

## Doing Business in Bangladesh

### Introduction

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The Bangladesh economy is developing and in transition. The ready-made garments industry is responsible for nearly 80% of the country's export revenue. Other sectors such as seafood, ceramics, pharmaceuticals and software development are growing and contributing positively to Bangladesh's economy. Foreign investment, including from the UK, has begun to filter into Bangladesh in these sectors, particularly in garments. Local companies involved in exporting need foreign machinery, equipment, services and expertise to improve the quality of the products they offer to international markets.

### **The Bangladesh economy, although an economy in transition, is developing relatively quickly and does offer opportunities in a range of sectors.**

Bangladesh remains an economy in transition. Its strategic vision for 2021 includes plans to undertake massive programmes for infrastructure development in partnership with the private sector and donor agencies.

### Key opportunities

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The priority sectors identified by UK Trade & Investment as offering opportunities for UK companies are:

- Education and Skills
- Energy (including power)
- Environment and water
- ICT
- Pharmaceuticals
- Ports & Logistics
- Textile Machinery

## Biotechnology and Pharmaceutical Sector in Bangladesh

### **The Pharmaceutical industry, one of the most dynamic and powerful sectors in Bangladesh, is technologically the most developed manufacturing industries and is the second-largest contributor to the government exchequer.**

### Market overview

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The pharmaceutical industry contributes about 1% of the total GDP. Whereas, healthcare expenditures consist of only 3.35% of GDP. However, increased awareness of healthcare, increase in per capita income, emergence of private healthcare services and the government's increased expenditure in this sector, together with other factors, have caused the demand to rise in recent years. The sector is also protected from external competition, as imports are completely restricted for similar drugs that are manufactured locally.

Bangladesh is exporting medicines to 83 countries across the world and it has already received global recognition from the UK, MHRA, EMEA, TGA and GCC. The country is also the global hub for the cheapest source of world-class generic medicine and contract manufacturing. During the last two decades the pharmaceutical industry of Bangladesh has scaled newer peaks. Besides meeting the 97 % need of local demand the country is exporting the medicines into 83 countries. This sector contributes a lot into the national economy by exporting raw materials and finished goods.

The domestic market of pharmaceutical products in Bangladesh has shown a tremendous growth over the last couple of years. There has been a marked value-wise growth of the market -- at the rate of 23.59 % in 2011 over that of 2010. This growth is significant since most of the developed countries have slow pace of growth -USA, UK, Germany all were growing at 3 % or less. Therefore, overall the market has been promising and will continue to be so in the coming years. There is a big market lying beyond the existing market in the rural areas as only about 20 per cent people in rural area are getting nursing and medical care leaving the rest of the rural market exploitable. When the entire population will be brought under healthcare the market will be automatically enlarged by several

times. After gaining independence in 1971, the pharmaceutical sector in Bangladesh had been gradually growing. From a mere 15% local market share in the initial days, today, the country's pharmaceutical sector has grown to US\$ 1.2 billion, catering to 97 % of its local market demand. Apart from meeting from internal demand, there are about more than 10 leading Bangladeshi pharmaceutical companies that are exporting generics to the international markets. Some of them are also emerging as competitors to Indian companies in certain areas.

The quality of the medicines is comparable to any country of the world. The companies are investing heavily in upgrading their manufacturing plants. They are obtaining certifications from developed countries like UK and Australia. Some foreign companies will start manufacturing in Bangladesh from this year e.g. Novo Nordisk, Mundipharma. Bangladesh pharmaceutical companies focus primarily on branded generic final formulations, mostly using imported APIs. About 85 % of the drugs sold in Bangladesh are generics and 15% are patented drugs.

Bangladesh manufactures about 450 generic drugs for 5,300 registered brands, which have 8,300 different forms of dosages and strengths. These include a wide range of products from anti-ulcerants, flouroquinolones, anti-rheumatic non-steroid drugs, non-narcotic analgesics, anti-histamines, and oral anti-diabetic drugs.

The contributing factors in the growth of this market include the development of healthcare infrastructure, increased health awareness, increased rural penetration of the manufacturers, fast increasing purchasing capacity of the people as well as different government policies to ensure health services and facilities we extend into the rural areas.

The top ranking companies have already developed world-class pharmaceutical plants with state-of-the-art technologies. There are world class machineries, tools, production facilities, HVAC system, effluent treatment, water generation plant, well equipped quality control system and well educated, skilled professionals working in these companies. These factors have made these companies ready to meet the expanded market demands and to increase export in terms of value and quantity as well. Besides regular forms like tablets, capsules & syrups, Bangladesh is producing specialized products like HFA inhalers, suppositories, nasal sprays, injectables, IV infusions, etc., and has been well accepted by the medical practitioners, chemists, patients and the regulatory bodies of all the importing countries. Bangladesh is also producing high-tech medicines like anticancer drugs, hormonal products, enzymes and coenzymes at a limited scale, meeting only 4% of the total requirements. As such, there lies a huge prospect of these pharmaceuticals categories.

Pharmaceutical sector is technologically the most developed manufacturing industries in Bangladesh and the third largest industry in terms of contribution to government's revenue. The industry contributes about 1% of the total GDP. There are about 250 licensed pharmaceutical companies operating in the retail market of Bangladesh; however, currently a little over 100 companies are in operation. It is highly concentrated as top 20 companies produce 85% of the revenue and top 10 produce 68% of the revenue. The top 10 manufacturers by market share/revenue are as follows: Square (19%); Incepta (9.5%), Beximco (9%); Opsonin (5%); Renata (4.9%); Eskayef (4.7%); ACI (4.3%); ACME (4.1%); Aritstopharma (4%); and, Drug International (3.7%). Local manufacturers dominate the industry, enjoying about 90% market share while multinationals hold little over 10%.

#### Key opportunities

The conventional drug market trend is shifting more towards unconventional drugs where there is an opportunity for foreign investment. The Bangladesh pharmaceutical market is growing to become a potential outsourcing hub. The areas of demand are:

- Veterinary vaccines and human vaccines
- Drug development/contract research outsourcing from European countries including UK (for instance, ophthalmic drugs, cardio-vascular drugs etc)
- R&D and bio-equivalence that is, clinical trial development of drugs
- Biological drugs (for instance, insulin, hepatitis etc)
- Disease modifying drugs (for instance, anti-cancer drugs)
- Hormonal drugs

About 85% of the drugs sold in Bangladesh are generics and 15% are patented drugs. Branded generic drugs represent about 25% on average of worldwide pharmaceuticals sales'; however, given the popularity in emerging markets like China, India and Latin America, branded generic drugs may well dominate the total sales within a decade.

The drivers behind market growth, based on some health indicators are:

- A gradual demographic shift - life expectancy improved from 64.7 in 2000 to 68.3 in 2009 which highlights the increased health consciousness among the people. Also the income level of the population increased over the last decade which allowed them to spend more for healthcare.
- The base was also low as healthcare expenditure was less than 3% of GDP in 2000 with total pharmaceutical sector size of BDT 24.5 billion only in that year.
- Increased medical coverage of population with new hospitals.
- Emergence of private healthcare service - a number of top class hospitals started operating which includes Apollo Hospitals, Square Hospitals, United Hospitals and others. These hospitals became very popular with the mass population due to their quality service; they have been a major factor contributing to increased healthcare expenditure.
- Although government expenditure as a % of total healthcare expenditure did not improve in the last decade, there has been increased expenditure in absolute terms. Growth in private expenditure was the primary reason behind fall in public % of expenditure.
- Income base of the population has been growing over the last decade. Health expenditure per capita doubled in the last decade, indicating people's willingness to spend more to remain healthy.

Comparatively, Bangladesh is way behind other countries since Government spending proportion is much lower than that in other regions - it is one possible area where future growth may come. Moreover, the total health expenditure to GDP ratio and health expenditure per capita of Bangladesh (both of which gradually increased from 2000) is very low in comparison to developed and developing countries. Since the base is still very low, we expect the recent growth in the local retail market to continue in the current decade. Some other factors that will also boost the industry growth includes:

- Increase in number of modern hospitals
- Increase in level of service/treatment provided in the hospitals with improved/more modern diagnostic equipment
- General people are getting more health conscious
- Growing income level of the people
- Export of pharmaceutical products

## **API**

About 80% of the Active Pharmaceutical Ingredients (APIs) are imported as there are only a few local companies (usually the leading ones) that are engaged in manufacturing APIs. However, the number is really small (below 50) compared to the total requirement. These local companies usually run the relatively easier final chemical synthesis stage with API intermediaries, instead of the complete chemical synthesis.

For many APIs, the domestic market is too small to justify an API manufacturing plant - the initial investment and the production scale required are high. However, the government has planned to set up an API park to facilitate the production of several APIs for the local manufacturers. The value addition for the backward linkage will not be much as the country will again need to import the basic chemicals for manufacturing APIs. It is estimated that cost of APIs will decrease by about 20% if the API park is established. Work for establishing API Industry Park is progressing fast at Gojaria upazila in Munshiganj. A total of 42 industries will be set up in the park, which will bring a revolutionary change in the pharmaceutical sector in the country creating employment for 25,000 people. The government is working to build Bangladesh an industrially developed country by 2021.

Since the APIs are imported, the companies are exposed to exchange rate risk. The local currency depreciated significantly against USD over the last decade. However, the local companies were able to contain the manufacturing cost by shifting the import source of APIs to low cost manufacturers. China and India currently accounts for more than two-thirds of the imported raw materials while the remaining materials are imported from Europe; back in 2000, 80% of the APIs were imported from Europe. The decrease in API cost from changing the source has offset most of the adverse movement in the exchange rate.

## **TRIPS**

The World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement permits Bangladesh to reverse-engineer patented generic pharmaceutical products to sell locally and export to markets around the world.

The advantages that TRIPS provide for Bangladesh are somewhat offset by the pace and competitiveness of the Indian and Chinese generic markets. In both the countries, companies can

produce drugs at highly competitive pricing, even with higher costs associated with buying patented APIs or paying royalties. Bangladesh will have to rely on the standard business practices of producing the highest quality product at the lowest price to compete on the international market, which may be difficult to achieve in the near term.

- Bangladesh has a competitive disadvantage (when compared to India and China), since the local pharmaceutical industry is not backward integrated. Most of the APIs have to be imported, and even if the APIs are manufactured in the country, the basic raw materials still have to be imported. As such construction of API Park is not likely to add too high a value in the pharmaceutical manufacturing value chain. This results into higher factor costs, especially in cases where the provider of the API is a competitor in selling the finished product. Building up backward-integration for all relevant APIs is also not a realistic option because of scale disadvantages and infrastructure constraints. The reliance on importing API remains to be the only significant threat for the pharmaceutical industry in Bangladesh.

#### Getting into the market

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The Directorate of Drug Administration (DDA), the national drug regulatory authority, regulates drug manufacturing, import and quality control of drugs in Bangladesh as well as fixing the price. It belongs to the Ministry of Health and Family Welfare. For more information please visit: [www.dgda.gov.bd/](http://www.dgda.gov.bd/) The government has given support to the manufacturing industry for decades. It adopted The Drug Act 1940 in 1974, originally adopted by the Indian government in 1940, and later by the Pakistani Government in 1957. The Drug Act gave protection to the local manufacturers by restricting import of pharmaceutical products that are manufactured in the country. It successfully prevented the Indian manufacturers, who could serve the market at competitive price, from entering the country. Going forward there is no regulatory risk that import restriction will be removed and local companies are likely to continue on dominating the pharmaceutical market.

Some larger firms have started producing anti-cancer and anti-retroviral drugs. Domestic manufacturers account for 97 % of the drug sales in the local market while the remaining 3% are imported. This is a complete turnaround over from two/three decades back when imports used to dominate the market. The imported drugs include essential life saving drugs and other high quality drugs. The ratio will further increase in favour of the local pharmaceutical companies since the Government of Bangladesh protects these big local players with various Protectionism Laws to help them manufacture these high quality drugs in-house in the future.

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 biochemical medicines were exempted from control under the legislation.

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 other 133 small local companies produced the remaining 10%. All these companies were mainly engaged in formulation out of imported raw materials involving an expenditure of USD 7.32 million in foreign exchange. In spite of having 166 local pharmaceutical production units, the country had to spend nearly USD 3.66 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 USD 13.4 million in 1981 to USD 206 million in 1999. At present, 97% 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.

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