

An A-Z of Pharma Industry Review: Bangladesh Perspective

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ABSTRACT

After liberation, Bangladesh pharma industry was largely dominated by the import dependent MNCs. On or before 1982 ordinance, 75% of the market was dominated by the MNCs and the rest share was with the other 133 local companies. After NDP formulation and the Drug Control Ordinance, there was a dramatic change of reverse. By 1994, a few pharma companies achieved a tremendous growth and they reinvest their profit for faster return. By next decade, Bangladesh is aiming to 30 world class drug manufacturers to establish strong footstep in global pharma market. Bangladesh, as an LDC got exempted from the obligation of patent and data protection in this arena until 2033. Interestingly, Bangladesh already passed across the LDC landmark to a developing country. So, there's window of opportunity of more than a decade to grow further from that aspect.

Keywords: National Drug Policy (NDP), The Directorate General of Drug Administration (DGDA), Pharmacy Council of Bangladesh (PCB), Bangladesh Pharmaceutical Society (BPS), Bangladesh Association of Pharmaceutical Industries (BAPI)

Purpose: Discussion and projection of Bangladesh pharma market in a multi-dimensional approach.

Methodology: Secondary data were used in preparing this study. Research conducted a comprehensive literature search, which included technical newsletters, newspapers journals, and many other sources. Medicine and technical experts were interviewed. Projections were based on estimates such as the history, current market scenario, drug users, dealers, mergers and acquisitions, new developments and market trends.

Findings: Bangladesh pharma market has tremendous hope, although going through lots of anomalies. Reasons behind are economic development, population blast, investment scopes, FDIs along with many other unexplained matters.

Research limitations: Market is too big to be explained in a single article. The term "A -Z" doesn't reveal all information about Bangladesh pharma market is accomplished, rather 26 letters used in 26 headlines, that means 26 points of this market is discussed that surely comprised a greater part of it.

Practical Implication: The soul of this article was to introduce students about Bangladesh pharma

market, that they have very few ideas. Along with students, researchers and professionals of different background and disciplines, e.g. Pharmacists, marketers, finance companies and regulatory authorities have to acquire much from this article.

Social Implication: Medicine manufacturers are an integral part of Bangladesh health sector. General people pay much interest but having little knowledge about them. The article should provide them a broader picture and unleash many unseen facts.

INTRODUCTION

In Bangladesh, the pharmaceutical sector is now one of the fastest growing sectors. The history of Pharmaceuticals industry dates back to 1950s. Over the years, the industry has gone through some significant changes. In the early post-independence period of Bangladesh, multinational companies (MNCs) dominated the pharmaceutical sector. According to Bangladesh Tariff Commission, 2010 eight leading MNCs enjoyed 75% of the total domestic market. In 1982, a defined guideline for the development of the industry was created through

the formulation of national drug policy (NDP), and drug control ordinance. Under the NDP, only local companies were allowed to produce vitamins, enzymes, and cough syrups. This led to the formation of local pharmaceutical companies and an increase in domestic production. And Bangladesh, which was once a drug-importing country, became a drug-exporting country by the late 80s. In 2004, it was estimated that the total size of the pharmaceutical market in Bangladesh was Tk. 28.416 million. With an annual growth rate of around 10%, the Bengali pharmaceutical industry is now moving towards self-sufficiency to meet local demand. The Bangladeshi pharmaceutical industry is the second largest contributor to the national treasure after garments, and is the largest sector of intensive employment of white-collar workers in the country. IMS (2015) report shows that the market size has reached \$ 1.6 billion. This industry serves almost 98% of demand through local production. The domestic market of pharmaceutical products has shown a tremendous growth over the last few years and the industry recorded 17.6% average growth between the years 2011-2015. Pharmaceutical industry has been ranked second in terms of gross value addition for many years after Readymade Garments (RMGs) and the sector has the potential to top the list. The imported medicines mainly include anticancer drugs, vaccines against viral diseases, hormones, etc. Indeed, the true growth of local pharmaceutical industries began after the promulgation of the "Drug Control Act" in 1982 in Bangladesh to limit the massive import of drugs and encourage local drug production. Many multinational companies (MNCs) were dissatisfied with this development. Category of the generic product prices are competitive, Bangladesh mainly concentrated this type of product about 80% drug because as labor cost is one of the lowest in the world. Bangladesh's pharmaceutical sector has been growing steadily over the last twenty years.

Regulatory regime

The Directorate General of Drug Administration (DGDA): DGDA is the drug regulatory authority of Bangladesh, which is under the Ministry of Health and Family Welfare. DGDA regulates all activities related to import and export of raw materials, packaging materials, production, sale, pricing,

licensing, registration, etc. of all kinds of medicine including those of Ayurvedic, Unani, and Herbal and Homoeopathic systems.

The Pharmacy Council of Bangladesh (PCB): PCB was established under the Pharmacy Ordinance in 1976 to control pharmacy practice in Bangladesh.

The Bangladesh Pharmaceutical Society (BPS) is affiliated with international organizations International Pharmaceutical Federation and Commonwealth Pharmaceutical Association. The National Drug Policy (2005) states that the WHO's current Good Manufacturing Practices (GMP) should be strictly followed and that manufacturing units will be regularly inspected by the DDA. Other key features of regulation are restrictions on imported drugs; a ban on the production in Bangladesh of around 1,700 drugs which are considered non-essential or harmful; and strict price controls, affecting some 117 principal medicines.

Government Incentive

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

Products of The Pharmaceutical Industry

The Directorate General of Drug Administration under the Ministry of Health & Family Welfare, Govt. of Bangladesh, is the Drug Regulatory Authority of the country. This Directorate supervises and implements all prevailing Drug Regulations in the country and regulates all activities related to import and procurement of raw and packing materials, production and import of finished drugs, export, sale, pricing, etc. of all kinds of medicine including those of Ayurvedic, Unani, Homoeopathic and Herbal systems (Web DGDA).

UNANI: At present, there are 295 Unani companies operating in Bangladesh.

AYURVEDIC: At present, there are 201 Ayurvedic companies operating in Bangladesh.

HERBAL: At present, there are 15 Herbal companies operating in Bangladesh.

HOMEOPATHIC: At present, there are 79 Homeopathic companies operating in Bangladesh.

ALLOPATHIC: At present, there are 258 Allopathic companies operating in Bangladesh.

INDUSTRY SCENARIO

A. Local Market Overview: The Bangladesh pharmaceutical marketplace is predominantly a branded generic marketplace. Pharmaceutical firms in Bangladesh can either sell to the private sector pharmacies, to the government and its public health care facilities, or to international organizations operating in Bangladesh (e.g. UNICEF). The top two domestic manufacturers, namely Square and Incepta Pharma are having a combined market share of near 30% of the total pharmaceutical market of the country. Bangladesh Association of Pharmaceutical Industries (BAPI) was instituted in 1972, since then BAPI playing a pivotal role in shaping up the industry (Janet et.al 2007).

B. Industry Structure: The industry has some distinct features compared to other countries. First, R&D activity is virtually nil in Bangladesh pharmaceutical industry – it is a branded generic market. Companies basically manufacture finished formulation by assembling known generic and patented (in some cases) product combination. Some firms have been engaged in producing APIs, the core of pharmaceutical products, but these productions are limited to synthesis stage (final stage) only.

C. Segmentation:

I. The primary layer is R&D Activities. This is often a very costly and high-risk business, and for many of global Pharmaceutical firms, represent the majority of costs. However, in Bangladesh, this activity is nil, and all the firms are producers of known and established drugs.

II. The second layer is manufacture of ingredients for finished formulations. These activities cover production of Active Pharmaceutical Ingredients (API), Excipients, and Solvents etc. that are used as

raw material in producing the final drug formulations. Historically, Bangladesh has been dependent on imports for APIs and other ingredients. The pharmaceutical manufacturers in Bangladesh procure raw materials from various countries namely UK, France, Germany, Japan, Holland, Italy, Denmark, China, Switzerland, Austria, Hungary, India, Ireland etc.

III. The final layer concerns producing final products, finished formulations. In this layer, there are both patented and generic products. However, in Bangladesh, only generic products are produced. Formulations represent the mainstream business in pharmaceuticals industry of Bangladesh. Presently, the market consists of approximately 8000 generic products and 258 firms with manufacturing capability, along with some imported patented products. (The Daily Star March 07, 2016)

D. Business nature:

1. High-End products (Anti-Cancer, Insulin, Vaccines etc.)

These are essentially products specific to market niches, i.e. Anti-cancer, Diabetic products, Vaccines etc. these products are usually high priced and represent a small portion of the market. Profit margin in such products is very high. Recently, domestic firms have been entering into this field, and competition is expected to drive prices and import dependency down.

2. Branded generics (Anti-Gastric, Anti-Biotic etc.)

This represents broadest segment of the market, comprising products with relatively stable margin and Brand orientation. This segment is dominated by local manufacturers, and due to high brand loyalty observed in our market, market share of manufacturers is usually moving rarely.

3. Low End generics

This segment is small, often for products with low branding possibility, and price war is most evident here. The number of competitors is very high, and market share of each competitor depends on success of marketing strategy (Ramesh S, Economitimes India).

4. Contract manufacturing (domestic and export)

Locally, this segment is small as almost every firm manufactures its own products. The business usually comes from Health organizations like SMC (Social

Marketing Company), UNICEF etc. to provide products such as saline, contraceptives etc.

Presently, a number of top firms engage in contract manufacturing. Competition is very low, as each firm engages based on foreign counterpart relations. Manufacturing technologies and accreditations play a vital role in developing contract manufacturing capability.

E. Export: Export of pharmaceutical products of Bangladesh is still in infancy. But the rate of establishment of pharmaceuticals industries in private sector is increasing and they have already entered the export market with their finished products. In 2000, Bangladesh imported US\$84,000,000 worth of medicinal and pharmaceutical products and had negligible exports and some recent statements by industry representatives suggest that exports will increase in the near future. Bangladesh is exporting their pharmaceuticals products to 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.

F. Import: Bangladesh is importing the medicinal products from different countries, especially from India and China. Different organizations of this country are related to import the pharmaceuticals products and raw materials of pharmaceutical industries. Novo and Medintis are importing maximum amount of these types of products. Other organizations are engaging to import the pharmaceuticals products. They are- Sanofi, Aventis, GSK (now closing operation), Sandoz, Novartis, Roche, Unimed, Servier etc.

G. Foreign Competitions: At the beginning the foreign pharmaceuticals were dominating the market in our country. Still now, Pharmaceuticals industries are facing foreign competition. But our industry is not afraid of this foreign competition. There are many multinational pharmaceutical organizations which have established their plants in Bangladesh and importing their raw materials from abroad. Among these competitors, Roche, Glaxo

SmithKline, Novartis are leading. In export market, the Novartis is playing the dominant role.

H. Dumping: Some Indian medicines are sold in the country market at a lower price than Bangladeshi medicines but the medicine of developed countries and their origin country are sold in a competitive price, even in higher price. This creates the barrier to capture the market share by Bangladeshi pharmaceutical industries. Owners of the pharmaceutical companies think that the government should take actions to stop this practice (Ahsan et.al 2011).

I. Problems of Marketing:

- Because of having no sufficient incentives in comparison with their effort, the turnover rate of medical representatives is very high.
- Most of the time costs of marketing hardly affect the price of the medicine.
- Professionalism in marketing is not achieved yet in Bangladesh like other developing countries.
- Lack of proper governmental laws and this implementation the law by the drug administration.
- Unstable political situation and different types of violence.
- Effect of globalization that has increased the competition.
- Smuggled production counterfeit, that's coming from the neighbor countries.

J. Five important JOB SCOPES in Pharmaceutical industries

1. Pharmaceutical industries (Finished medicines, Active Pharmaceutical Ingredients/APIs, and Excipients Manufacturing industries): In Production, Quality Control (QC), Quality Assurance (QA), Product Development (PD), cGMP Training, Warehouse, Drug Research and Invention, and Technical Services Department (TSD).
2. Pharmaceutical Marketing: Product Management Department (PMD), Medical Services Department (MSD), Sales Promotion/Medical Promotion, Clinical Services, Training for field forces, and International Marketing (IM) departments.
3. Drug Testing Laboratories (Dhaka and Chittagong)
4. Research & Development in Pharma industries, educational and research institutes (Research for

new drug molecules, Novel Drug Delivery Systems, Improved Healthcare, Clinical aspects, etc.)

5. Hospital Pharmacy

K. Key points of National Drug Policy of 1982

- To provide administrative and legislative support for ensuring quality of essential drugs which are relevant to the national health need.
- To reduce the price of medicine by ensuring the lowest competitive price.
- To eliminate non-essential medicine from the market.
- To promote production of local drug and raw materials.
- To develop proper drug monitoring and information system to prevent wasteful misuse and to ensure the proper utilization of the drugs.
- To ensure GMP and qualified pharmacist in manufacturing companies.

L. Some major characteristics of BD drug marketing sector:

- Their distributional channel includes invoice system, own distribution channel.
- Medical representatives are the key persons in marketing.
- For promotion, the groups such as doctors, surgeons are targeted.
- Major promotional strategies include printed promotional materials, physical sample, and clinical materials.
- Special incentives are given to the doctors. For example, the doctors are given honeymoon packages, the cost of which is borne by the pharmaceuticals.
- The field level executives are playing the imperative role for marketing division. Basically, they have taken the responsibility to market the products of their companies. So, the success of a pharmaceutical industry intensively depends on the efficiency and effectiveness of the medical representatives. If an organization wants efficient employees in this section, he should to satisfy these representatives. (Ahsan et.al 2011)

M. API Business: In Bangladesh, companies have only recently entered API business. At present, there are 21 companies in Bangladesh manufacturing 41

APIs. Industry participants claim already becoming self-sufficient in some APIs, namely, Penicillin, Cephalexin, NSAID and Anti-Pyretic. The production of APIs is confined to the last stage of Synthesis. Presently, Local APIs take a 20% share in domestic production. The rest 80% is imported. These imported APIs represent majority of raw materials import by Bangladesh, approximately 70%. But the overall production is very low compared to total demand. While the industry is achieving self-sufficiency, it yet procures 90% of raw materials from 98 indenters around the world as only one company (Active Fine Chemicals) produces raw materials independently. There are 3000 valid sources of raw materials including countries like China, India, Korea & Italy. API consists a significant percent of total cost in medicine which can run up to 30-40%. At present, only a few companies – Square, Beximco, Ganasastha Pharmaceuticals, Globe and Active Fine – are manufacturing raw materials for drugs like paracetamol, amoxicillin, flucloxacillin, ampicillin and metformin, on a limited scale. Ganashastha Pharmaceuticals Limited (GPL) alone accounts for about 60% of the raw materials manufactured in Bangladesh. Bangladesh is trying to establish an industrial park for pharmaceutical production. One such park in Munshiganj near Dhaka is nearing completion and it might result in a big jump in the income from pharmaceutical exports. A National Control Laboratory Project is taken by the govt. for facilitating the pharmaceutical sector. The proposed API technology Park in Munshiganj, which was scheduled to be completed by July 2012, is delayed with the cost of the project now increasing by 55%. This delay has been a major hurdle for the pharmaceutical industry to gain better control over the inputs and improve operational efficiencies. India, the major generic drug player, has more than 3500 Drug Master File (DMF) approval for APIs whereas we have none (Pratik 2015).

N. Access to essential drugs: Although official documents indicate that 80 per cent of the population has access to affordable essential drugs, there is plenty of evidence of a scarcity of essential drugs in government healthcare facilities. One study conducted in four district hospitals and one medical college hospital showed that only eight per cent of patients received the prescribed medicines from

these facilities. In another report, two major hospitals in the capital city of Dhaka were operating without essential medicines for eight consecutive weeks. There are countless such incidents relating to the supply of essential medicines in Bangladesh. In most such cases, government officials and health professionals are responsible for the shortage as they often sell government-supplied drugs to local drug stores instead of dispensing them to poor patients. The government must be cognizant of this fact, but rarely takes any action.

O. Quality of available drugs: Of the 300 pharmaceutical companies in Bangladesh, only the 20 to 25 top ones produce drugs of standard quality. Reports show that numerous small companies' market substandard drugs in the country. Fake or substandard medicines, including lifesaving ones, with an estimated worth of US\$ 150 million per year, are flooding the domestic market. In its annual testing in 2004, the government laboratory detected 300 counterfeit or very poor-quality drugs out of 5,000 drug samples. A recent assay involving 15 brands of ciprofloxacin showed that 47 per cent of samples contained less than the specified amounts of the active ingredient. Another report noted that 69 per cent of paracetamol tablets and 80 per cent of ampicillin capsules produced by small companies were of substandard quality. Good manufacturing practice (GMP) is a major criterion to maintain standard quality in drugs, and it was one of the principal objectives of the NDP to ensure standard manufacturing practices for drug manufacturers. But there are some 265 pharmaceutical companies in Bangladesh that do not follow or comply with GMP. It is widely alleged that adulteration flourishes in the country because of poor government vigilance and supervision over drug manufacturers and sellers. Unfortunately, a section of corrupt physicians and government officials is involved in these underhand dealings. The government states that it has limited manpower and facilities to cope with the country's fast expanding pharmaceuticals sector. In fact, the regulatory authorities have given scant attention to quality matters in Bangladesh.

P. Lack of control over drug prices: In Bangladesh the maximum retail price (MRP) of every essential drug is fixed by the Directorate of Drug

Administration (DDA); for all other drugs the DDA endorses the companies' quoted prices. Drug prices are quite high in Bangladesh in comparison to neighboring countries. The drugs control authority is apparently reluctant to negotiate with the companies to fix prices. The regulatory authorities have virtually no control over drug prices in Bangladesh. Indiscriminate pricing can be observed in all therapeutic classes of drugs. For example, prices of various ciprofloxacin brands range from Taka (Tk) 5 to 14 (US\$ 0.07 to 0.20) per unit. The price of dexamethasone eyedrops extends from Tk 24 to 90 (US\$ 0.34 to 1.29) per 5ml, and diclofenac eye drops are available at a price range from Tk 40 to 200 (US\$ 0.57 to 2.86) per unit. These are a few of the existing price discrepancies in the country. Easy excessive profits made pharma companies reckless and making misleading statements implicating of Dollar Taka conversion rate as a reason for increase price. As a counter misinformation, continuously propagating that pharma exports will soon overtake garment export. Present pharma export is not even 1 percent of total national export.

Q. Patterns of drug use: To ensure rational and appropriate use of drugs in Bangladesh was another prime concern of the NDP. But there has been no drug use study in the country. Clinically inappropriate and inefficient use of medicines is a serious problem. More than half the medicines in Bangladesh are inappropriately prescribed, dispensed or sold. Despite legal prohibitions, numerous drugs with similar or no significant benefits are available in the market. As a specific example, there are seven members of the angiotensin-converting enzyme (ACE) inhibitors available in the country. The efficacies and chemical structures of these molecules are more or less similar, but their price vary significantly. The drug policy clearly prohibits the production of multi-ingredient preparations of vitamins and minerals with the exception of B-complex vitamins. But a mixture of 32 vitamins and minerals including selenium, vanadium, molybdenum, tin and many other unnecessary ingredients has been marketed in the country for a few years, violating the principles of the NDP. The need for these trace elements in Bangladesh is not established whereas nutritional deficiencies are mainly related to vitamins A and B-

complex, iron, calcium, iodine and zinc. Irrational prescription and use of antibiotics are rampant throughout the country, with an estimated half of all antibiotics being sold without prescriptions. Self-medication is widespread, and all types of medicines can be purchased without a prescription. There are about 30,000 illegal and 80,000 unlicensed drug stores operating in the country. It is alleged that both legal and illegal drug dealers are engaged in selling fake, smuggled and adulterated medicines in the country (Mohammad 2008).

R. Domestic drug distribution: Bangladesh's drug distribution marketplace is composed of small independent pharmacies. This structure combined with an under-regulated industry, few firms manufacturing pharmaceuticals, and companies competing to sell branded generics based on brand names provides ample opportunity for the sale of low-quality drugs at higher prices. And this partly explains why the quality of drugs available for sale varies significantly in Bangladesh. Pharmaceutical firms can sell their products to private sector pharmacies, the government and its public health care facilities, or to international organizations operating in Bangladesh (e.g., UNICEF). Government sales are not as profitable as private sector sales because the government pays less, on consignment, and at times, after considerable delay. Pharmaceutical firms nevertheless still target public facilities because doctors become acquainted with the firms' drugs and then prescribe them in their private practices. And, because drugs are not readily available at public facilities, patients receiving treatment there may still go to a private pharmacy to procure the required drugs. Without these public sector connections, many firms would turn more attention to the private sector. Although there are approximately 200,000 private pharmacies in Bangladesh, the government lists officially only 76,000 pharmacies. The rest are illegal, without a license or a licensed pharmacist on staff. Pharmacists have varying education levels and many lack adequate training. For example, a visit to four pharmacies in Dhaka and ten pharmacies in the bordering Gazipur, Narayanganj, Keranigonj and Manikgonj Districts revealed that each had one professional pharmacist, who had four years of coursework; while the two medium-sized

pharmacies visited had one person with a year's training and several untrained coworkers, all of whom were working as pharmacists. Rural pharmacies may have pharmacists with high school education and approximately two weeks training. The Bangladesh Pharmacist Society is currently implementing the first phase of a three-phased program to improve skills of pharmacists. The program should be completed in seven to eight years. Most pharmacies are individual shops, though some chains are starting to develop, especially in urban areas. Large pharmacies visited reported buying medicines according to sales trends, e.g., what sells the most. The medium and small pharmacies visited reported linkages with a medical doctor. Their sales were therefore usually skewed towards that medical professional's preferences. Several brands of each drug, with variable quality levels, are on the market. In urban areas, the visited pharmacies tended to sell higher quality brands, whereas in more rural areas, pharmacies visited tended to sell lower quality, lower cost brands. This may be due to a district's political sway influencing brand selection. The pharmacies visited tended to have brands associated with people who held power in that district. Those more distant from the city center also had increasingly more ayurvedic and herbal medicines. The top 20 pharmaceutical manufacturing firms have established extensive sales and distribution networks. Each pharmacy visited has 10-50 pharmaceutical firms supplying their medicines daily. For example, Beximco Pharmaceuticals has 1,200 representatives visiting pharmacies daily to take drug orders. Each pharmacy receives approximately 12- 15 Beximco shipments per month. Acme Pharmaceuticals has 1,100 representatives and Square Pharmaceuticals has 950 representatives visiting pharmacies. None of the pharmacies visited restock any medicine that does not sell well. The small pharmacies report only keeping a medicine for a maximum of six months. A significant number of drug consumers obtain drugs without a prescription. When consumers lack a prescription, they will usually either ask a pharmacist for a specific drug or describe their ailment to a pharmacist who diagnoses the problem and recommends a drug on the spot. Popular products include a variety of antibiotics, painkillers, and gastric remedies. Consumers purchase one to ten

tablets or capsules at a time. The quantity of drugs purchased often depends more on the consumer's finances of than on the required dose of medicine (Janet et.al 2008).

S. Most pharma companies tempt doctors with 'gifts': With a view to popularizing their brands, most of the pharmaceutical companies in the country allegedly practice unethical drug promotion alluring doctors with free samples and gifts to prescribe their medicines. To stop such unethical promotion of drugs, there was no effective implementation of the Drugs (Control) Ordinance, 1982 that regulates manufacture, import, distribution and sale of drugs in Bangladesh. The Drug Administration, which regulates manufacture, import and quality control of drugs in the country, is also inactive to put a stop to such unethical practices. Pharmaceutical companies practice drug promotion to boost sales and earn more profit, although it is clearly unethical. Bangladeshi pharmaceutical companies produce standard medicines but all companies cannot produce quality products. According to the industry sources, the pharmaceutical companies allocate huge sums in their annual budget for gifts to be distributed among the medical practitioners. A number of representatives of pharmaceutical companies, both local and multinational, said they often bribe doctors to promote their particular drugs. Pharmaceutical companies offer attractive gifts to the doctor on various occasions from pens to cash money - as part of their promotional activities. Sometimes they even undertake decoration of the doctors and also offer sarees for doctors. This gift (bribe) culture is reportedly higher in urban areas. Bangladesh Legal Aid and Services Trust (BLAST) stressed full implementation of the Drug Act as well as effective inspection and monitoring on manufacturing, marketing and use of drugs. BLAST also suggested the government to recruit more manpower in the Drug Administration to make it more effective as well as effective monitoring and checking 'Code of Marketing' to prevent unethical practice to save the lives of people (The Daily Star February 12, 2011).

T. Necessity of Pharmacovigilance:

a) Diethylene glycol tragedy in Bangladesh: Diethylene glycol is a highly toxic organic solvent that

causes acute renal failure and death when ingested. Its toxicity became apparent in the 1930s when it was used to prepare a sulphanilamide elixir in the United States. The deaths of at least 76 people from ingestion of this sulphanilamide elixir prompted the promulgation of the United States Food, Drugs, and Cosmetics Act in 1938, which regulates the evaluation and use of new drugs or foods. Diethylene glycol is occasionally identified in medical preparations or foods, though rarely in lethal concentrations. Drug toxicity due to formulation alteration is very much common. There are a lot of examples of this type of malpractices. It gets importance because of some recent incidence. In 2009, 26 children died due to formulation alteration in case of paracetamol syrup, where propylene glycol was replaced by diethylene glycol as a solvent. Health officials in the country said that so far 26 children aged between 11 months and three years have died after taking paracetamol (acetaminophen) syrup contaminated with diethylene glycol that was manufactured by local drug producer Rid Pharmaceutical Co (Arrest warrants issued after DEG kills 26 infants in Bangladesh). The trade name of the drug was Temset (paracetamol suspension). In addition, three hundred thirty-nine (339) deaths attributed to paracetamol syrup contaminated with diethylene glycol in 1990-1992. This incidence shows that, the formulation alteration by harmful chemical can pose a serious threat to health care system.

b) Substandard vitamin A tragedy in Bangladesh: Vitamin A deficiency may be a major threat to the health and survival of children and mothers. Effects of vitamin A deficiency extend much beyond blindness alone. Vitamin A deficiency increases the risk of child deaths from diseases such as measles and diarrhea. These infections contribute to over one-third of deaths among children aged 0-5 years in Bangladesh (UNICEF- Bangladesh media center, 6 June 2009). For this reason, the Government of People's Republic of Bangladesh conducts National vitamin A plus campaign every year. In 2013 due to ingestion of substandard vitamin A capsule many children became sick, and online reports talked about some patients experiencing vomiting sensation and feeling unwell. Children were reported sick at Chittagong, Cox's Bazaar and Lakhimpur among other places. Rumors of death were also reported with one report claiming a child had died

from administration of Vitamin A capsule which were supplied by Indian source, Olive healthcare (Nusrat et.al 2017).

c) Doctors are writing more prescriptions for Nitazoxanide instead of Metronidazole for amoebiasis and diarrheas; Azithromycin for diarrhea, typhoid and PID. Other misused drugs are caffeine with paracetamol, Diclofenacs, Statins, Irrational vitamin preparations with all sorts of mineral which cannot be detected in Government Drug Laboratory; Benzodiazepines, sex hormones, steroids, Terbinafine, Butenafine, Crotamiton etc. Promoting Directly to Consumers through daily newspaper with separate advertising sheet on Dukoral (a Swedish company, Crucell product) for prevention of diarrhea and cholera tactfully using name of WHO and ICDDR,B. Aggressive and unethical promotion increases irrational prescriptions leading to multiplication of profit of the companies. Counterfeit version of costly drugs surfacing in progressive order. More spurious and substandard drugs freely moving into the market (Development dialogue 1995:1).

U. Contract manufacturing brings new hope for pharma companies: Pharmaceutical companies are increasingly engaging in toll or contract manufacturing, a development that allows them to utilize unused capacities and reduce the need for fresh investment. Toll manufacturing, ushered in by the government in the National Drug Policy 2005, is an arrangement in which a company with specialized equipment processes raw materials or semi-finished goods for another company. Around 30 drug makers including Renata, Beximco and Popular are currently engaged in toll manufacturing for their local counterparts or even multinational companies, a sum which was less than 10 a couple of years ago. Currently, some foreign companies make a certain portion of their drugs for the domestic market through contract manufacturing, which lowers their operating costs. Contract manufacturing is mainly used for specialized or high-tech products, the facilities for which require considerable capital investment. An industry official said that it is unfeasible for a firm to develop facilities to make a single product. Insiders said the scope for toll manufacturing has enabled firms, especially the newly-established ones, to better utilize their capacities as they are yet to create a strong presence

in the market. The system also becomes beneficial to those firms that do not have enough manufacturing capacity but register increased demand for drugs (Sohel 2015).

V. Emerging business of herbal medicines: Herbal medicines are increasingly popular in local and global markets. More than 20 firms seek licenses to come into the sector. Herbal medicines are set to witness an investment boost as over 20 companies have lined up for licenses from the drug administration to manufacture such medicines to exploit business potentials in the sector, still almost untapped, industry people said. "A new avenue for herbal medicine has opened up as many investors are looking for venturing in making such medicines," a senior official of Directorate of Drug Administration told The Daily Star (Sohel 2009). Officials said the drug regulator has received nearly two dozen of applications seeking approval to make herbal medicine. Of the applicants, four got licenses and around 20 companies are awaiting approval. The latest approval was given to Radiant Nutraceuticals Ltd, which is set to join the fray with three existing operators -- Square, ACME and Modern -- with Square Herbal and Nutraceuticals being the pioneer in the segment. Industry insiders said allopathic pharma market in Bangladesh is worth around Tk 4,000 crore, while the market size for herbal medicines including Ayurvedic and Unani stands at more than Tk 1,000 crore. Industry people observed that scopes to exploit the untapped herbal medicine now lure investors to the segment with majority of applications coming from new investors along with allopathic drug makers. Stakeholders said some of the well-known allopathic drug makers are gearing up for establishing herbal medicine units. The sector started pulling attention after the government had endorsed herbal medicine in the drug policy along with two other traditional branches of medicine -- Ayurvedic and Unani. Later the sector received a further boost as the government termed herbs and herbal medicine as one of the five priority sectors to diversify the country's export basket. Industry people observed that Bangladesh has prospect in making footsteps on the global market for medicinal plant and products as nearly 650 medicinal plant species have been identified to be in use in Bangladesh with around 25 plants having high value. Sector people

said herbal medicine differs from Ayurvedic and Unani medicines due to its unique manufacturing process, although all the three branches of medicine depend mainly on medicinal plants. The herbal medicine market, which has been expanding gradually since 1980, will exceed Tk 2,500 crore by 2020, herbalists predicted. The sales volume of herbal medicines jumped to Tk 1,000 crore in 2010 against Tk 1 crore in 1980. The nation's 210 Ayurvedic establishments produce 272 types of medicines (Unb Dhaka 2012).

W. MNCs facing a lot of problems: In pharmaceutical sector, multinational corporations are more concerned about research and development than locally owned companies. The implication is that MNCs will need to find ways to increase their R&D productivity, and it also means that Indian and Chinese firms with relatively novel approaches to product and process development may find opportunities opening up for them, whether through go-it-alone strategies or through co-operative R&D partnerships with MNCs. Right after liberation war three fourth of the pharmaceutical industries was dominated by multinational companies. In view of the caliber of machinery and technical know-how which lies in their hands for producing important and innovative drugs for the country, the task of producing antacids and vitamins will lie solely with the national companies, leaving the multinationals free to concentrate their efforts and resources on those items not so easily produced by smaller national companies. Multinationals will, however, be allowed to produce injectable vitamins as single-ingredient products (Development dialogue 1995:1 Making National Drug Policies a Development Priority). No multinational company without their own factory in Bangladesh will be allowed to market their products after manufacturing them in another factory in Bangladesh on a toll basis. Multinational companies (MNCs) are allowed to manufacture all registered drugs except antacid and vitamins provided they have their own factories in Bangladesh. However, MNCs will be allowed to produce injectable vitamins because of higher technology. No foreign brands will be allowed to be manufactured in Bangladesh under third party license. Imports will not be allowed if similar products are manufactured locally. The

impact of 82' ordinance was dramatic. Total number of registered products both locally produced and imported from 122 foreign companies of 22 countries were 4340 of which 1742 were found to be harmful, inappropriately formulated or therapeutically ineffective. Out of 1742 harmful and/or ineffective drugs, 176 were imported and 949 were manufactured by 156 local manufacturers. Capitalist countries had exported more ineffective, useless or harmful drugs than that of socialist countries. West German and Swiss Companies ranked very high in mischiefs. However, these decisions kept MNCs on fire. The National Drug Policy (NDP) in 1982 and 2005 has major impact in the development and growth of the Bangladesh pharmaceutical industry. The need for NDP was very evident. Almost all the multinational companies were producing simple and non-essential drugs in Bangladesh like vitamins mixture or cough syrups. They used to import their raw materials from abroad at high prices. There was a need for vast quantity of essential, useful and economic drugs in Bangladesh. It was essential and important for Bangladesh to introduce a drug policy for the betterment of national health by availing international standard medicine in lower cost to Bangladeshi people. Precisely, multinational companies were prevented to reduce their unessential drugs production and discouraged to import raw material at high process. Under the Drug (Control) Ordinance 1982, the Government determines Maximum Retail Prices (MRP) of 117 essential drug chemical substances. This price determination is only for the local producer companies and still now the multinational organizations are determining their price by their own way. Many LDC countries have implemented full TRIPS patent protection or expanded TRIPS-plus patent protection in advance of the 2016 deadline. Activists say this is due to pressure from multinational pharmaceutical companies or developed country governments while MNCs say that IP laws are individual to each country and may reflect other trade and policy priorities. The role of multinationals in providing medicine for this country is acknowledged with appreciation. As NDP 1982 implemented, most multinational companies sold their business to local pharmaceutical. This fueled to the evolution of the local pharmaceutical sectors. According to the Directorate General of Drug

Administration (DGDA) website, the value of the locally produced drug was 175 crores in 1981 that increased to 325 crores by 1985. Many multinational companies (multinationals) were dissatisfied with this development. GSK Bangladesh has convened a meeting next month as it seeks shareholders' nod to close its unprofitable pharmaceuticals business in the country. Meanwhile, nearly 200 employees of the local operations of the British multinational pharmaceuticals company have been staging a sit-in on the factory premises in Chittagong for the last 50 days to protest the closure decision. The demonstration began after the GSK Bangladesh board on July 26 proposed to shut down the plant, saying it was making losses. A senior official said its product portfolio lacks medicines that sell the most in the local market. GSK Bangladesh also blamed the gap in the product portfolio for the losses (Ahsan 2018). Earlier, Beximco completes Nuvista (formerly Organon) acquisition in a first for Bangladesh pharmaceutical industry (Bdnews24 03.04.2018). Nuvista, formerly Organon (Bangladesh) Ltd, was a subsidiary of the Netherlands-based Organon International. It was sold out to the current Bangladeshi management in 2006. Pfizer Bangladesh started its operations in 1972 as Pfizer (Bangladesh) Ltd. In 1993, Pfizer transferred the ownership of its Bangladesh operations to local shareholders and the name was changed to Renata Ltd (Renata LTD. Website). Sales of SK + F were worth Tk 1 crore in 1990 when it started its journey, a successor of Smith, Kline & French in Bangladesh, was acquired by Transcom in 1990. The company was renamed Eskayef Pharmaceuticals Limited (The Daily Star. 2015-12-29). In 1973, the UK based multinational pharmaceutical company, ICI plc, established a subsidiary in Dhaka, known as ICI Bangladesh Manufacturers Limited. In 1992, ICI plc divested its share to local management, and the company was renamed Advanced Chemical Industries (ACI) Limited (ACI website). As part of the World Cancer Day, Apollo Hospitals Dhaka organized a rally jointly with Roche Bangladesh Limited and Sanofi Bangladesh Limited inside the Bashundhara residential area to increase awareness against the disease in the community (The Daily Star February 11, 2018). Both of these MNCs are facing potential competition in

market and a negative sales growth every year, earlier faced by GSK Bangladesh as well.

X. High Court bans 34 pharmaceutical companies from producing medicines: The order by Justices came after hearing of a rule issued earlier on a petition filed by the Human Rights and Peace for Bangladesh (HRPB) to stop production and marketing of substandard medicines. The order asked the Bangladesh drug regulatory authority to regularly monitor whether these companies continued to produce and market medicines and file a report to the High Court after every four months. HRPB counsel informed that the government has already cancelled the license of 7-8 of these 34 companies (bdnews24). The High Court has constituted a five-member committee to examine fresh application by those companies who have not had their license cancelled, if they agreed to abide by existing drug regulatory parameters. The committee consists of a representative each from World Health Organization, Bangladesh Drug Regulatory Authority, Dhaka University's Pharmacy department and the Health Ministry. Twenty companies banned from producing all medicines namely Exim Pharmaceuticals, Avert Pharma Ltd, Bikalpa Pharmaceuticals Ltd, Dolphin Pharmaceuticals Ltd, Drugland Ltd, Globe Laboratories Pvt Ltd, Jolpa Laboratories Ltd, Kafma Pharmaceuticals Ltd, Medico Pharmaceuticals Ltd, National Drug Pharma Ltd, North Bengal Pharmaceuticals Ltd, Rimo Chemicals Ltd, Rid Pharmaceuticals Ltd, Skylab Pharmaceuticals Ltd, Spark Pharmaceuticals Ltd, Star Pharmaceuticals Ltd, Shunipun Pharmaceuticals Ltd, Today Pharmaceuticals Ltd, Tropical Pharmaceuticals Ltd and Universal Pharmaceuticals Ltd. Fourteen companies banned from producing antibiotics Ad-dwin Pharmaceutical Ltd, Alkad Laboratories Ltd, Belsen Pharmaceuticals Ltd, Bengal Drugs and Chemicals (Pharma) Ltd, Bristol Pharma Ltd, Crystal Pharmaceuticals Ltd, Indo-Bangla Pharmaceuticals Ltd, Millat Pharmaceuticals Ltd, MST Pharma and Healthcare Ltd, Orbit Pharmaceuticals Ltd, Pharmic Laboratories Ltd, Phoenix Chemical Laboratory Ltd, Rasa Pharmaceuticals Ltd and Save Pharmaceuticals Ltd (The Daily Star February 14, 2017, The Daily Sun 13th February, 2017).

Y. The PCB has revoked the registration examination system: The PCB has revoked the registration examination system for the evaluation of graduate pharmacists for the issuance of Registration for Pharmacy practice. By dint of revoking examination, Pharmacy graduates from any public or private university would be awarded professional registration without any qualifying examination. To a new Pharmacy graduate this option may be seemed to be happy news because they don't need to sit for any examination and they can get the certification for Pharmacy practice without any qualifying test. But practically this option may lead Pharmacy profession to challenge in the long run. The number of graduate Pharmacists coming out from private universities is 6 times greater than that of public universities. Recently, many intellectuals raised questions about the educational status and quality of some of the private universities although most of the private universities are doing pretty well. Whatever the private or public universities, the examination systems is maintained in all the developed countries like USA, UK, Canada, Australia, Japan, etc. on order to obtain the registration for pharmacy practice. So, what is the problem in our case? If the pre-qualifying examination is maintained, this will surely ensure the quality of Pharmacists suited for the practice of Pharmacy profession in Bangladesh. The examination system would enhance the ability of any graduate Pharmacist whether from private or public universities. At least they may learn/study many aspects of Pharmacy profession if they have to prepare for qualifying examination, that will help them to practice their profession. Therefore, at least a minimum evaluation test (that would ensure the basic and minimum knowledge of Pharmacy) must be conducted by the Pharmacy Council of Bangladesh before issuing professional registration for the practice of Pharmacy in Bangladesh. Obtaining registration after passing pre –qualifying evaluation will carry the dignity of graduate Pharmacists in their profession; otherwise registration will not have any evaluation in practical job markets (Mokles academia.edu).

Z. Job crisis in the Pharmaceutical industries for the pharmacists: Few years ago, students of pharmacy got job during final year of their bachelor degree.

The number of pharmacy graduate increasing day by day. After that student finishing bachelor degree got job after the bachelor course. Now a days, number of pharmacy students became so high that even they are not getting job after their master degree. Besides, job sector for the pharmacist also increased but not sufficient. They are working in Product Development, Quality Assurance, Quality Control, Production, Marketing, Sales, Training, Regulatory Affairs, Commercial department etc. Few years ago, many pharmaceutical companies assigned chemist to perform laboratory work but now pharmacist start to replace chemist from pharmaceutical industry. Pharmacists are also working in veterinary industries. Today new job area for Bangladeshi pharmacist is Hospital Pharmacist and Clinical Pharmacist. Their working place is the hospital and deals with the patients and help the doctors to prescribe medicine. Thus, error in prescribing wrong medicine and miss-dose also reduced. New opportunity in another sector is cosmetic industry. Bangladesh is a land of medicinal plants. Thus, herbal medicinal industry also developing day by day. Some giant groups focusing their concentration in herbal industry. So, the demands of pharmacist in herbal industry are increasing day by day. Though food is one of the important parts of our daily life, one of the main causes of disease development is food habit. But pharmacist is not part of this industry. Pharmacist should develop their career in food industry. The pharmaceutical sector of Bangladesh has developed in the manufacturing of finished pharmaceutical products; the API and Excipients based industries have not yet remarkably advanced in this country. So, Bangladeshi Pharmacists have job scope limited to pharmaceutical finished products manufacturing industries. At present, industrial jobs also are saturated or will saturate soon. Therefore, getting entrance of new Pharmacists to Pharmaceutical Industries become quite tough or have narrow scope for new Pharmacists and also the problems to be faced for new pharmacist if having poor training, lack of in-depth knowledge of fundamental concepts and practical skills (Zubair 2013). No person shall manufacture any drug except under the personal supervision of a pharmacist registered in Register 'A' of the Pharmacy Council of Bangladesh: Provided that this provision shall not apply to the manufacture of any drug under the ayurvedic, unani, or

homeopathic or biochemic system of medicine. Also, this act 13 (1) (Employment of Pharmacist) of the DRUGS (CONTROL) ORDINANCE, 1982 (ORDINANCE NO. VIII OF 1982) was abandoned earlier by government to create job opportunities for non-pharmacists.

FUTURE CHALLENGES

Lack of API Support: API/Raw Material Production Plant: The major advancement of Bangladesh pharmaceutical sector has been occurred only in the production of finished products. Manufacturing of pharmaceutical products are vastly dependent on imported raw materials, as almost 90% of raw materials are now being imported. This dependency on imported raw materials is resulting in increased production cost of the finished products. Ultimately the competition to offer export prize is becoming tougher, which is one of the major challenges of pharmaceutical sector of Bangladesh. Setting up of a standardized Active Pharmaceutical Ingredient (API) plant is very essential. Local production of raw materials will greatly contribute to pharmaceutical export to extend export volume, and also can potentially contribute to the country's economy.

Bioequivalence Test Facility: Bioequivalence study of a product is a must for the registration of that product in many of the moderately regulated and regulated countries of the world. There is no standard facility for bioequivalence study in Bangladesh. In order to register a product, a pharmaceutical company has to carry out this test in foreign country by spending of a huge charge. 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.

Modern Drug Testing Laboratory: A major limitation of drug control authority of Bangladesh that also affects pharmaceutical export is unavailability of a modern, well equipped drug testing laboratory (DTL) with the engagement of 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.

Regulated Markets: To register pharmaceutical products in regulated markets it requires highly standardized documents. There are regulations directed by the regulatory authorities of United States of America, European Union, Australia and Japan along with other highly regulated and semi regulated countries. To meet all their requirements sophisticated and accredited manufacturing plant, standardized manufacturing process, proper quality control and above all highly skilled professionals are required. It is tough to meet all the requirements by small pharmaceutical companies of Bangladesh.

RECOMMENDATIONS

The proposed suggestions may help the pharmaceutical industries to reduce the problems in different areas. These are as follows:

- The medical representative's turnover is not adequate and equitable. So, the organizations can take measures to increase the salary for the medical representatives.
- Advertising cost should be reduced and this is necessary to make the marketing people aware of their profession.
- The local pharmaceutical companies should produce quality product by using the updated equipment and raw materials, which can help them to acquire the market share.
- Pharmaceutical companies should produce world class medicine which may increase the demand for Bangladeshi drug in the world market.
- Industry should make the people aware of the local products and with that they should ensure the quality medicine to earn confidence.
- The pharmaceutical companies should not violate the law imposed by the government,

which can hamper the trust of the people of the country.

- Organizations should produce their product in a hygienic environment and maintain the highest standard.
- Government should take measures or formulate some clear-cut rules to restrict the foreign pharmaceutical organizations to practice the concept of dumping in this country. Backward integration into API is also very important to reduce import cost.
- Providing cash incentive by the govt. to the medicine exporters, like RMG may encourage pharmaceutical exporters.
- International fair arrangement by Export Promotion Bureau (EPB) is a very effective way to search buyers and to establish business in a new country. A lot of initiative have been taken by BAPI (Bangladesh Association of Pharmaceutical Industries) in different times, such as, high level pharmaceuticals delegation team visited foreign countries to explore export initiated

by BAPI. 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.

- In the context of Bangladesh, E-commerce is a new concept. Again, trust and security issues can come in the way of its implementation in the pharmaceutical sector. That is because both electronic money transaction and sensitive items like medical equipment and medicines are likely to provoke doubts in the minds of customers. In this situation, the actually renowned pharmaceutical companies can have an option of ordering online in the already existing websites on a trial basis at first stage (Journal of Business Studies, Vol. XXXIV, No. 3, December 2013 recommendation).

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