

## **Problems of Export of Pharmaceutical Products from Bangladesh : An Analysis**

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***Abstract:** The pharmaceutical industry is one of the most technologically advanced sectors in current Bangladesh. It has grown in the last two decades at a rapid rate. Efficiency of the professionals and innovative ideas of the people involved in this industry are the key factors for these developments. The industry consists of about 275 pharmaceutical companies which are providing almost 97 percent of the local demand for drugs. Drastic developments in the pharmaceutical sector have enabled Bangladesh to export medicine to global markets. This sector has the opportunity to flourish as the second leading export sector of Bangladesh very soon if it keeps its momentum. But some obstacles are there to achieve that target. Therefore the present study is to find out the problems of export of pharmaceutical products from Bangladesh. The study reveals that the country has tremendous opportunities for pharma export, particularly for value added generics in the regulated markets. The pharmaceutical companies are successful in local market with huge import substitutions and now flourishing in the international market mostly due to the opportunity of patent exemption by the TRIPs till 2033. To boost up the export performance of this sector, some impediments have been identified and also some recommendations have been made to the government and other concerning authorities for API Park, bioequivalence test laboratory, central drug testing laboratory, cash incentives, problems in remittance transfer and sample sending etc.*

***Keywords :** TRIPS, API, GMP, DTL, NCL, DMF, SEZ, NIPER.*

### **1. Introduction**

The economy of Bangladesh is moving forward day by day on the back of her industries. Apart from the textile and garments industry that accommodates most of the employment and export share, there are other industries that are supporting the economy and providing a balanced growth through import substitution. These industries have great potentials to flourish as the country's leading export earner sectors if properly attended by the government and the policy makers. The pharmaceuticals industry is one of the most promising sectors of Bangladesh which is currently contributing significantly to the country's economy. (Sultana, 2016) Pharmaceuticals industry is the heart of healthcare sector of Bangladesh. Comparing with other sectors, it is the most technologically advanced sector of Bangladesh. The pharmaceuticals industry has grown and developed surprisingly in the last two decades. During these decades, the pharmaceuticals sector has achieved an exalted position in domestic and international markets. The success story of Bangladesh pharmaceutical sector is legendary. The growth of pharmaceuticals industries of Bangladesh is remarkable and there are a lot of potentials. (Bashar, 2014) It had to travel a long way to achieve the present prestigious position in domestic and international markets.

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Pharmaceutical companies fulfill more than 97 percent of local demand of medicines and about 30 companies export a significant quantity of medicines to 107 countries, including Germany, the USA, France, Italy, UK, Canada, the Netherlands and Denmark. International regulatory authorities like UK-MHRA, Australia-TGA, EU have already certified some pharmaceutical companies and the giant Beximco Pharmaceutical Ltd. (BPL) and Square Pharmaceuticals Ltd. (SPL) have already received the certification by the US-FDA. In case of earning foreign currency, the pharmaceuticals sector has become the second largest potential sector of Bangladesh and this sector's contribution to the GDP is growing rapidly.

Bangladesh can continue to produce patented products till 2033 as per Trade Related Intellectual Property Rights (TRIPS) because the WTO has granted Least Developed Countries (LDCs) relaxation on the same till 2033. The industry is legally permitted to reverse engineer, manufacture and sell generic versions of on-patent pharmaceutical products for domestic consumption as well as for export to other LDCs. Though Bangladesh still have to import some medicines which are not more than 3 percent of her total demand, but in the near future, the local pharmaceutical companies will be ready to fulfill 100 percent of local demand of medicines as well as to start exporting to reduce trade deficit. Although highly successful in developing the domestic market, the pharmaceuticals sector of Bangladesh is beset with several long standing challenges which need to be addressed to realize its actual export potentially. It is unfortunate that the industry has in fact gained nothing out of this TRIPS flexibility since Doha declaration in 2003. Against this backdrop, the present study is a modest endeavor to find out the problems of export of pharmaceutical products from Bangladesh. This paper consists of four sections – the first of which offers a brief overview of the pharmaceuticals sector of Bangladesh. Export performance of this sector has been discussed in the second section of this paper. Third section thereof deals with some major obstacles impeding the export performance of pharmaceuticals sector, and finally, the last section offers some recommendations to overcome those obstacles to smoothen the path of growth of this sector.

### **Review of Literature**

A brief review of literature of the pharmaceuticals sector of Bangladesh has been presented in this section.

Habib, *et al.* (2011) in an article entitled “*Business Analysis of Pharmaceutical Firms in Bangladesh: Problems and Prospects*” have tried to point out the major problems of marketing, exporting, production and operations, quality control in the pharmaceuticals sector of Bangladesh and have proposed some strategies to overcome these problems. Attempts have also been made to identify the area of prospects of pharmaceutical industry in Bangladesh through their study.

Hoq, *et al.* (2013) reported through their paper on “A Study on SWOT analysis of Pharmaceutical Industry: The Bangladesh Context” the affect of various macroeconomic factors on the strength, opportunity, weakness, and threat of pharmaceuticals industry in Bangladesh with some related problems and prospects for their future.

Bhuiyan, *et al.* (2011) in an article named "*Analysis of Pharmaceuticals Industry of Bangladesh: It's Challenges and Critical Success Factors*" studied the challenges and critical success factors of pharmaceuticals industries of Bangladesh and suggested the establishment of bioequivalence test facilities and more foreign investment for the further growth and development of this sector.

A research report by EBL Securities Ltd. (2015) on "*Pharmaceutical Sector Review*" reveals that the industry is growing at 11.37 percent and has a CAGR of 21 percent. Bangladesh could be ideally positioned to gain from generic drug opportunities with its cost advantages and skilled manpower, but she needs to address key challenges faced by the industry in order to gain further competitive advantages and build presence in the global generics. ([www.eblsecurities.com](http://www.eblsecurities.com))

The review of the literature reveals that there are several studies on pharmaceuticals market analysis, export opportunity and obstacles in overall pharmaceutical sector in Bangladesh. But there is hardly any study carried out only for the export related problems of pharmaceuticals sector of Bangladesh in details. Therefore this paper is a modest attempt to fill this gap. This paper is designed to have a close look into the problems being faced by the pharmaceuticals sector of Bangladesh and also have studied some ways and means to overcome those problems to smoothen the path of growth of export to this sector.

### **Objectives of the Study**

- To explore present export market of pharmaceutical products.
- To identify the problems of exporting pharmaceutical products.
- To identify the prospects in different areas of pharmaceutical export.
- To suggest some policy guidelines for resolving these problems and to cope with the new regime of globalization.

### **Methodology**

Descriptive research design has been selected to study the export related problems of pharmaceutical products from Bangladesh. Both primary and secondary data have been used to construct the body of this paper with secondary data predominating. Primary data have been collected by means of personal interviews and discussions with the concerned ten executives of top five pharmaceuticals companies in Bangladesh, officials of the Directorate of Drug Administration (DGDA) and Export Promotion Bureau (EPB). Annual reports of the stated companies, newsletters, company brochures, published articles in home and abroad, website opinions of the industry experts have been used as the sources of secondary data to prepare this paper. Simple statistical tool- percentiles method has been used to analyze and interpret the field data to be presented in the form of tables and diagrams.

## **2. The Pharmaceuticals Industry in Bangladesh**

The pharmaceuticals industry in Bangladesh is one of the most developed hi-tech sectors within the country's economy. Before the liberation of Bangladesh, there was hardly any pharmaceutical company in the than East Pakistan. In 1971, there were only 33 pharmaceuticals companies in

Bangladesh under Bangladesh Association of Pharmaceutical Industries (BAPI) (Hossain and Shoaib, 2014). The development of pharmaceuticals industry has increased at a speedy rate after the transmission of Drug Control Ordinance-1982. Bangladesh's contrasting experiences with its drug policy in 1982 and its health policy in 1990 illustrates a number of lessons about health policy reform in developing countries. (Rich, 1994). The skills and knowledge of the professionals and innovative ideas of the people involved in this industry are the key factors for this development (EBL Securities Ltd. 2015). The pharmaceutical industry of Bangladesh had the potential to grow and compete in the international market. This is because from the essential life-saving medicines, it has now improved a lot. The ability to provide improved quality assurance provides this industry the competitive advantage, and at present, most companies are following the Good Manufacturing Practice (GMP) standards, set by the UN World Health Organization (WHO). ([www.slideshare.net](http://www.slideshare.net))

Bangladesh is currently enjoying the trade-related benefits of intellectual property rights, that allow developing and poor nations to produce generic drugs and export till 2033 without compulsory licenses or paying the patent holders. According to a report of the International Management System (IMS) published in June 2015, the size of the pharmaceutical market of Bangladesh is estimated to be approximately 117 billion Taka, with an annual growth rate of about 11.37% (Hossain and Shoaib, 2014). 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 Practice (GMP) or drug laws. About 300 pharmaceuticals companies are operating in Bangladesh at this moment manufacturing about 5600 brands of medicines in different dosage forms. There were, however, 1495 wholesale drug license holders and about 37700 retail drug license holders in Bangladesh. The pharmaceuticals industry in Bangladesh is now self-sufficient in meeting the local demand and a contributor to the national exchequer, and it is the largest white-collar intensive employment sector of the country employing around 115000 workers (EBL Securities Ltd., 2015).

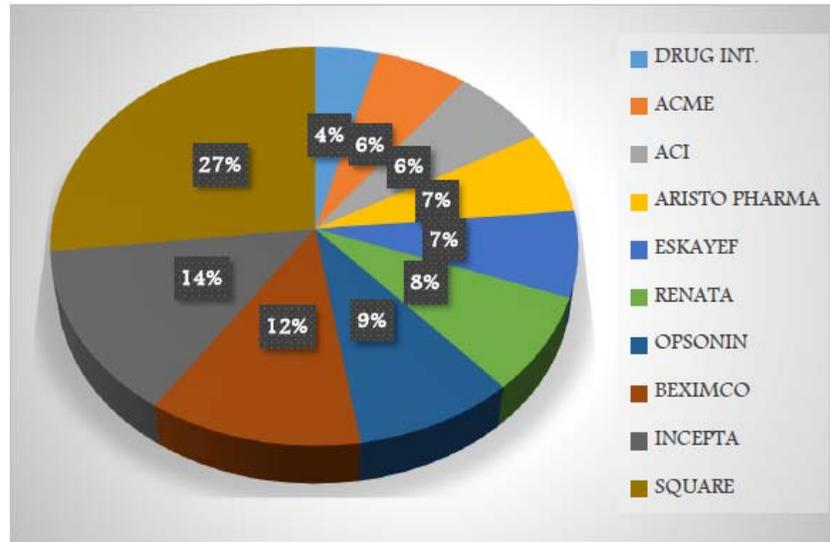
The pharmaceutical export basket is growing fast, as Bangladesh now exports a wide range of major therapeutic capsules, syrups, and tablets. Recently, the companies exports high-tech specialized products like HFA, inhalers, suppositories, hormones, steroids, oncology, immunosuppressant products, nasal sprays, injections and IV infusions. The industry now serves medicines for epidemics like malaria, dengue, cholera, and typhoid, which are available and affordable. The Government of Bangladesh controls three drug-manufacturing units, of which two units are in Dhaka and another one is in Bogra. The name of these units is Essential Drug Company Ltd. (EDCL) that is working as a Public limited company under the ministry of health and family welfare. The pharmaceutical industry in Bangladesh has otherwise the potential to grow and enjoy a number of competitive advantages. Quality assurance has put the industry on a solid base. Almost all companies follow the World Health Organization (WHO) Good Manufacturing Practice (GMP) standards.

Bangladesh's strict quality compliance gives pharmaceuticals an advantage to compete with producers in India, China, Brazil and Turkey in the overseas export markets. The capability of the industry has helped it achieve excellence as per the general international standards. A good number of local pharmaceutical companies have won accreditation from the overseas regulatory authorities including some of those in the developed countries. Some local companies Such as Square Pharmaceuticals Limited (SPL) and Beximco Pharmaceuticals Limited (BPL) have been accredited by EMEA (Austria) the Therapeutic Goods Administration (TGA-Australia), MHRA(UK), TFDA (Thailand), Health Canada, BPOM (Indonesia), ANVISA (Brazil), AGES (Germany), GCC DR (Gulf Central Committee for Drug registration) and USFDA. The accreditation facilitates their entry into the lucrative market as reputed players. Bangladesh's national drug policy requires strict standards compliance from the pharmaceutical manufacturers. The Current Good Manufacturing Practice (CGMP) is recognized worldwide for its holistic approach for the control and management of manufacturing and quality control testing of food and pharmaceutical products.

The sector is active in API (Active Pharmaceutical Ingredients). Many companies now locally manufacture a good number of APIs. However, compared to large local demand, more API industries are needed to be set up. Pharmaceutical industries' potential has multiplied with the recently approved API industrial park in Munshigonj. The API can save at least 70 per cent of the cost of import of pharmaceutical raw materials from abroad. Skilled professionals at home and abroad are joining the industry's human resources pool every year. Currently, bio-equivalency tests are conducted in Singapore, Malaysia and in European countries, resulting in some hefty operational expenditure on the part of pharmaceutical industries. More investments in these sub-sectors would be needed in future. Foreign investors can take advantage of the flourishing industry. It is estimated that over \$250 million have been invested in this sector over the recent years for facility modernization and setting up of new facilities. All of these investments were for developing full GMP compliant facilities to meet the stringent regulatory requirement of any country of the world. The investment has already started paying off as most of the companies have either already received certification or are about to get the approval from more regulatory authorities at abroad. This has opened up wider opportunities for the Bangladeshi companies to claim a bigger share in the large global pharmaceutical market.

#### **Top 10 Pharmaceuticals in Bangladesh**

1. Square Pharmaceuticals Ltd.
2. Incepta Pharmaceuticals Ltd.
3. Beximco Pharmaceuticals Ltd.
4. Opsonin Pharma Ltd.
5. Renata Ltd.
6. Eskayef Bangladesh Ltd.
7. ACI Ltd.
8. ACME Laboratories Ltd.
9. Aristopharma Ltd.
10. Drug Internationals Ltd.



*Figure-1: 10 Major Players in Local Pharma market*

### 3. Pharmaceuticals Products in the Overseas Market

Bangladeshi pharmaceuticals companies are expanding their exportable items. The country is now exporting a reasonably wide range of pharmaceutical products covering therapeutic classes and dosage forms like tablets, capsules and syrups. Bangladesh also exports some high-tech specialized products like, HFA, inhalers, suppositories, hormones, steroids, oncology, immunosuppressant products, nasal sprays, injectibles and IV infusions. The sector stands on a sound footing due to the growing demand of medicines for the country's 160 million people. The history of pharmaceutical export from Bangladesh dates back to late 80's. At that point in time, only one or two pharmaceutical companies of Bangladesh took proactive efforts to initiate export of pharmaceuticals from Bangladesh. Despite the fact that there was no support or incentive from the Govt., these companies with their own initiative started exporting finished formulations to some of the neighboring less regulated overseas markets like Myanmar, Sri Lanka and Nepal.

After being successful in these less-regulated markets, in early 90's few major companies of this country also took initiative to explore some of the more-regulated markets like Russia, Ukraine, Georgia and Singapore. Success in registering and marketing these products in these countries was a major breakthrough for Bangladesh pharmaceutical industries.

Today, Bangladesh pharmaceutical industry has successfully started exporting its quality products to about 107 countries across four continents. Although volume wise the amount may not appear to be huge, but most importantly it is growing at a very fast pace. Today, Bangladesh is exporting a wide range of pharmaceutical products covering all major therapeutic classes and dosage forms. Beside regular brands, Bangladesh is also exporting high-tech specialized products like Inhalers, Suppositories, Nasal Sprays, Injectables and Infusions. The product quality, packaging and presentation of the products have been highly appreciated in all of the countries of export destination. Bangladeshi firms can export to the following markets:

- **Regulated:** Beximco Pharmaceuticals and Square Pharmaceuticals are the Bangladeshi pharmaceutical firm accredited in a regulated market, received the USFDA's regulatory approval in 2015. Other firms' biggest barriers to regulated markets are manufacturing facilities (at a cost of at least \$50 million) and know-how.
- **Moderately Regulated:** Some markets, such as Tanzania and Malaysia, are moderately regulated. While countries do not always require stringent certification, a certification from a regulated market signifies quality and provides a firm with a competitive advantage.
- **Unregulated:** Most Bangladeshi pharmaceuticals are exported to less than fully regulated markets such as Bhutan, Pakistan, Sri Lanka, Nepal, Vietnam and Myanmar.

### Export Scenario

Bangladesh is now the largest producer of formulation products in Least Developed Countries (LDCs); and is exporting to more than 107 countries and has 18 percent share in the international business, with exports to Asia, Africa, Europe, and Latin America.

The industry is also exporting abroad. Currently, formulations are exported to 107 countries around the world. The major destinations for Bangladeshi medicines are Myanmar, Sri Lanka and Kenya, while nearly 50 countries import Bangladeshi medicines regularly. The growth in exports has averaged over 10% from 2010 to 2014. The export value of pharmaceuticals is growing at a reasonable rate every year. Exports increased from \$8.2 million in 2004 to \$72.6 million in 2015 and posted further gains last year. Export destinations are also increasing in number. Pharmaceutical companies are trying to export to regulated, unregulated and moderately regulated markets. Bangladesh Association of Pharmaceutical Industries (BAPI) (Bangladesh Aushad Shilpa Samity) has recently organized 'the three-day Expo' in an effort to brand Bangladesh's 'robust' drug industry in the global market for boosting export. At present, Bangladeshi companies are in a position to export pharmaceutical products to any part of the globe.

### Growth of Bangladeshi pharmaceuticals products in international markets:

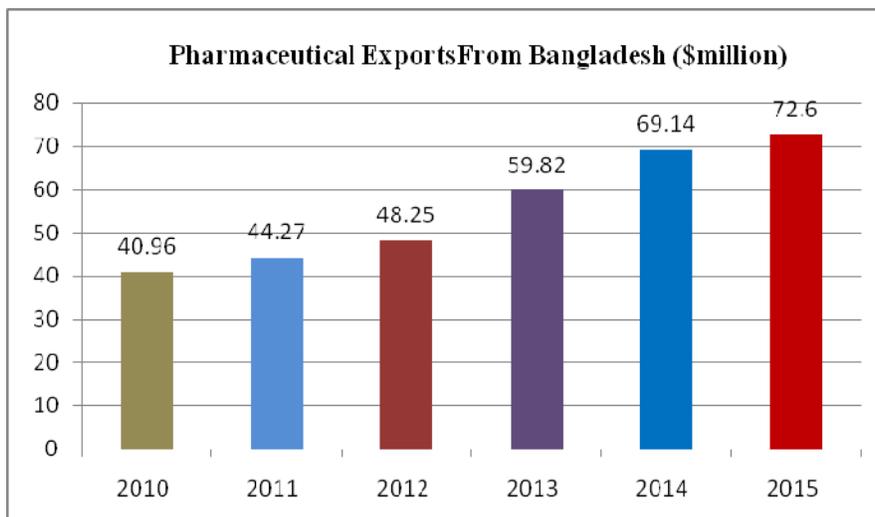


Figure-2: Exports growth (Source: EPB: Export Promotion Bureau Bangladesh: [epb.portal.gov.bd](http://epb.portal.gov.bd))

**Table-1: Country-wise export from Bangladesh (in US \$)**

SL No.	Country of Export	2013 -14	2014-15
1.	Afgnistan	3230163	3385519
2.	Brazil	1276942	--
3.	UK	3431664	2522477
4.	Kenya	4003133	3742058
5.	Combdia	1013409	1557473
6.	Sri Lanka	6836085	8330115
7.	Myanmar	11683303	11506483
8.	Nepal	1260415	1335936
9.	Philippines	5728297	6459903
10.	Singapore	1285486	--
11.	Slovenia	2651843	3446917
12.	Somalia	1205005	1402731
13.	Vietnam	4767339	5375950
14.	South Africa	1999737	2468335

Source: EPB: Export Promotion Bureau Bangladesh: [epb.portal.gov.bd](http://epb.portal.gov.bd))

#### **4. Problems of Export of Pharmaceuticals Products of Bangladesh**

##### ***Restrictions of Bangladesh Bank to remit transfer hampering pharmaceutical exports:***

Bangladesh bank permits to remit maximum 30,000 USD in a year. Payment for company and product registrations, office establishment and maintenance, manpower cost, marketing expenditure/promotion of drugs, and miscellaneous export related expenditure becomes much higher than the above limit. The government should really understand that this barrier is hampering our export activities. Therefore, remit limit for smooth operation of pharmaceutical export activities should not be imposed. It is worthy to mention here that BAPI leaders/authority and many business experts urged to the proper authority of our government, also discussed and urged in different seminars/meetings to solve this issue in different times, but the problem has not yet been solved. So, for the sake of pharmaceutical export, the govt. should immediately remove the restrictions imposed by Bangladesh Bank to remit money for export activities.

##### ***Custom harassment in sending drug sample interrupts export promotion:***

The customs authority of Bangladesh imposes lot of restrictions in sending drug samples to the importing countries. Instead of doing favor they are rather interrupting our normal export activities. Sometimes they apply many restrictions on giving permission to sending drug samples, also limit the quantity of samples to be sent, and above all, don't allow sending drug sample more than BDT 4000 without VAT. It must be realized that without sufficient drug samples, no foreign buyers will be interested to buy our products. Besides, for the testing and promotion purposes, 30-40 percent samples are required by the importing countries. Therefore, understanding the reality the custom authority should allow at least 30-40 percent samples to be sent to the importing countries without VAT.

***Lack of bioequivalence test facility is a major limitation of pharmaceutical export:***

Bioequivalence study of a product is a must for the registration of that product in many of the moderately regulated and regulated foreign countries. At present, we don't have any facilities for bioequivalence study. In order to register a product, a pharmaceutical company has to carry out this test in foreign country by spending of a huge testing charge (USD 50,000-100,000/product)<sup>13</sup>. For this reason, many pharmaceutical manufacturers don't show interest to register their products in foreign countries that require Bioequivalence study. It is relevant here to mention that BAPI and pharmaceutical exporters first felt the necessity of having Bioequivalence test facility in our country and they proposed and demanded to set up a modern Bioequivalence test center to the govt. for the promotion of pharmaceutical export. But it's a matter of great regret that still no step has been taken by the govt. It hampers our overall export activities. The government of Bangladesh should immediately set up an independent modern Bioequivalence test laboratory in our country to gear up the overall export activities and to save huge foreign currency that our pharmaceutical companies are currently expending. Alternatively, our pharmaceutical manufacturers can make an agreement with International Center for Diarrhoeal Diseases and Research in Bangladesh (ICDDR,B) and/or Bangladesh Council for Scientific and Industrial Research (BCSIR) for Bioequivalence study with reasonable cost (USD 10,000-15,000/product).

***Setting up of API Production Park may remarkably reduce the production cost of medicines thus potentiality contributes to pharmaceutical export:***

The major advancement of Bangladesh pharmaceutical sector has been occurred in the production of finished products. At present, we are greatly dependent on import of raw materials (more than 90 percent raw materials are imported) for the production of finished drugs. Although our labor cost, white color labor cost, utility service charges, etc. are very low compared to any other countries, only because of our dependent on imported raw materials, the production cost of our finished products become higher than that of India and China. That's why, we can't compete with the Indians and Chinese companies to offer export price. Hence, the setting up of an Active Pharmaceutical Ingredient (API) plant is very urgent issue. Due to the claim and urges of BAPI and pharmaceutical business entrepreneurs, the government of Bangladesh has taken an initiative to establish an API near Dhaka. Long time has already been passed after taking decision of establishing an API but still the API has not yet come true. Local production of raw materials in API will greatly contribute to our pharmaceutical export to extend export volume, and also can potentially contribute to the country's economy.

***Country image and production of substandard/fake drugs by some companies hampering the acceptance of our products to international community***

Some small scale companies in our country are still producing substandard or spurious drugs which damage the overall image of Bangladeshi products to the international community, thus making our export difficult. BAPI can play an important role in this regard by establishing an effective mechanism by their own arrangement or help the drug controlling authority - Directorate General of Drug Administration (DGDA) or other controlling authority of the government to control the production of fake/substandard/adulterated/spurious drugs. The government and the

drug control authority should strictly control the manufacturing of spurious or substandard or adulterated drugs to maintain a clean image of Bangladeshi products home and abroad as well as for the health safety of the nation.

***Lack of a modern drug testing laboratory is a major limitation of drug control authority of Bangladesh that also affects pharmaceutical export:***

We don't have a modern, well equipped Drug Testing Laboratory (DTL) with sufficient and skilled pharmaceutical scientists. Due to lack of this, our drug control authority cannot monitor the quality of drugs manufactured by different pharmaceutical companies in Bangladesh. Moreover, foreign buyers and regulatory authorities raise question about the status of our drug testing laboratory, the central quality monitoring facilities of drug authority of Bangladesh. Our existing drug testing laboratories need massive improvement in this respect. The government should immediately do the necessary work to establish whether a modern DTL or National Control Laboratory (NCL) with sufficient skilled manpower to monitor the quality of drugs manufactured by different pharmaceuticals.

**The regulatory authorities of importing countries are not satisfied with the status, activities and documents of drug administration of Bangladesh**

The documents provided by the Drug Administration of Bangladesh are not impressive; represent the poor status of drug regulatory authority of Bangladesh to the business community and to the regulatory authorities of importing countries. Besides, the website of DGDA is still lacking lot of necessary and up-to-date information, required and inspected by the business partners and regulatory authorities of importing countries. The website should be updated regularly. It is noteworthy to mention here that export of medicine is not as usual as other products like RMG, leather, etc. The importers and regulatory authorities of medicines have a lot of queries and technical aspects to know to assure the quality of medicine and reliability of their business. The present status of DGDA website is better than the previous time and many aspects have been developed and included. Yet, many more things have to do to make it suitable for international business.

**The regulatory authorities of importing countries are charging high registration fees**

Regulatory authorities are charging high amount of registration fees which creates an obstacle for the pharmaceuticals company. Often the small companies do not go to get registered their products on those markets which have cost much for maintain their expenses and they found less profitability. Therefore only big companies are taking the opportunities and markets are limited for those companies only.

**Uneven registration expenses increase cost**

There are some hidden charges which have to pay by the Bangladeshi companies to registration pharmaceutical product in LDC's countries. Some third party agency required agency fees and also take the speed money to bias the person who are responsible in regulatory authority to reduce the uneven time schedule to register a product in those countries. Sometimes Industry inspection

by importing country also cause increases in expenses due to they are charging hi amount of speed money to give bias inspection report.

#### **Medicine export looking for rather than emphasized to LDCs**

Some companies are aggressive to enter the highly regulated overseas markets, such as, USA, Australia, Europe, Canada, France, and Golf countries. But the practical observation is that getting export status to those countries requires huge investment in the manufacturing plant to achieve certification from different international drug regulatory authorities, highly sophisticated documentation, and huge initial capital investment. The main reason of this attitude is to achieve high quality status of the company that uplifts the dignity of the company to our national and international markets. Actually the export volume to the highly regulated countries will not be easily feasible; rather we can perform pretty well and can potentially increase our export if our exporters become more attentive to LDCs. Among 50 LDCs, only Bangladesh has its strong fundamental and modern manufacturing base, hence we can easily share the drug market of rest of the LDCs. So, considering the practical situation, the LDCs should be the targeted markets of our pharmaceuticals, of course, side by side, moderately regulated and highly regulated markets may be explored gradually. However, we can establish joint-venture, tool manufacturing, and contract-manufacturing business with the companies of developed countries, not only for exporting medicines.

#### **Export cells by the government private consultancy firms are not properly promoting pharma export**

Government usually not taking any initiative to establish specialized Export Cell to promote exports of pharmaceuticals to grab and capitalize the huge export opportunities in LDCs Some private consultancy firms having experience and expertise in drug export professionally can be engaged to assist the pharmaceutical companies who do not have the technical and expertise know-how to go through the entire process of export, or have lacking in documentation skills or even do not have the skilled man power to deal with the drug export. Thus, consultancy firms can play a significant role to explore export to maximum countries, accelerate export activities, and to reduce the overall cost of export. Even some small companies having International Marketing Department (IMD) can explore the benefits of outsourcing by hiring Export Consultants to reduce its overhead expenditure and make a comparative study of cost-benefit ration to justify having IMD.

### **5. Recommendations for Export**

#### ***Backward integration into API***

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 pharma industry to gain better control over the inputs and improve operational efficiencies. (www.dhakatribune.com) India, the major generic drug player, has more than 3500 Drug Master File (DMF) approval for APIs whereas we have none. We must strengthen our synthetic chemistry skills for improving API capabilities.

### ***Central bioequivalence and drug testing laboratory***

Bioequivalence testing is conducted to see if the generic version is identical to originator brand and this is mandatory for product registration in any developed market. This testing is very expensive if done in US or Europe. The government should support in setting up such a centre which would help the industry in a big way. The country also lacks a state of the art drug testing lab to routinely and accurately monitor quality of drugs produced locally.

### ***Strengthening of Drug Regulatory Authority***

The industry needs a highly credible drug regulatory authority similar to US FDA to regulate drugs as well as food products. Continuous training and exchange programs with global regulatory bodies would help them equip with the skills and knowledge to perform their duties responsibly.

### ***Special Economic Zone (SEZ) for Pharma***

The government should formulate a policy for setting up pharma SEZ with the intention of providing an internationally competitive and hassle-free environment. This should offer to the manufacturers tax and other benefits to encourage export. Both China and India have successfully created numerous SEZs for boosting pharma export.

### ***Export incentives from government***

Bangladesh has the opportunity to excel in high quality generic drug manufacture for export. Government incentives in various forms can help the pharma companies to focus more on export and improve sectoral performance. These can be in the form of excise duty exemptions, income tax holidays, investment subsidy (on capital investment) and interest subsidies. India has created Pharmaceutical Export Promotion Council under the Ministry of Commerce to promote export of pharmaceuticals.

### ***Capacity building in IP/regulatory and legal affairs***

To be able to operate in regulated markets such as USA, EU or Australia, any aspiring generic drug company must have the sufficient knowledge and expertise to deal with increasingly important legal and regulatory issues including patent litigations. This is a critical area for a knowledge based industry like pharma where our industry is still in its early stage. Government grants/assistance can help establish IP Centers and the government should also emphasise on strengthening its Patent Office in order to keep pace with WTO/TRIPS agreements and changing landscape of global trade.

### ***Building biosimilar capabilities***

Valued at nearly \$200 billion, Biologic drugs have been a major segment in global pharma market today with seven of them occupying the top 10 positions. Biosimilar or generic versions of these biologic drugs are increasingly becoming a major focus for pharmaceutical companies across the globe. As the number of patent expiry is rising every year in this category, which offers greater

opportunities for generic manufacturers, we should also enhance biosimilar capabilities with appropriate regulatory guidelines in place.

#### ***Industry and academia collaboration***

To build and strengthen pharma capabilities in different areas namely developing specialized drug delivery systems, biosimilars and vaccines, drug research, patent due diligence, etc, there must be strong collaboration between industry and university. Specialized pharmaceutical research institutes can be established to promote research and develop human resources for the industry. The government of India has established the National Institute of Pharmaceutical Education and Research (NIPER). There are seven such institutes and ten more are being established at a cost of \$500 million. These provide post graduate and PhD level education and contribute to thousands of Masters and PhDs per year.

#### ***Incentive for promoting R&D activities***

Reverse engineering is the key to success for any generic drug company and it requires significant investment in building capabilities to create strong differentiation. This is a continuous process and to encourage R&D there should be incentives from the government. For example Indian pharma industry enjoys increased weighted deduction of up to 200 percent on in-house research and development (R&D) expenses.

#### ***Export promotion scheme***

A government scheme may support activities for the pharma sector by promoting seminars, conferences, exhibitions, sending delegations to and from the country for promotion of exports as well as investments, conducting studies/consultancies.

#### ***Venture capital fund***

The idea of the venture capital fund will be to offer financial incentives to companies focusing on research, for example, in the areas of biosimilar, NDSS or early-stage drug development. This would promote entrepreneurship in the sector and support the development of a self-sustaining environment for R&D in the country. India has set up a venture capital fund of \$370mn to promote R&D in the pharma sector.

#### ***Infrastructure for exporting high-end pharmaceuticals***

Creating dedicated cargo storage and handling zone exclusively for sensitive pharmaceutical products such as biologics, insulins, vaccines, etc which require cold chain system. India already has Pharma Zone for such products.

#### ***Contract manufacturing***

The industry also needs to find new opportunities of growth in contract manufacturing and research, clinical research and custom synthesis. Pharmaceutical contract manufacturing is already a 55-60 billion dollar business and increasing number of MNCs are looking for outsourcing their production from cost effective destinations like India or China. Having considerable cost

advantages in manufacturing, Bangladesh is in a position to offer this service to global clients as the country has a sound track record of partnerships with a number of major multinational companies.

### Conclusion

The pharmaceutical sector of Bangladesh is the second largest export earning sector after RMG. The country has built a solid base for this sector to emerge as a potential sector in the upcoming days to support our economy. The pharmaceutical companies are successful in local market with huge import substitutions and now flourishing in the international market mostly due to the opportunity of patent exemption by the TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) until 2033. To boost up this sector's elevation the obstacles should be reduced in a short period of time. Some steps have already been taken by the government, which is offering of cash incentives to the medicine exporters and the Export Promotion Bureau (EPB) is arranging international trade fair to attract the foreign buyers. The companies are also trying on their own to expand business in new countries. BAPI is arranging visits for the experts to foreign countries so that they can adopt modern technology and implement it in the local factories. This organization also upheld the demand and urged to the government and other concerning authorities for API Park, bioequivalence test laboratory, central drug testing laboratory, cash incentives, problems in remit transfer and sample sending etc. But many issues are yet to resolve. We have already wasted our valuable time and still losing to build our infrastructure for export. We should complete our infrastructure as soon as possible because TRIPs patent protection may be adapted after 2033. The government should really be attentive to remove all the obstacles and solve all the problems to see pharmaceutical sector as a vital player in the international market.

### Text References

- Bashar, S. M. and Islam, M. I. (2014). Determinants of Profitability in the Pharmaceutical Industries of Bangladesh. *Journal of SUB*, 5, 56-76.
- Bhuiyan, M. A. R., Monuiruzzaman and Sultana, S. (2011). Analysis of Pharmaceutical Industry of Bangladesh: It's Challenges and Critical Success Factors, *Bangladesh Research Publications Journal*, 5(2): 142-156.
- Habib, M. A. and Alam, M. Z. (2011). Business Analysis of Pharmaceutical Firms in Bangladesh. *Journal of Business and Technology (Dhaka)* Volume-VI, Number-01, January-June.
- Hoq, M. R., Ahsan, M. A. and Tabassum (2013). A Study on SWOT Analysis of Pharmaceutical Industry: The Bangladesh Context. *Global Disclosure of Economics and Business*, Volume 2, No. 2.
- Hossain, M. M. and Shoaib, S. M. (2014). Role of Pharmaceutical Sector in the National economy of Bangladesh, *World Journal of Pharmacy and Pharmaceutical Sciences*, Vol. 3, Issue 2, pp. 951-960.
- Reich, M. R. (1994). Bangladesh Pharmaceutical Policy and Politics. *Health Policy and Planning Oxford University Press*, 9(2), pp. 130-143.
- Sarker, M. M. R. (2010). Export opportunities in LDCs. *The Pharma World*, Vol. 2, No. 17, pp. 55-56.
- Sultana, J. (2016). Future Prospects and Barriers of Pharmaceutical Industries in Bangladesh. *Bangladesh Pharmaceutical Journal*, 19(1), pp. 53-57.

**Website References**

<http://www.slideshare.net/samrat23/export-potentiality-of-pharmaceutical-goods-in-bangladesh>

[http://www.eblsecurities.com/AM\\_Resources/AM\\_ResearchReports/SectorReport/Pharmaceutical%20Industry%20Overview-%20EBLSL.pdf](http://www.eblsecurities.com/AM_Resources/AM_ResearchReports/SectorReport/Pharmaceutical%20Industry%20Overview-%20EBLSL.pdf)

<http://www.dhakatribune.com/long-form/2015/feb/13/prescription-growth>

<http://epb.portal.gov.bd>

<http://www.assignmentpoint.com/science/pharmacy/assignment-on-pharmaceuticals-sector-of-bangladesh.html>

<http://www.beximcopharma.com>

[http://www.academia.edu/2250607/Pharmaceutical\\_Export\\_Facts\\_and\\_Challenges\\_hat\\_should\\_not\\_be\\_ignored-An\\_Analysis](http://www.academia.edu/2250607/Pharmaceutical_Export_Facts_and_Challenges_hat_should_not_be_ignored-An_Analysis)

[http://asiapharma.org/ape/ape\\_organisers.html](http://asiapharma.org/ape/ape_organisers.html)