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PHARMACEUTICAL INDUSTRY OF BANGLADESH



Pharmaceutical Industry of Bangladesh

A. Industry Classification:

International Standard Industrial Classification	Code
Manufacture of pharmaceuticals, medicinal chemical and botanical products	210
• Manufacture of pharmaceuticals, medicinal chemical and botanical products	2100

B. Industry Analysis:

Introduction:

Bangladesh is a country of emerging economy. The reason of the country's rising economy is high growth rate of industrialization and investment in different sectors. One of them is healthcare sector. Pharmaceuticals industries are the heart of this sector. The Pharmaceuticals industries have grown and developed surprisingly in the last two decades. During these decades pharmaceutical sector achieved an exalted position in international and domestic market. Pharmaceutical companies fulfill more than 97% of local demand of medicines and about 30 companies export a significant quantity of medicines to 107 countries, including Germany, USA, France, Italy, UK, Canada, Netherlands and Denmark. International regulatory authorities like UK-MHRA, Australia-TGA, EU have already certified some pharmaceutical companies and soon some others are going to be certified and approved by US-FDA. In case of earning foreign currency, pharmaceutical sector has become the 2nd largest potential sector of Bangladesh and this sector's contribution to the GDP is growing rapidly.

History:

Prior to the Liberation war of 1971 there was hardly any pharmaceutical company in Bangladesh, even after the liberation war the new government could not allot enough budget for health sector and the sector was prominently dominated by Multi-National Companies. The MNCs possessed more than 75% of market share and some 133 local companies controlled rest of the market share. The sector started to improve from the 80s and has grown in the last two decades at a considerable rate. The National Drug Policy (NDP) in 1982 and 2005 has prime influence in the prosperity and outgrowth of the Bangladesh pharmaceutical industry. After the annunciation of Drug Control Ordinance - 1982, the sector started to expand vertically. As the local Pharmaceutical companies were the beneficiary of NDP, they started to expand their business. Meanwhile, the MNCs sold their business shares to local companies. According to the Directorate General of Drug Administration (DGDA), the market share of the locally produced drug was 175 crore in 1981 that increased to 325 crore by 1985.

Industry Overview:

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. 20 years ago, 75% of the drugs needed to be imported. Now, only 2% of the drugs are imported, the remaining 98% come from local companies. Since the promulgation of Drug Policy in 1982, the sector has grown from BDT 1730 mn to more than BDT 113 bn (\$1.5 bn). 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. 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. According to IMS report of 2014, the total size of the pharmaceutical market of Bangladesh is estimated to be approximate Tk. 113 bn. With an annual growth rate of about 11.37 %, 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 employing around 115,000 workers.

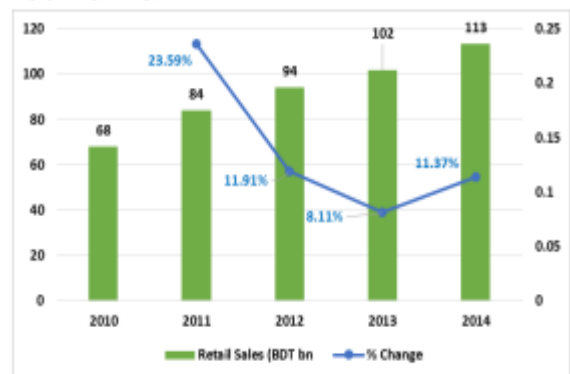
Raw Materials & API Sector:

While the pharmaceutical industry is achieving self-sufficiency, it yet procures 90% of raw materials from 98 indenters around the world as only one company (Active Fine Chemicals) produces raw materials independently. There are 3000 valid sources of raw materials including countries like China, India, Korea & Italy. API consists a significant percent of total cost in medicine which can run up to 30-40%. At present, only a few companies – Square, Beximco, Ganasastha Pharmaceuticals, Globe and Active Fine – are manufacturing raw materials for drugs like paracetamol, amoxicillin, flucloxacillin, ampicillin and metformin, on a limited scale. Ganashastha Pharmaceuticals Limited (GPL) alone accounts for about 60% of the raw materials manufactured in Bangladesh. Bangladesh is trying to establish an industrial park for pharmaceutical production. One such park in Munshiganj near Dhaka is nearing completion and it might result in a big jump in the income from pharmaceutical exports. A National Control Laboratory Project is taken by the govt. for facilitating the pharmaceutical sector. The proposed API technology Park in Munshiganj, which was scheduled to be completed by July 2012, is delayed with the cost of the project now increasing by 55%. This delay has been a major hurdle for the pharmaceutical industry to gain better control over the inputs and improve operational efficiencies. India, the major generic drug player, has more than 3500 Drug Master File (DMF) approval for APIs whereas we have none.

Local Sales:

Annual pharmaceutical sales are likely to hit \$2 billion by 2018, riding on increasing demand for good-quality medicine, according to a study by IMS Health, a leading global information and technology service provider to healthcare and life sciences industries. Pharmaceutical sector local market Sales rose by 11.37% in 2014 to BDT 113 billion due to increased medical coverage of the population & easy access to Health Care Services because of strong distribution network. According to IMS Health, Annual Pharmaceutical Sales in the Local Market are likely to hit BDT 160 billion by 2018. Sales of Square (the market leader) in 2014 was BDT 21 billion followed by Incepta with Sales amounting BDT 12 billion & Beximco with Sales of BDT 10 billion Taka.

LOCAL SALES:

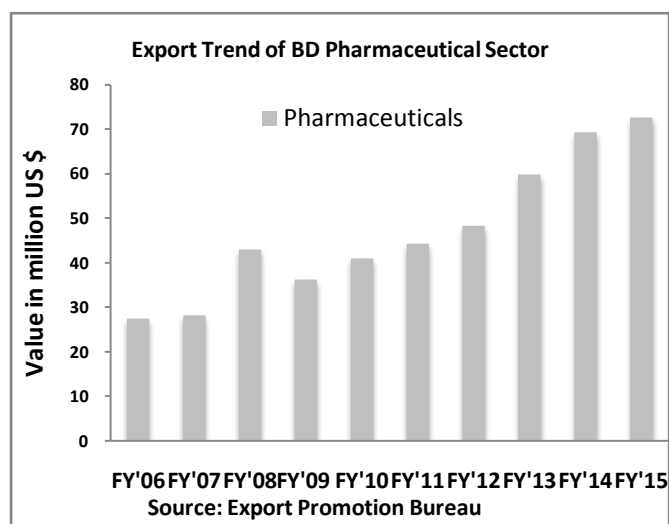


Source: IMF 4th quarter report

Export Performance:

Bangladesh exports about 500 pharmaceutical items, including active pharmaceutical ingredients and a wide range of pharmaceutical products covering all major therapeutic classes and dosage forms, to about 100 countries. Bangladesh Pharmaceutical Industry exports a wide range of products covering all major therapeutic classes and dosage forms to 92 countries. The major destinations for Bangladeshi medicines are now Myanmar, Sri Lanka and Kenya while nearly 50 countries import Bangladeshi Pharmacy products regularly.

Beside regular forms like; Tablets, Capsules & Syrups, Bangladesh is also exporting high-tech specialized products like HFA Inhalers, CFC Inhalers, Suppositories, Nasal Sprays, Inject able, IV Infusions, etc. 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 equivalent to any international standard and have been



accepted by them. In the fiscal year 2016 (Up to December) total export from pharmaceutical sector is 43.09 million US Dollar. Pharmaceutical exports rose 11.02 percent year-on-year to \$26.7 million in July-October, according to the Export Promotion Bureau. In 2014, the global pharmaceutical export market was estimated to be worth more than \$520 billion. According to EPB in the fiscal year 2015 total pharmaceutical export was \$73 million; in FY2014 it was \$69.24 million.

Market Share:

According to IMS-Health, the top 10 players took 68.1% of the market. Companies ranked 11th to 20th took 17.50% of the market; the next 11 companies took 8.60% while the remaining 222 companies shared 5.8% among them. Square Pharmaceuticals led the industry with a market share of 18.70%. Incepta and Beximco took 2nd and 3rd positions with market shares of 10.4% and 8.5% respectively. Interestingly except for Square, Beximco, Renata and ACI, none of the other leading 6 companies in the top 10 are listed in the Dhaka Stock Exchange (DSE) or Chittagong Stock Exchange (CSE). Growth of Healthcare Pharma was highest in 2014 while Square had the least growth. Of the total pharmaceutical market, local companies are enjoying a market share reaching around 90%, while the multinationals are having a 10% share of the medicine-market. Out of the top fifteen pharmaceutical companies in Bangladesh only two are MNCs. Among the MNCs Sanofi has the highest market share while Novartis had the highest growth in the year (2014).

Regulations:

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 nonessential or harmful; and strict price controls, affecting some 117 principal medicines.

Government Initiative:

This sector has been considered as a thrust sector in the export policy since 2006. Customs duty on 40 basic raw materials used in medicine manufacturing were reduced to 5% from 10%-25% rate. Customs duty on 14 items used in anti-cancer medicines have been withdrawn. (Budget 2014-15). Government has been facilitating this industry through reducing customs duty on raw materials. The government recently gave 200 acres of land for the API Park in Munshiganj. It is also planning to give 10% cash incentives to boost the pharmaceutical sector. (Source: The Independent, 9 th January 2015).

Backward Integration:

Due to lack of backward integration, the sector is at a competitive disadvantage, as pharmaceutical players still have to import 90% of raw materials from 98 indenters around the world. Most APIs or their raw materials have to be imported from countries like China, India, Korea & Italy. This generates higher factor costs which can be up to 30-40% of the cost of medicine. At present, only a few companies – Square, Beximco, Ganasastha Pharmaceuticals, Globe and Active Fine – are manufacturing raw materials for drugs like paracetamol, amoxicillin, flucloxacillin, ampicillin and metformin, on a limited scale. Ganashastha Pharmaceuticals Limited (GPL) alone accounts for about 60% of the raw materials manufactured in Bangladesh. The API Park which was supposed to be established has been delayed due to various problems like rise in production cost, slow gas connection and slow handover. The manufacturers are also concerned about their capability to shift their entire production in the API Park. For many APIs, The domestic market is too small to justify an API manufacturing plant other than the reduction of cost. Although the companies have the technical knowledge to produce APIs, there is not enough demand in the market. This means that once the API Park is established, we would need to export the additional products abroad. Export channels need to be set up now.

Porter Five Forces Analysis:

1. Rivalry Among the existing Competitors:

This rivalry among firms usually takes the form of jockeying for position using tactics like price competition, advertising battles and product introductions. It can be intense if companies are scrambling for market share, but if the overall market is in growth or the position of the company is protected through patents, then the rivalry are likely to be less intense. Rivalry between competing departments from different companies may also be powerful due to limited patient's numbers and when the buyer is head office, they may be seeking the lowest price per patient. In our pharmaceutical Industry, here are high entry barriers due to costs associated with research & development of new drugs pharmaceutical industry. And the threat of entry posed by new or potential competitor is a LOW competitive force due to the above barriers & regulatory constraints.

2. Threat of new Entrants:

The pharmaceuticals industry is a highly attractive industry for potential new comers. New entrants into the industry affect the competitive dynamics and need to be taken in to consideration when analyzing the competition. New entrants see the market as attractive, they bring new capacity and resources, new ideas along with a desire to gain market share. Their impact depends on the barriers to entry already present, together with the anticipated reaction of existing competitors. There are many barriers that can be created to prevent new entrants or to slow down their arrival in the pharmaceutical Industry; a new entrant may be faced with various hurdles erected by established businesses, such as:

- ❖ Economies of scale – manufacturing, R&D, marketing, sales, distribution.
- ❖ Product differentiation – established products, brands and relationships
- ❖ Capital requirements and financial resources

- ❖ Access to distribution channels: preferred arrangements
- ❖ Regulatory policy: patents, regulatory standards
- ❖ Switching costs – employee retraining, new equipment, technical assistance.

3. Threat of Substitute Products:

Substitute products perform the same function as the product, and are a competitive force as they can take away demand or tie up those customers who choose to use the substitute instead of your product. The demand for generic versus brand name drugs has increased because the cost of drugs has increased because the cost of drugs is decreasing and general people can easily buy the drugs. In the market, there are some substitute products, like herbal medicine & homeopathic medicine, are available. As a result, the demand decreases. So the pharmaceuticals industry needs to introduce herbal medicine. Generic drug companies do not have the high cost associated with the research & development of new drugs and that to sell at cheaper prices.

4. Bargaining Power of Buyers:

In the pharmaceuticals industry, the buyers are the patients, the family members, the PBAC, the PBPA, the finance departments, the hospital boards, the tender boards, and the chief pharmacist along with a range of other buyers, depending on the specific business. Their influence needs to be considered. In various ways, buyers can affect a business by seeking price reductions, demanding higher quality and demanding better service. In short, buyers can exercise power by seeking price reduction and threatening to go to other suppliers to get their products. Powerful buyers demand costly service. The government requires an in-depth analyst that costs money, and customers require up-to-date and relevant medical information- another costly service. Hospitals & other health care organizations buy in bulk quantities and exert pressure on pharmaceutical companies to keep prices in check. Regular patients have lost bargaining power due to price increases in generic drugs.

5. Bargaining Power of Suppliers:

The bargaining power of suppliers is a rather marginal force in the pharmaceutical industry. The large pharmaceuticals companies are usually vertically integrated backwards and as such do not face strong threats from suppliers. For the majority of pharmaceutical products, raw materials supply is not a bottleneck. The exception is bio-technology and genome technology, where supply is often more of a problem because of the highly specialized nature of the inputs. Another area where the supply might be an important constraint is, for example, the scarcity of donor organs which severely limits the growth of immunity drugs. If labor is included as a supply force, significant bargaining power might exist for specialized R&D personnel in attractive research areas. Unions may also play a role as bargaining in the pharmaceutical industry, not so much to protect salaries, but more so to enforce strong and expensive safety measures for the work environment.

Conclusion:

Sales of generic drugs in Bangladesh will treble to Tk 30,300 crore a year by 2024, thanks in part to the recent extension of the medicine patent waiver, which will make quality products more accessible. 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. As the industry is growing at 11.37% and has a CAGR of 21%, it has a lot to offer given that the government provides incentives & the investment in R &D increases among the companies. In 2015 alone, patented drugs worth \$60bn are going off patent which opens up opportunities for generic manufacturers around the world. Bangladesh could be ideally positioned to gain from generic drug opportunities with its cost advantages and skilled manpower, but we need to address those key challenges faced by the industry in order to gain further competitive advantages and build presence in the global generics.