Volume 19 Issue 4
Originally issued as H1

GLOBAL JOURNAL OF HUMAN-SOCIAL SCIENCE: H
INTERDISCIPLINARY
Volume 19 Issue 1 Version 1.0 Year 2019
Type: Double Blind Peer Reviewed International Research Journal
Publisher: Global Journals
Online ISSN: 2249-460X & Print ISSN: 0975-587X

Potentials of Bangladesh Pharmaceutical Industry: A Comparative Study

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Abstract- This article attempts to examine the current scenario of the pharmaceutical industry in Bangladesh and its possible impact on national growth. Bangladesh is a country of an emerging economy. The significant high growth rate of industrialization and investment in variant sectors are the main reasons behind its rising economy. Healthcare sector is one of those potent sectors, wherein the Pharmaceutical industry is the sole entity and one of the fastest growing industries in the world. As of late, the Pharmaceutical market of Bangladesh has formed as a sizeable industry that has prospective global standards. It has grown and developed surprisingly in the past two decades. During these years, the pharmaceutical sector succeeded a dignified position in the international and domestic market. Today, pharmaceutical companies fulfill more than 98% of the local demand and export a significant quantity of medicines to more than 100 countries, including Germany, USA, France, Italy, UK, Canada, Netherlands, and Denmark. International regulatory authorities like UK-MHRA, Australia-TGA, US-FDA, and EU have already approved and certified some of the pharmaceutical companies.

GJHSS-H Classification: *FOR Code: 671704p*

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Potentials of Bangladesh Pharmaceutical Industry: A Comparative Study

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Abstract- This article attempts to examine the current scenario of the pharmaceutical industry in Bangladesh and its possible impact on national growth. Bangladesh is a country of an emerging economy. The significant high growth rate of industrialization and investment in variant sectors are the main reasons behind its rising economy. Healthcare sector is one of those potent sectors, wherein the Pharmaceutical industry is the sole entity and one of the fastest growing industries in the world. As of late, the Pharmaceutical market of Bangladesh has formed as a sizeable industry that has prospective global standards. It has grown and developed surprisingly in the past two decades. During these years, the pharmaceutical sector succeeded a dignified position in the international and domestic market. Today, pharmaceutical companies fulfill more than 98% of the local demand and export a significant quantity of medicines to more than 100 countries, including Germany, USA, France, Italy, UK, Canada, Netherlands, and Denmark. International regulatory authorities like UK-MHRA, Australia-TGA, US-FDA, and EU have already approved and certified some of the pharmaceutical companies. In case of earning foreign currency, the pharmaceutical sector has turned out to be the 2nd largest potential sector of Bangladesh, and its contribution to national GDP is mounting rapidly. How the industry is continuously booming and its possibilities for more growth in the future, will be discussed in the present study.

I. Introduction

Being one of the world's leading industries the global pharmaceutical industry revenue is forecasted to reach an estimated $1,226.0 billion by 2018, with good growth over the next five years (2013-2018). The industry is expected to register growth led by aging population, changing lifestyles, hectic daily activities, unhealthy eating habits, increasing incidence of chronic diseases across the entire global population providing growth opportunities for the industry players[1]. The Industry has seen remarkable changes in the present years that leave another heap on payers, suppliers, and producers. Today it is the core of Bangladesh's Healthcare sector. With an evolutionary history, the industry has now become one of the most successful pharmaceutical manufacturing industry amongst the growing nations. Currently, the industry meets 98% of local demand and exports to more than 125 countries.

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There are two effective policies that have noticeably, boosted up the growth of the Pharmaceutical Industry. One was the Drug Control Ordinance 1982, which barred foreign companies from selling imported pharmaceutical products in Bangladesh. The other regulatory framework was WTO's agreement on TRIPS (Trade-Related Aspects of Intellectual Property Rights) relaxation, which permitted Bangladesh to reverse engineer patented generic drugs and it was extended until December of 2032. Though, due to the recent graduation from LDC in 2018, this may change. But we can expect the relaxation will continue, until UN announces its elevation to the status of a developing country in 2024. The industry size was only BDT 1.7 billion in 1982, which eventually grew ninety times by 2018. Gradually, it has been expanding locally and internationally. Some of the leading pharmaceutical companies of Bangladesh has already got accreditation from international regulatory authorities like UK-MHRA, Australia-TGA, US-FDA, and EU.

II. Historical Background

The pharmaceutical industry discovers, develops, produces, and markets drugs or pharmaceuticals for use as medications. Pharmaceutical companies are allowed to deal with generic or brand medications and medical devices. They are subject to a variety of laws and regulations regarding the patenting, testing and ensuring safety and efficacy and marketing of drugs. The majority of leading pharmaceutical companies also work in Consumer Health, Animal Health, Nutritional Products or Medical Devices/ Diagnostics business segments[2]. Therefore, the main aim of Pharmaceutical companies is to work for the betterment of health and care of the people, and they devote their utmost effort to give their best. Their products do not only comprise of drugs that help in curing diseases but also consists of numerous nutritional supplements, and with the means of trading these products are sent in all over the world.

Following those objectives, the pharmaceutical sector is now one of the 'thrust' sectors in Bangladesh. Before Liberation, there was barely any pharmaceutical enterprise in Bangladesh (then East Pakistan). Though, during the 50s and 60s, a few local pharmaceutical companies started operations. Nevertheless, after several years of liberation, the government could not increase budgetary allocations for the improvement of

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the health sector, as the sector was prominently dominated by Multinational Companies, whereas, local companies were suffering from proper infrastructure, modern equipment, and technology. Moreover, there was no regulatory authority. Most of the people had little access to the essential lifesaving medicines[3]. According to the World Development Report published by world bank, in the early 1980s, Bangladesh ranked as the world's second poorest country, with average per capita income of US$130, and with about 95 million people in a land area of 144 000 square kilometers, giving it the highest population density in the world….a large portion of the Bangladesh population had limited access to modern drugs, with estimates varying from 30% of the population2 to 85%.3 In 1981, the national market consisted of about US$75 million in allopathic drugs, less than 0.1 % of the total world drug market[4].

Then, from the 1980s, pharmaceutical sector started to improve. In the last two decades, it has grown at a considerable rate. After the promulgation of Drug Control Ordinance-1982, the development of the pharmaceutical industry has accelerated. As the local Pharmaceutical companies were the beneficiary of the NDP, they started to expand their business. Meanwhile, the MNCs sold their business shares to local companies. The drug policy had two immediate consequences. First, it eliminated the importation, sale, and production of drugs declared to be dangerous or useless. While groups differed in their assessment of the costs (and desirability) of removing so many drugs from the market, most groups agreed that the policy succeeded in achieving this goal. Second, it reduced the cost of essential drugs within Bangladesh (with savings to consumers, government, and foreign exchange reserves) by decreasing import prices and the value of imported finished products[5]. According to the Directorate General of Drug Administration (DGDA), the market share of the locally produced drug was 175 crores in 1981 that increased to 325 crores by 1985. Since the promulgation of Drug Policy in 1982, the sector has grown from BDT 1730 million to more than BDT 113 bn ($1.5 bn). In 2000, there were 173 active and licensed allopathic drug manufacturing units in the country, while the figure now stands at 300. There are two organizations, one governmental the Directorate General of Drug Administration (DGDA), Under the Ministry of Health and family welfare. DGDA regulates all activities related import and export of raw materials and finished products, packaging materials, production, sale, pricing, license, registration, etc. of all kinds of medicine including those of Ayurvedic, Unani, Herbal and Homeopathic system and one semi-Government. The pharmacy council of Bangladesh (PCB) regulates the practice of Pharmacy throughout Bangladesh control pharmacy practice in Bangladesh.

Table 1: Bangladesh Pharmaceutical Market Before 1982

Government Spending	BDT 1,500 million per year
Number of brands in the market	3500
Number of manufacturers	177
Multinationals	8
Retail Pharmacists	16000
Number of Wholesalers	1300
Private Sector	90% available drugs
Government Utilize	10% available drugs

Source: Bangladesh Pharmacy Council (BPC), Annual Report – 2009

III. Industry Overview & Growth Rate

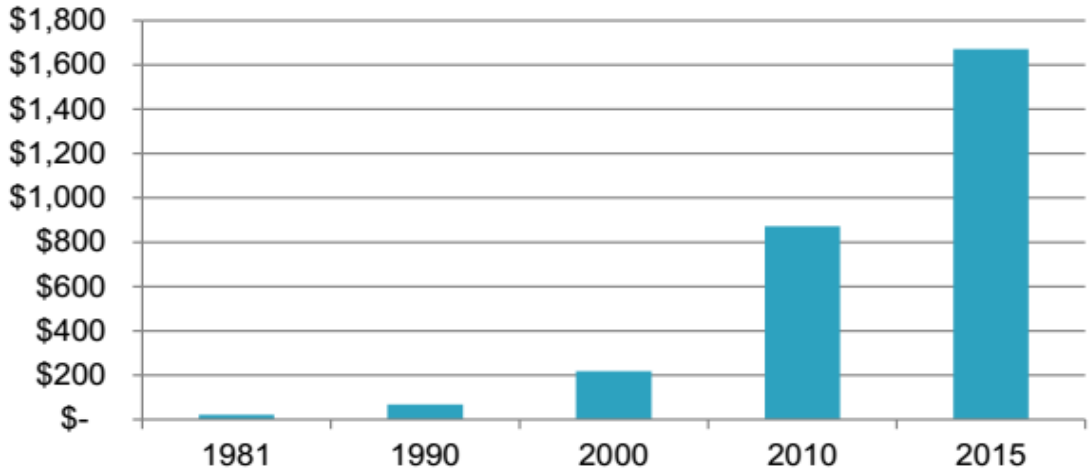
There are several sectors on which Bangladesh can be proud of and undoubtedly the pharmaceutical industry is one of these sectors, which is the second-largest contributor to the government exchequer. There are however, 1,495 wholesale drug license holders and about 37,700 retail drug license holders in Bangladesh. Following the IMS report of 2014, the overall size of the pharmaceutical market of Bangladesh is estimated to be approximate Tk.113bn. With an annual growth rate of about 11.37%, Bangladesh Pharmaceutical Industry is now self-sufficient in meeting the local demand, and it is the largest white-collar intensive employment sector of the country employing around 115,000 workers. As indicated by IMS Health, annual pharmaceutical sales in the local market may reach BDT 160 billion within 2018. By 2020 the market is estimated to be $3,369bn[6]. Bangladesh's pharmaceutical sector will grow 15 percent year-on-year to reach $5.11 billion by 2023, propelled by high investments by local companies as they seek to grab a big share of the global market. By 2022, the market size will be more than doubled to $4.44 billion from $2.02 billion now[7].

The pharmaceutical industry of Bangladesh is primarily a generic one. There are about 5,300 different brands which meet 97% of the domestic demand. The

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local companies have 90% share of the market while MNCs hold only 10%. Domestically, Bangladeshi firms generate 82% of the market in pharmaceuticals; locally based MNCs account for 13%, and the final 5% is imported. Although 257 pharmaceutical companies are registered in Bangladesh, only about 194 are producing drugs. The top 20 companies generate 85% of the revenue. The top 30 to 40 companies dominate almost the entire market; the top 10 hold 70% of domestic market share; and the top two, BEXIMCO and SQUARE, capture over 30% of the market that demonstrates the relatively concentrated business structure of the industry. Comparatively, the top ten Japanese firms generated approximately 45% of the domestic industry revenue in 2006, while the top ten UK firms generated approximately 53%, and the top ten German firms generated approximately 60%. Out of 257 registered companies, the top ten companies account for almost 70% of the total market. Total market size of CAM (Complementary and alternative medicine) companies are about USD 0.18 Billion. Below here, is a chart to show the rapid growth of the pharmaceutical market since 1981 to 2015 which is e stimated to grow around $1,900.000 in 2017.

Table 2: Bangladesh Pharmaceutical Market growth since 1981 (USD)



Source[8]

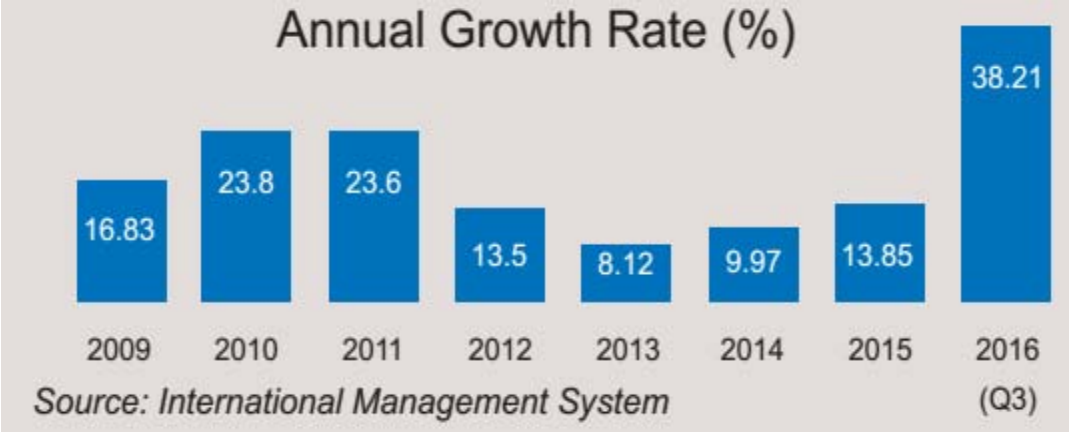
The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Doha Declaration and the succeeding decisions of the council of TRIPS allowed all LDCs to have pharmaceutical patents immune from the ambit of patentability till 2016 (later the patent waiver period was extended up to 2033). This TRIPS flexibility has helped companies in operating in Bangladesh develop generic versions of pharmaceuticals that are under patent protection elsewhere and to sell these products in local markets or to other LDCs or non-members of WTO which have not implemented patent protection. The proper utilization of this patent waiver flexibility made Bangladesh become the only LDC country with adequate pharmaceutical manufacturing ability and almost self-reliant. However such exemption will no longer be permitted when the country will be finally graduating from LDC to the category of developing country.

The TRIPS agreement has turned Bangladesh into a center for affordable and high-quality generic medicines and contract manufacturing, with exports to potentially more than 100 countries across the world. Even, more than ten leading Bangladeshi pharmaceutical companies are exporting generics to international markets. A number of these firms are also evolving as contenders to high-ranked Indian companies in certain areas. The pharmaceutical companies of Bangladesh are investing comprehensively in upgrading manufacturing plants and obtaining certifications from United States, Australia, Canada, and Europe. Beximco Pharma and Square Pharma, each successfully completed FDA inspection of their solid oral dosage producing facilities and received notification in June 2015. These allow them to penetrate regulated and unregulated markets. The top-ranking companies have already developed world-class pharmaceutical plants with the most progressive and up-to-date technology. About 85 percent of the drugs sold in Bangladesh are generic, and 15 percent are patented drugs as the pharmaceutical companies focus primarily on branded generic final formulations, using both imported and domestically produced Active Pharmaceutical Ingredients (APIs). The country manufactures more than 450 generic drugs for 5,300 registered brands, which have 8,300 different forms of dosages and strengths. These include not only tablets,

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capsules and syrups but also a wide range of products from anti-ulcerates, fluoroquinolones, anti-rheumatic non-steroid drugs, non-narcotic analgesics, antihistamines, and oral anti-diabetic drugs. Bangladesh also produces high-tech medicines such as anticancer treatments, hormonal products, enzymes and coenzymes on a limited scale, but it is currently only able to meet four percent of local requirements[9] (Export Promotion Bureau of Bangladesh). The facility of exemption from obligations to implement patents and data protection for pharmaceutical products gives the local pharmaceutical industry an advantage over India and China who do not come under the exemption agreement. After entering the international market, Bangladesh pharmaceutical industry has made prominent growth in export.

Table 3: Pharmaceutical Industry annual growth rate



Bangladesh is in a position to emerge as one of the regional R&D centers for pharmaceutical research as reverse engineering has ended in China and India. So, there is a great opportunity to vie with the Contract Research and Manufacturing Services (CRAMS) model of India. Currently, more than 80% of the APIs are imported from abroad. But with the establishment of adequate reverse engineering and API manufacturing facilities, the local demand for raw materials can be met without import. Bangladesh can provide a strong platform for offshoring/outsourcing generic bulk and formulation drugs due to a cheap labor force and established infrastructure. Bangladesh can present itself as an attractive destination for off-shoring as more and more western companies are concentrating more on the high-cost patented drugs and seeking new sources to cut cost in their manufacture of bulk drugs. Besides, the industry can emerge as a regional hub for pre-clinical testing and clinical trials with the establishment of modern technical facilities. The Contract Research Organization (CRO) model success of India can act as a template to emulate as the subject cost will be very low in Bangladesh as compared to that of western countries[10]. There is an opportunity for substituting import of vaccines, injectables through manufacturing it domestically. Many local entrepreneurs are searching for new ways to amplify their operations beyond the country borders. They are also trying to emulate the buying of distressed companies in the west to attain immediate market access.

EXPORT

Pharmaceutical export is contributing significantly to the GDP of the country, and every year the contribution is increasing rapidly. Since 2004, exports have increased multifold, with export destinations rising from 37 in 2004 to 127 in 2017. Bangladesh exported $37.9 million (about Tk. 3.0 billion) worth of drugs in the fiscal year 2015-2016.

Generic drugs exported from Bangladesh amounts to 25% of the worldwide pharmaceutical sales. Bangladesh earned $82.11 million, a 13.04% up, in the fiscal year 2015-2016, compared to 72.64 million a year ago. The sector has exceeded the export target by 2.64%. Pharmaceutical export grew around 25% in the last seven years. The amount stood at $60.19 million in the first eight months of this fiscal year, registering a 9.94% rise compared to the same period a year ago. Bangladesh has an export target of $95 million, this fiscal year 2016-17, according to data from Export Promotion Bureau[11].

Bangladesh is exporting their pharmaceutical products to 125 countries including Vietnam, Singapore, Myanmar, Bhutan, Nepal, Sri Lanka, Pakistan, Yemen, Oman, Thailand, and some countries of Central Asia and Africa. It also has a large market in European countries.

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Table 4: Drug Export in millions (USD)



Source: Export Promotion Bureau of Bangladesh

Due to the relaxations provided by TRIPS, APIs can bring a bunch of opportunities for exports. For, API (also known as Bulk Drugs), there is no stringent registration requirement and the operational, as well as promotional charges, are also nominal. The only crucial factor in this regard is the cost competitiveness. Bangladesh can export API to several countries if cost-effectiveness is ensured. But being restrained to synthesis stage only, Bangladesh has to rely on import of core compound, solvent, and other intermediates. Thus, the cost-effectiveness of local production can be a bit dependent on import costs. Alongside, these productions often also entail effluent treatment plant, requiring a high investment. Though, the economy of scale is yet to achieve, and high investment requirement has troubled to achieve entrepreneurs' attention. But developments will soon come forward, as some of the firms are manufacturing raw materials locally. The Active Pharmaceutical Ingredients Park in Munshiganj, around 40 km from the capital, will help the sector manufacture at an economy rate, with plans to establish 40 API industries inside the park, including a central effluent treatment plant and incinerator amongst many other facilities.

Import

Every year Bangladesh imports a huge amount of both, finished products and raw materials from out of the country. More than 90% of 4.700 crores (TK) worth of raw materials are imported every year. Over and above 700 different types of finished products and 750 numbers of raw materials including packaging materials come into Bangladesh for the use of the local pharmaceutical companies. Two categories of raw materials used and imported 1. Active ingredients/ basic materials and 2. Excipients. Different organizations of Bangladesh are associated with the import of pharmaceuticals products and raw materials of pharmaceutical industries. Mostly, MNC's are engaged to import the pharmaceuticals products. Imported drugs mainly comprise of cancer drugs, vaccines for viral diseases, hormones, etc. Bangladesh pharmaceutical industry is now heading towards self-reliance in meeting the local demand. However, developments are taking place through a number of firms' manufacturing small amount of raw materials locally. Additionally, the government has already completed the construction of API (Active Pharmaceutical Ingredient) industrial park that will go into operation in 2018. Costs of APIs are estimated to decrease by about 20%, if the API Park is launched.

According to experts, Bangladesh has a competitive hindrance when compared to India, since its pharmaceuticals production is not backward-integrated. Even if the API is manufactured in Bangladesh, the raw materials have to be imported, which generates 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 not a realistic option: scale disadvantages and infrastructure of constraints are more relevant in the early stages of the value chain, where the products have strong commodity character.

Bangladesh import Organic Chemicals mainly from Indonesia, USA, Japan, Taiwan, Germany, Malaysia, Republic of Korea, Singapore, China, India and others Pharmaceutical Products Import from USA, China, Korea, Japan, Greece, Cyprus, Hungary, Ireland, United Kingdom, UAE, Austria, Singapore, India, Italy, Belgium, Netherlands, Germany, France, Demark, Spain, and Switzerland etc. Half of the total raw materials are imported from China, 20% from India and the rest 20% are from other countries. Again, the machineries for pharmaceutical manufacturing also has to be imported while Indian manufacturers can source those equipments nationally. It's a cost disadvantage for Bangladeshi companies. The leading manufacturers

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import most of their equipment from Europe or Japan, China, India, etc. Here is a chart to explain, the gradually increasing amount of pharmaceutical import since 2000-2010.

Table 5: Pharmaceutical Import to Bangladesh

(USD Million)	2000-01	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10
All Products	9335	8540	9658	10903	13147	14746	17157	21629	22507	23505
Pharmaceutical Import	33	39	44	45	41	50	49	62	80	82
Pharma % of Total	0.35%	0.46%	0.46%	0.41%	0.31%	0.34%	0.29%	0.29%	0.36%	0.38%
Yearly Growth for Pharma	18.18%	12.82%	2.27%	-8.89%	21.95%	-2.00%	26.53%	29.03%	36.30%	38.01%

Source: Bangladesh Bank, Bangladesh Bureau of Statistics

Considering the socio-economic scenario, increasing per capita income, and the literacy rate in the country and also due to increased concern about the health of a certain group of people in the urban areas, it is assumed that total demand for all kinds of medicines and healthcare products will grow in Bangladesh shortly. Simultaneously, with the increasing trend in the export of pharmaceuticals, the demand for raw materials will also increase substantially. However, taking into consideration of the past performance as well as the introduction of new entrants in the sector, it is expected that the import will experience at an annual average growth rate of at least 10% in the next 4-5 years.

IV. Growth Potential

According to Industry Insiders, the pharmaceutical industry of Bangladesh is gifted with high potentials to grow in the days ahead as they enjoy a number of competitive advantages. Almost all pharmaceutical companies are well-equipped with WHO Good Manufacturing Practice (GMP) standards. It has a strong ability to face competition from developing countries like India, China, Brazil and Turkey in its export markets due to strict quality compliance[12].

R&D Activities, formulation, and market are three primary concerns for a strong API base. Whereas our industry does not have R&D activities, we have good domestic formulation industry and a moderate size domestic market. Alongside, we have trained local human resources to support development in the industry. With the government proposed utility and ETP (Effluent Treatment Plant) benefits, and present regulatory structure, it is possible for Bangladesh to develop a good base in the formulation of API and formulations for generic products. Alongside, due to growth factors such as low manufacturing labor cost, availability of relevant manufacturing technology and entrepreneurial assertiveness, the domestic market is to become an emerging market. Change in affordability, the strength of continuous investment, the rapid spread of urbanization and education will result in high growth of the industry in the coming years.

Being a part of the healthcare sector, the growth of the pharmaceutical industry is related to several economic variables. A gradual demographic shift, including increased life expectancy over the last two decades, has translated into proliferated health consciousness and needs, encouraging people to spend more on healthcare services. The income base of the population has been growing over the last decade. Health expenditure per capita doubled during that same period, indicating people's willingness to spend more on health as their disposable incomes increase. Further, with the emergence of private healthcare service - a number of high-quality private hospitals began operating, including Apollo Hospitals, Square Hospitals, United Hospital, and others. These hospitals have become popular due to their high-quality service. They have been an important factor contributing to increased healthcare expenditure and have substituted for regional healthcare travel. Although government expenditures as a percentage of total healthcare expenditures remained stable over the last decade, they have increased in absolute terms[13].

At present, Bangladesh has a quite good outlook on its demographics. GDP growth has been roaming around 6% over the last few years. With average population growth life expectancy at birth has increased by 0.89% annually, along with poverty level reducing 1.68% each year. Most importantly, healthcare expenditure per capita grew by at 8.7% per year, and private healthcare expenditure raised by 3.16% annually, demonstrating a growing propensity among people for healthcare expenditure. With all these positive indicators, more than 15% growth rate is expected now for the local market API industry can provide another growth opportunity in the export market. Exports presently amount to 5.93% of total size (local + Export) of the pharmaceutical market on average. With a vision

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to attain double-digit growth in 2018, the current government has set a target to achieve a higher growth rate. So, it is expected that the actual growth rate in GDP will be 7% within five years and the healthcare expenditure is likely to be more than that estimated value of around 17%. Now, the retail Pharmaceutical market size is about 1% of GDP and health expenditure is about 3.7% of GDP. As a result, the Pharmaceutical sector revenue accounts for almost 30% of the healthcare expenditure. If this situation continues over the coming five years, pharmaceutical revenue will also mature at par at 16.67% annually over the next five years. In the export market, as TRIPS relaxation extended, and present effort towards improving international reach continues, the industry can expect another period of good growth, with more growth coming from exports.

Currently, 48 LDCs, including Bangladesh, are not obliged to enact legislation on product patent rights. Taking the fast growth of the economy into consideration, there is growing concern that the bonanza might end soon for Bangladesh. However, based on international standards and previous examples, it is believed that Bangladesh will continue to enjoy TRIPS benefits at least until 2025. Moreover, since partners are encouraged not to abruptly end LDC support, Bangladesh can enjoy limited TRIPS support even after that with some competent negotiations[14].

V. Conclusion

Today, it's needless to say that the Pharmaceutical industry has already declared as one of the powerful and dimensional sectors of Bangladesh. The pharmaceutical industry is growing at our expected rate with the development of healthcare infrastructure and an increase in health awareness and the purchasing capacity of people. Apart from that, while most of the emerging and LMIC (lower-middle-income countries) drug markets are dominated by multinational Pharma companies, Bangladeshi Pharma companies can penetrate these markets. Being thriving in domestic market Bangladesh pharmaceuticals Industry is successfully exporting active pharmaceutical ingredients (APIs) and a wide range of Pharmaceuticals products covering all major therapeutic class and dosage forms to more than 125 countries. To achieve a new peak, we have to find new markets, enhance quality of products, enhance productivity, branding and overall efficiency to sustain in the global competition. New technology should be developed to generate new kinds of medicines are added to the product line, and it can be used in various establishments. Progress in Pharmaceutical industry means progress in the economy. The growth of the pharmaceutical industry depends on the advancement of the economic condition. The pharmaceutical industry also faces many problems. So, if government develops policies to support this industry as well as to overcome its obstacles, this industry will flourish and its contribution to employment, other sectors of the economy and growth of export earnings from the present level of five thousand million would be more. Hopefully, within a short time, Pharmaceutical manufacturing industries of Bangladesh would become a 'generic player' in the world.

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