

A Review on Revolution of Pharmaceutical Sector in Bangladesh after Liberation War and Future Prospects and Challenges

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ABSTRACT

Pharmaceutical is the core of Bangladesh's Healthcare sector with an annual average growth rate consistently in the double digits. The real growth of local pharmaceutical industries started after the "Drug Control Ordinance-1982". Objective of the review is to identify the historical background, explore the overall situation and future opportunities of Pharmaceutical industry of Bangladesh. In Bangladesh overall growth of industries virtually polarized in three big metropolitan areas of Dhaka, Chittagong and Khulna, mainly in Dhaka. Presently, the industry meets 97% of local demand and exports to more than 80 countries. As a Least Developed Country (LDC), the country is exempted from obligations to implement patents and data protection for pharmaceutical products until 2033. Generic drugs in Bangladesh estimates to reach BDT 30,300 core by 2024. A number of companies have achieved accreditation from different world-famous regulatory bodies like US-FDA, UK-MHRA, Australia-TGA, EU for quality management and quality products manufacturing. A local industry supporting drug policy and effective regulatory framework, along with trade related

aspects of intellectual property rights relaxations are the key reasons for success of the industry. Prime Minister Sheikh Hasina has named pharmaceuticals the Product of the Year for 2018. Prospect of the sector depends largely on the interactions among the proprietors, regulatory bodies and the government, whether they can meet up the requisites to continue growth of the sector while facing the challenge.

Key words: Pharmaceutical, Generic, Trade, Drug policy, Prospect.

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INTRODUCTION

The pharmaceutical industries are one of the most promising sector and second-largest contributor to the government exchequer with an annual turnover of about \$715 million.¹ Bangladesh's pharmaceutical industry contributes almost 1.85% of GDP.² Skillful attitudes, knowledge and innovative ideas from the professionals are the key reasons why this industry grew in the way it did. The country's pharmaceutical sector has been one of the success stories of Bangladesh in the last three decades.³ This sector started to improve from 1980s.⁴ The Drug (Control) Ordinance in 1982 was the key factor of success of pharmaceutical industries in Bangladesh.⁵ 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.^{6,7} 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.⁸ The value of locally produced medicines rose from Tk 1.1 million in 1981 to Tk 187,566 million 2017.⁹ Government has set target to earn \$5 billion from the pharmaceuticals by 202.⁹ Two decades ago, most of the drugs needed to be imported. In the current scenario, as the national companies are taking over, about 97% need is fulfilled domestically while 3% are covered by imports.^{10,11} According to the information of the Director General of Drug Administration of Bangladesh (DGDA) now there are 271 Allopathic, 268 Unani, 205 Ayurvedic, 79 Homeopathic, Herbal 32 drug manufacturing companies in Bangladesh.¹² Bangladeshi pharmaceutical firms focus primarily on branded generic final formulations using imported APIs (Active Pharmaceutical Ingredients). According to Director General of Drug Administration (DGDA), the industry has 3,575 generics of Allopathic medicine, 2313 registered Homeopathic drugs, 6046 registered

Unani Drugs and 3,966 registered Ayurvedic drugs and 506 registered Herbal drug.¹³ Annual growth rate of Bangladesh pharmaceutical market about 11.37%.¹⁴ Sales of generic drugs in Bangladesh will treble to BDT 30,300 core per year by 2024.¹⁵ However, the trend now seems to be favorable to the country as the domestic pharmaceutical industry as well as the companies from neighboring countries like India, China and even MNCs have queued up to put in investments on this front as every stakeholder will benefit of vast potential that Bangladesh can offer. With the development of healthcare infrastructure and increase of health awareness and the purchasing capacity of people, this industry is expected to grow at a higher rate in future. Healthy growth is likely to encourage the pharmaceutical companies to introduce newer drugs and newer research products, while at the same time maintaining a healthy competitiveness in respect of the most essential drugs. In this review, the past and current scenario of pharmaceutical industries of Bangladesh has been presented along with an analysis of its prospects and challenges. We investigate the historical background of pharmaceutical industry of Bangladesh, education system, overall situation of Pharmaceutical industry of Bangladesh, growth projection of this industry and future prospects and challenges.

METHODS

This research is based on Primary and secondary data which together provided more comprehensive information. Collected data has been analyzed on the basis of the objective of the study. Primary data is open discussion method was followed to gather primary information by informally interviewing the various Departmental Head, executives of the company. Secondary data were collected from the existing writing in the field of both local and international pharmaceutical part. It has been

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used combined information collected from several recognized journals, magazines, newspapers and websites of both local and international pharmaceutical companies and various published materials on the topic.

RESULTS

Historical Background of Bangladesh Pharmaceutical Industry

The National Drug Policy (NDP) in 1982 and 2005 has major impact in the development and growth of the Bangladesh pharmaceutical industry.^{16,17} The Census Manufacturing Industries 1983-84 has shown that over 88 percent of the total industrial assets have found accommodation in Dhaka and Chittagong divisions, while only 5.82 percent and 5.15 percent of the capital formation- took place in Khulna and Rajshahi divisions respectively.¹⁸ The land price of Dhaka was very high among other districts. Mainly land prices in the areas of Dhaka Metropolitan city were too high. To reduce land cost Drug industries are gradually moving towards fringe areas. Labor cost of different pharmaceutical industries varies from company to company. For skilled labor the monthly wages varies between Tk.700 to Tk. 5000 and for unskilled labor the monthly wages varies between Tk. 400 to Tk. 2990.¹⁸ Drug Industries depend on Imported Raw Materials. About 68 to over 77 percent raw materials of different drug industries of are imported from foreign countries.¹⁸ Table 1 shows Bangladesh Pharmaceutical Market Prior to 1982.

Pharmaceutical Regulations: Relevant Laws and the Regulatory Body

In Bangladesh, key legislation relating to pharmaceuticals includes the *Drugs Act, 1940* and its amendments (the *Drug Rules, 1945* and the *Drug Rules, 1946*); and the *Drugs (Control) Ordinance, 1982* (DCO 1982) and its amendments [*Drug (Control) (Amendment) Ordinance, 1984* and *Drugs (Control) (Amendment) Act, 2006*]. The *Drugs Act, 1940* regulates the import, export, manufacture, distribution and sale of pharmaceuticals in Bangladesh^{19,20} (Table 2). The Act was originally enacted by the Government of India in 1940, was adopted by the Government of Pakistan in 1957 and then subsequently adopted in Bangladesh in 1974 (20).

Pharmaceutical Education

Professor Dr. Abdul Jabbar was the initiator of Pharmacy education in Dhaka University (21). Pharmacy Department was started by starting B. Pharm degree in 1964 this is converted to B. Pharm (Hons) in 1965. First M. Pharm course started in 1969.²¹ Currently, there are 12 public universities and 31 private universities in Bangladesh offering Bachelor of Pharmacy and Masters of Pharmacy Programs.²² In addition, there are 50 colleges/institutes in Bangladesh offering Diploma in Pharmacy program. Most of the universities are offering 4 years Bachelor degree and 1 year master degree.²² Pharmacists having 'A' grade registration are eligible to Practice Pharmacy in Bangladesh but now registration examination is off.²³ The PCB provides 'B' grade registration to the students who have passed the 3-year diploma in Pharmacy course.²⁴ Those who can pass 3-month special courses designed and jointly conducted by Bangladesh Pharmaceutical Society (BPS) and Bangladesh Chemists and Druggists Society (BCDS) are categorized as 'C' grade pharmacists by PCB and they usually work in community pharmacy or run their own pharmacies.²⁴

Present perspective Pharmaceutical Industries

Domestic market of Pharmaceutical products in Bangladesh has shown an increasing trend over the past few years and the market size is BDT 187,556 million as on 2017 (Figure 1).^{25,26} According to industry experts,

market size of pharmaceuticals may reach about BDT 330,000 million by 2020.²⁷

The Executive Committee of the National Economic Council (ECNEC), gave green signal to the Active Pharmaceutical Ingredient (API) Park in Munshiganj recently at an overall project cost of Tk 2.13 billion.²⁸ A total of 30 drug companies have already applied for plots at the API park.²⁸ They have the money ready to establish plants. According to Bangladesh Association of Pharmaceutical Industries (BAPI), approximately 1,200 pharmaceutical products received registration for export over the last

Table 1: Bangladesh Pharmaceutical Market Prior to 1982.

Government Spending	BDT 1500 million per year
Number of brands in market	3500
Number of manufactures	177
Multinationals	8
Retail Pharmacists	16000
Number of Wholesalers	1300
Private Sector	90% available drugs
Government Utilize	10% available drugs

Table 2: Milestones in the gradual development of pharmaceutical regulation in Bangladesh.

1940	Drugs Act (XXIII of 1940)
1945	Drug Rules, 1945 (under the Drugs Act, 1940)
1946	Bengal Drugs Rules, 1946
1966	Gazette of Pakistan: Office of the Chief Controller of Imports and Exports. Public Notice, 1966
1970	Dacca Gazette, Part I: Government of East Pakistan, Health Department Notification, 1970
1976	Directorate of Drug Administration (DDA), the national regulatory authority for drugs, is created
1982	Drugs (Control) Ordinance, 1982, Drugs (Control) (Amendment) Ordinance, 1982 and National Drug Policy, 1982
1984	Drugs (Control) (Amendment) Ordinance, 1984
1992	Institute of Public Health produces tetanus vaccines First edition of the National Formulary published
2001	WHO approves oral cholera vaccine tested at the International Centre for Diarrheal Disease Research, Bangladesh (ICDDR-B)
2002	ICDDR-B studies establish that zinc treatment of diarrhea reduces under-5 mortality by 50%
2003	Second edition of the National Formulary published
2005	National Drug Policy, 2005
2006	Drug (Control) Ordinance Amendment Act, 2006 Third edition of the National Formulary published
2009	South-East Asia Regional Office/Department of Family and Community Health/Immunization and Vaccine Development mission to discuss institutional development plan to build DDA capacity
2010	DDA upgraded to the Directorate General of Drug Administration (DGDA) WHO mission to assess pharmaceuticals in healthcare delivery in Bangladesh
2012	Revised New Drug Policy, 2012 drafted and submitted for approval
2016	DGDA has sent their recommendations for the proposed Drug Act 2016 and Drug Policy, 2016 to the Ministry of Health and Family Welfare.

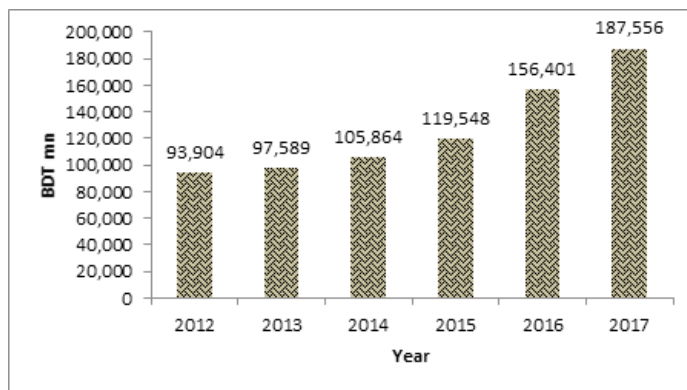


Figure 1: Pharmaceutical products of Bangladesh and growth (2012-2017).

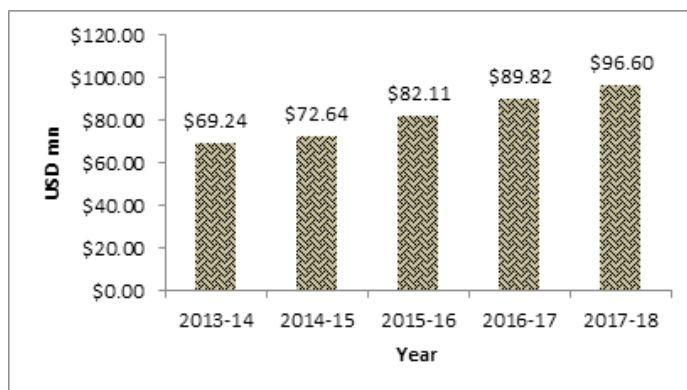


Figure 2: Export of Pharmaceutical Product of Bangladesh and Growth (USD mn).

two years.²⁹ According to Bangladesh Export Promotion Bureau, Bangladesh exported pharmaceuticals product to 107 countries in the fiscal year 2016-17.^{2,25} During this period, Bangladesh has exported pharmaceutical products worth USD 89.17 million as against USD 82.11 million in 2015-16 (Figure 2).^{2,25}

DISCUSSION

The pharmaceutical sector is one of the thrust sectors in Bangladesh. After several years of liberation, the government could not increase budgetary allocations for the improvement of health sector. This benevolent policy could not immediately win the approval of the people of Bangladesh, even though they had suffered from the high prices of important life-saving drugs. Instead the major newspapers regarded the policy as a hare-brained populist policy improvised by the military government and as doomed to be crushed by pressure from abroad. Indeed, the US ambassador came to Ershad immediately and began bringing relentless pressure on the Bangladesh government to reverse the decision.^{16,17} The ambassadors from the UK and Germany soon followed lead. Their pressure included the threat of stopping assistance from their countries to Bangladesh. Similarly, the multinationals threatened explicitly to stop the supply of medicines to the country completely. However, it was carefully crafted by an expert committee consisting of Professor Nurul Islam of Dhaka University, Zafrullah Chowdhury and other six professionals, such as military surgeons, with considerable experience and expertise.³⁰ *Drugs Act, 1982* is the key regulation relating to pharmaceuticals 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. Two

organizations regulate drugs and pharmacies in Bangladesh,³¹ one "The Directorate General of Drug Administration (DGDA)" and another one is "The Pharmacy Council of Bangladesh (PCB)". Currently, there are 12 public universities and 31 private universities in Bangladesh offering Bachelor of Pharmacy and Masters of Pharmacy programs.²² From 2012 to 2017, historical five years CAGR was 15% and from 2014 to 2017, historical three years CAGR was 21%.²⁵ Recently, extension of the TRIPS deadline from 2016 to 2033.³² Bioequivalence study is the core of registration of any product in many of the moderately regulated and regulated countries of the world. So, the stakeholders should take initiatives to establish bioequivalence test facilities as soon as possible. Recently, NCL (National Control Laboratory) has been established and equipped with many modern instruments, but there are very few trained personnel to operate these.³³ The API Park should be completed as early as possible with the intervention of government. Strict application of standard operating procedure in all aspects of production. Promoting knowledge-based marketing strategy and establishment of bioequivalence test facilities, Establishment of CRO (Clinical Research Organization) to conduct clinical trials. Practicing strict rules and regulations to fight against counterfeit drugs. Establishment of hospital pharmacy and making people more health conscious. Export Promotion Bureau (EPB) can play an effective role by arranging international fair frequently. Proper selection of raw materials and machineries for better product quality. More attention should be given to research and development sector.

CONCLUSION

Bangladesh has built a strong baseline and going towards the self-sufficiency for the production of medicine. Before 1982, location of industries has tended to be urban-based. Now, we getting the opportunity of patent exemption by the TRIPS until 2033 and the government have started the process of constructing an active pharmaceutical ingredient industrial park in Munshiganj. Thus, the future holds good for the local manufacturers as Bangladesh's pharma market is becoming a potential hub for generics. The government should really be attentive to remove all the obstacles and solve all the problems to see highest spectacle of pharmaceutical sector as a vital player in international market.

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CONFLICT OF INTEREST

The authors declare they have no competing interests.

ABBREVIATIONS

US-FDA: United States- food and drug administration; **UK-MHRA:** United Kingdom- medicines and healthcare products regulatory agency; **TGA:** Therapeutic goods administration; **EU:** European Union; **GDP:** Gross domestic product; **MNCs:** Multinational companies; **DGDA:** Director general of drug administration of Bangladesh; **APIs:** Active pharmaceutical ingredients; **NDP:** National drug policy; **DCO:** Drugs control ordinance; **PCB:** Pharmacy council of Bangladesh; **BPS:** Bangladesh pharmaceutical society; **BCDS:** Bangladesh chemists and druggists society; **ECNEC:** Executive committee of the national economic council; **BAPI:** Bangladesh association of pharmaceutical industries;

CAGR: Compound annual growth rate; **NCL:** National control laboratory; **CRO:** Clinical research organization; **EPB:** Export promotion bureau; **TRIPS:** Trade related aspects of intellectual property rights.

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