They are becoming more popular for providing quality services and contributing to increased healthcare expenditures. The people who used to travel outside the country for medical treatment are now more comfortable about obtaining services from these hospitals.

Export to developed countries: Healthcare expenditures have increased significantly in the developed countries in the recent years. As Bangladesh is now producing world standard generic medicines, some of the developed countries have started importing medicine from Bangladesh. It is definitely a huge opportunity for our pharmaceutical sector. (www.koreatimes.co.kr, 2011)

New export destination: Abdul Muktaadir, Secretary General of Bangladesh Association of Pharmaceutical Industries (BAPI) indicated that the pharmaceutical industry plans to export drug items to all 120 destinations from the existing 84 countries that is soon to propel the industry's growth. He further stated that those days are not far off when Bangladesh would earn thousands of crores of takas from export of pharmaceutical products and this is possible in the next five to seven years (<http://www.bssnews.net>, 2011).

Local and foreign accreditation of top companies: The top pharmaceutical companies like Square, Beximco, Incepta, Renata and SK&F received the United Kingdom's Good Manufacturing Practice (cGMP) certificate in 2011. A few more companies also have applied for this certificate an hope to get it very soon. These certificates would not only help to increase the credibility of local medicines but also expedite Bangladesh's export to potential destinations.

Grabbing the international donor market: Pharmaceutical exports may see a massive boom in the coming days as the local producers are preparing to join the billion dollar medicine supply chain of different international charities. Global medicine donors like the Clinton Foundation, the Bill and Melinda Gates Foundation, Oxfam and other agencies every year donate drugs worth billions of dollars to poor countries. These charitable organizations have shown interest to import generic drugs from Bangladesh as the products are complying with WHO guidelines (www.thefinancialexpress-bd.com, 2011).

Commercial production of herbal medicine: Few of the top pharmaceutical companies (e.g., Square, Acme, IbnSina, and Radiant) have started producing herbal products. Few others like Renata are waiting to get approval from the Directorate of Drug Administration (DDA). As the side effects of herbal medicine are negligible, they are popular all over the world and their demand is increasing (<http://www.bonikbarta.com>, 2012).

12 Challenges Associated with Pharmaceutical Companies in Bangladesh

In spite of thriving and continuously maintaining double-digit growth rates, Bangladesh's pharmaceutical sector still suffers from a number of hindrances:

Most of the APIs used are imported: 70% of the APIs used for production of pharmaceuticals are im-

Table 2: Factors contributing to pharmaceutical sector growth

Health Indicators	2009	2008	2005	2000
Life expectancy	68.30	68.00	66.90	64.70
Govt. expenditure in health care services (%)	31.70	31.40	34.90	39.00
Health care expenditure in % of GDP (%)	3.35	3.32	3.21	2.82
GDP per capita (current US\$)	607.80	546.90	428.80	363.60
Poverty level (%)	31.50		40.00	48.90

Source: World Bank

ported. Although a few top pharmaceutical companies came forward to produce APIs in our country, yet the number is 22 up to September, 2012. The startup cost of API production is too high as each of the API molecules need separate establishment. However, the net profit margin from APIs is as high as 35% which may attract local companies.

Competition with drugs without license: The top pharmaceutical companies are producing drugs with approval from DDA. But many small producers don't care to take approval. They are especially active in the rural areas & selling medicines at lower price. The quality drugs producers have to face fierce competition with these companies (The Daily Inqilab, 2006).

Substandard products: Few small companies don't maintain quality during production of homeopathic, allopathic, ayurvedic and unani medicines. People living in rural areas being less conscious about quality are consuming these products (The New Nation, 2005).

Lack of supervision: Most of the pharmacies are not supervised frequently enough to ensure the quality of drugs sold there. It is alarming that out of 64 districts in Bangladesh, the DDA has no representatives in 39 districts to examine the quality of drugs being sold in the pharmacies (The Daily Ittefaq, 2006).

Capacity of Drug Administration: The DDA is responsible for registration of drugs marketed in Bangladesh and for inspection of premises and licensing. The DDA with its present set up and inadequate strength often finds it difficult to carry out the large volume of its assigned work. Drug testing laboratories (one in Mohakhali, Dhaka, and the other in Chittagong) are not properly equipped with skilled manpower and equipment to carry out their testing functions (The Daily Ittefaq, 2006).

Moreover, the pharmaceutical executives and pharmacists do not have enough training in assessing bioequivalence studies. In the absence of appropriate bioequivalence test facility, in-vitro study is done in Bangladesh (Yusuf M.

A., 2006). This in-vitro study is of no use when pharmaceutical companies want to have their products registered in the developed country markets.

13 Policy Implications

The present growth of the pharmaceutical sector can be expanded if some strategic measures are taken. To overcome the challenges of the sector as well as ensuring growth, the following strategies are recommended:

Development of the pharmaceutical sector: To exploit the TRIPs flexibilities, the local companies should be developed. Proper documentation, bioequivalence laboratory facility, more investment in research & development activities will improve the sector.

More facilities to establish API parks: Around 70% of the APIs used for pharmaceutical production is imported which incurs huge costs. This dependency can be minimized if the local companies start producing APIs. The government can provide more facilities for API producers which will eventually help the pharmaceutical sector.

Exclusive market right: The major companies should negotiate with patent holders for "exclusive marketing rights" for a stated period which may initially cause a certain degree of price increase but will provide benefits in the long run. Joint ventures, trade licensing, product licensing, etc., have already started which can be expanded on a priority basis.

Encouraging mergers in the local market: Mergers in the local market have become a need of the day. This will also ensure development of management capabilities, since the company will have to plan based on macro environmental forces.

Increased R&D activities: Joint R&D activity by the pharmaceutical companies with various universities and research laboratories should be initiated without delay. This will not only enhance the overall strength of the pharmaceuticals but will also develop the overall academic base of the universities,

and thus open up a new horizon for management of the pharmaceutical companies.

Promotional activities in different destinations:

Promotional activities of our pharmaceutical companies should be increased. The potential buyers should clearly know about our competitive advantages. Our world-class quality at significantly lower prices should be highlighted. This will certainly improve exports further which are already growing fast.

14 Recent Initiatives

Fiscal budget 2012–13: Several measures have been taken in the budget of 2012–13 to help the pharmaceutical companies in Bangladesh:

- Import duty on machineries for pharmaceutical industries (air handling unit and air conditioner) have been reduced sharply to 3% from 152%.
- Import duties on streptokinase and insulin pens have been waved.
- Import duty and taxes on 46 essential items for the pharmaceutical industries have been reduced to 29% from 59%.

Tax reduction on capital machineries will attract new pharmaceutical companies to establish business as well as encourage the existing firms to expand capacity and product lines. With significant incentives in importing raw materials, pharmaceutical companies are expected to maintain sustainable growth and increase margins in the coming days.

Getting new boost to recent export policy: Drug makers in Bangladesh will soon be able to send samples worth up to \$60,000 annually to prospective buyers overseas. The amount, twice the current limit, has been suggested in the export policy proposed for 2012–15 to boost pharmaceutical exports (The Daily Star, 2012).

15 Conclusion

Pharmaceuticals are vital to Bangladesh's healthcare sector and represent one of the most important sectors of the manufacturing industry. The sector is almost self-sufficient as 97% of the total demand is met by the local manufacturers. Yet 70% of the raw materials (APIs) used in the pharmaceutical sector are imported. Few of the local companies have started producing APIs though very little in quantity compared to the total demand. The pharmaceutical sector has huge potential to export as the developed countries have showed interest to import generic

drugs from Bangladesh. Few of the top local firms have obtained accreditations from USA, UK and Australia; a few others are waiting in the wings. Almost all the firms are upgrading their facilities and taking precautions for the post-2016 scenario, while aggressively expanding in both local and export markets. Though the TRIPs stipulations and dependence on imported raw materials have been challenging to the sector, the pharmaceutical companies are trying to develop quality products. The Government of Bangladesh, regulatory authorities, and stakeholders should come forward to help this promising sector.

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