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AN A-Z OF BANGLADESH PHARMACEUTICAL INDUSTRY

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ABSTRACT

Objective: Discussion and projection of Bangladesh pharma market in a multi-dimensional approach. **Methodology:** Inclusive data collection from newspapers, journals, newsletters, news reports and updates. The true focus was on historical data collection, current market scenario, projections by experts in related fields, drug dealers, mergers and acquisitions, market trend analysis reports and newer development prospects. **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. 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. **Limitation:** 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:** 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.

Keywords: API Project; National Drug Policy (NDP), The Directorate General of Drug Administration (DGDA), Export-Import; Unethical Promotion; Market Competition; Generic Drugs

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Introduction

Pharma market is now a days one of the fastest growing sector of Bangladesh. Considering 1950 to present, significant changes taken place. A former volume drug importing country, Bangladesh is now converted to export-oriented country, adapting newer technologies and flourished opportunities of contract manufacturing for both home and abroad. An Annual growth of 10% every year for the last decade, a historical 21% growth over last 3 years (2014-2017). Market volume is close to BDT 190 billion (IMS 2017, Q2). Around 98% of local demand served by the market along with a little volume import of vaccines, hormonal and anti-cancer drugs. The MNC domination, as detailed by the Tariff Commission has totally turned around. Indeed, the true growth of local pharmaceutical industries began after the 1982' ordinance came into effect, to limit the massive import of drugs and encourage local drug production. The market is focused on generic drugs, comprising 80% of the total market, enjoying the lowest labor cost to get a steady growth over the last 20 years. Citigroup, JPMorgan Chase and Merrill Lynch consider Bangladesh to be the next Asian success story.

Regulatory regime

The DGDA (Directorate General of Drug administration) regulates the overall export, import, manufacturing, sales and distribution which is under the Ministry of Health and Family Welfare (MHFW). 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. The PCB (Pharmacy Council of Bangladesh) was established through Ordinance 1976, considered as the controlling authority of pharmacy education and practice. BPS (Bangladesh Pharmaceutical Society), affiliated with Commonwealth Pharmaceutical

Association and International Pharmaceutical Federation.

Government Incentive

This sector is considered as a thrust sector in the export policy since 2006. Raw material custom duty is reduced by the government to facilitate the industry. The government recently sanctioned 200 acres of land for the API Park in Munshiganj (Ministry Portal, Export Policy 2015-2018). A 10% cash incentive is also under consideration by the authority to boost pharma sector. Customs duty on 40 basic raw materials used in drug manufacturing was reduced to 5% from 10%-25% rate. Customs duty on 14 items used in anti-cancer drugs have been withdrawn (Budget 2014-15).

TRIPS Exemption

Bangladesh got exemption from WTO TRIPS, signed in Doha, 2002 as 49 Least Developed Countries (LDCs) have been allowed to export patent free drugs to any country between 2006 to 2016. This allowed Bangladesh to reverse engineer the original patented medicine to produce generic version of that particular drugs without taking prior permission from patent company. Also, Bangladesh has the opportunity to export to any country if the medicine is not under patent in that particular country. Bangladesh has the strongest base to manufacture pharmaceuticals drugs, among the 49 LDCs due to cheap labor. The privilege was further extended in 6th November, 2015 considering the LDC status of the country. Being an LDC, Bangladesh has been exempted again from the TRIPS obligations for pharmaceutical products until January 2033 by the WTO.

The Pharmaceutical Industry at a Glance

A. *Local Market Overview:* The top 20 companies Pharma are having a combined market share of near 80% of the total pharmaceutical market of the country⁽²⁾. The market was doubled between 2012 to 2017, according to IMS report, from around 9000 crores to 18000 crore BDT, which was only 170 crores in 1982. Square (1100crore),

Renata (290 crore), Beximco (240 crore) and Acme (1500 crore) earned highest profit growth respectively. According to BAPI (Bangladesh Association of Pharmaceuticals Industries) Square is with nearly 19% market share. Incepta 10% share, Beximco 8.5 %, Opsonin 5.6 %, Renata 5% and Eskayef 4.5 %. According to Bangladesh Bureau of Statistics the industry contributed 1.85% to the GDP in 2016-2017 ⁽²⁾.

B. *Industry Volume/Structure*: The industry has distinct features, first, R&D activity is virtually nil, it is a branded generic market. Companies basically manufacture finished products by assembling known generic and patented (in some cases) product combination. Some companies are engaged in API production, the core of pharmaceutical products, but productions limited to synthesis stage (final stage) only. Presently, the market consists of approximately 8000 generic products and 258 firms with manufacturing capability, along with some imported patented products.

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 virtually 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 Pharmaceuticals Ingredients (API), solvents and excipients used as raw material for drug formulations. Historically, Bangladesh is an import dependent country for API and others. The local manufacturers arrange raw materials from China, India, Japan, Germany, France, Holland, Italy, Switzerland, Austria, Hungary, 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 more than 4500 generic products and 800 registered companies (Table 1) with manufacturing capability, along with some imported patented products ⁽³⁾.

Table 1. Products of The Pharmaceutical Industry

Company Type	Number of Registered Manufacturer	Number of Registered Generic	Number of Registered Brands	Number of Retail Pharmacy
Allopathy	258	3534	28508	107446
Homeopathy	42	322	2313	2152
Unani	272	345	5771	642
Ayurvedi	201	299	3899	367
Herbal	32	39	451	10

(Source: Report EBL Securities 29.11.2017 and WHO/SEARO workbook Tool, 2014)

D. *Business nature*:

1. High-End Biotech Products

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 Generic Products (Anti-Gastric, Anti-Biotic, pain killers 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 smaller, often for products with low branding possibility, and cut-throat competition is there. The number of competitors is very high, and market share of each competitor depends on success of marketing strategy ⁽⁴⁾.

E. Export: Present Bangladesh pharma sector is not only catering 98% domestic needs, but also exporting to more than 125 countries including the US and EU countries. Pharmaceutical exports were close to USD 100 million in fiscal 2016-17 which was a 16% growth from the last year. The figure was 84 million in year 2000, with major exports to Africa, some countries of central Asia, Thailand, Oman, Sri Lanka, Nepal, Bhutan, Myanmar, Singapore and Vietnam. According BAPI, approximately 1,200 pharmaceutical products received registration for export over the last two years. As a counter misinformation, continuously propagating that pharma exports will soon overtake garment export. Present pharma export is not even 1% (36.7 billion Vs 103 million in 2017-2018) of total national export.

E. Import: Bangladesh relies largely on imports for raw materials in the absence of local source of APIs, about 95% of the Tk 5,000 crore raw materials are procured from abroad. Novo and Medintis are importing maximum, Others engaged in import are-Sanofi, Aventis, Sandoz, Novartis, Roche, Unimed, Servier etc. However, to prevent this

excessive reliance on import the government will give unconditional tax-holiday to all API and laboratory reagents producers, both local and joint ventures, for five years from fiscal 2016-17 to fiscal 2021-22. If a producer can manufacture at least five molecules every year it would get 100% tax holiday from fiscal 2021-22 through to December 31, 2032.

G. Foreign Competitions: The beginning was dominated by MNCs. Still now, Pharmaceuticals industries are facing foreign competition. MNCs have established their plants in Bangladesh and importing their raw materials from abroad. Among these competitors, Roche and Novartis are leading. In export market, the Novartis is playing the dominant role. GSK recently and also Organon, ICI, Pfizer closed their operation at different periods of times. Although foreign companies have better equipment and worldwide support to loss coverage, the competition is taken positively from quality drug manufacturing competition perspective.

H. Dumping: Some Chinese and Indian companies are selling their products by luggage parties, imported unethically. Bangladeshi medicines and the medicine of developed countries are sold in a competitive price, even in higher price. This creates the barrier to capture the market share by Bangladeshi pharmaceutical industries. Seizing fake and unauthorized drugs from different medicine market is common. shops were found to have stored medicines meant for free distribution at government hospitals, counterfeit drugs. These illegally imported medicines are given to physicians as samples by pharmaceutical companies. Owners of the pharmaceutical companies think that the government should take actions to stop this practice ⁽⁵⁾.

I. Problems of Marketing:

- A lack of sufficient compensation benefits and job nature cause the medical representative turnover.

- Cost of marketing is not feasible compared to sale volume or product price more often.
- Professionalism in sales profession is not achieved properly rather we can say declined in the past few years.
- Lack of proper vigilance by the government authorities on sales marketing activities, specially many of them using gimmicks for raising sales volume.
- Uncertainties in terms of political turmoil and violence.
- Competition raised due to globalization.
- Smuggled drugs from neighbor countries, substandard and counterfeit drugs.
- Provides administrative and legislative support to ensure quality of essential drugs
- Ensures the lowest competitive price to reduce healthcare cost.
- Instructs to develop proper drug monitoring and information system to prevent wasteful misuse and to ensure the proper utilization of the drugs.
- Also instructs GMP and qualified pharmacist in manufacturing companies.
- A view to eliminate non-essential drug products from the market.
- An urge to promote local drug and raw materials production.

J. *Five Important JOB SCOPES in Pharmaceutical Industries*

1. Pharmaceutical Marketing: Medical Services Department (MSD), Product Management Department (PMD), Clinical Services, Training Sales Executives/MPO, Sales Promotion/Medical Promotion and International Marketing (IM) departments.
2. 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).
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 jobs, becoming increasingly prospective as offered by different top to mid-level hospitals of Bangladesh e.g. Square, BRB, Ad-Din, Apollo, United etc. ⁽⁶⁾

K. *Key points of National Drug Policy of 1982*

L. *Some Major Characteristics of BD Drug Marketing Sector:*

- Medical representatives are the key personnel in marketing.
- Distributional channel includes invoice system having own distribution channel.
- Surgeons and doctor groups are targeted for promotion
- Major promotional strategies include printed physical sample, promotional materials and clinical materials.
- Cash incentives/costly gifts are given to the doctors. For example, honeymoon packages, pleasure trip, treats in luxury restaurants
- The cash/gifts and other kinds are not the sole of promotion, the most important thing is to counter watch of prescription share of that doctor ⁽⁵⁾.

M. *Backward Linkage/API Business:* 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 requirement. 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 Italy, India, Korea and China. API consists a significant percent of total cost in medicine which can run up to 30-40%. At present raw materials for drugs like metformin, ampicillin, flucloxacillin, paracetamol and amoxicillin manufactured by Beximco, Ganasastha, Globe, Square and Active Fine on a limited scale. Ganashastha Limited (GPL) alone manufactures 60% of the raw materials in Bangladesh. Bangladesh is trying to establish an industrial park for pharmaceutical production. The project was supposed to handed over by 2012 and slow progression will cost more than 50% of the total project cost. India, the major generic drug player, has more than 3500 Drug Master File (DMF) approval for APIs whereas we have none ⁽⁷⁾.

N. *Access to Essential Drugs:* Although officially more than 75% population has access to affordable essential drugs, there is plenty of evidence of a scarcity of essential drugs in government healthcare facilities. Studies conducted in district and public medical college hospital showed that less than 10% of patients received the prescribed medicines from these facilities. A surprising report was found in two major hospitals in the capital city of Dhaka, 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. *Substandard Accessible Drugs:* Only 20 to 30 top companies among the 258 produce standard quality. Reports show that numerous small companies' market

substandard drugs in the country. Fake or substandard medicines floating with a worth of USD 150 million per year. Two national Drug Testing Laboratories detected 300 and 5000 counterfeit or very poor-quality drugs respectively. 15 brands of Ciprofloxacin found potency less than 50%. Paracetamol and Amoxicillin also found substandard in 70% and 80% samples respectively. Approximate 270 companies found to be non-compliant to GMP guidelines. This is due to poor vigilance by the authority. Moreover, underhand dealings reported with corrupted physicians and government officials. Government authorities used to give careless statements of limited manpower and facilities this regard.

P. *Non-selective Drug Prices:* Easy excessive profits made pharma companies reckless and making misleading statements implicating of USD Taka conversion rate as a reason for increase price. Non-selective pricing observed in all therapeutic classes of drugs. For example, the price of dexamethasone eyedrops extends from Tk 90 (USD1) from 24 (USD 0.25) per 5ml. And diclofenac eye drops are available at a price range from Tk 200 (USD 2.5) from 40 (USD 0.45) per unit. Prices of various brands of Ciprofloxacin range from Taka (Tk) 5 to 14 (US\$ 0.05 to 0.15) per unit. These are a few of the existing price discrepancies in the country.

Q. *Wrong Methods of Drug Uses:* Inappropriate diet and literacy costs pharma products to 100% growth over a five-year period. Nearly 50% of the total sold pharma products are GI drugs. Irrational and inefficient drug use raise another problem. More than 50% drug prescription, dispensing and sales are illogical. It is alleged that both legal and illegal drug dealers are engaged in selling fake, smuggled and of less significant use in the country. 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 insignificant, 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 Molybdenum, Selenium many other useless ingredients have been marketed for few years, violating the principles of the NDP. Self-medication is widespread, and all types of medicines can be purchased without a prescription. There were about 1,10,000 illegal and unlicensed drug stores operating in the country as reported by Bangladesh chemist and druggist association back in 2010. ⁽⁸⁾.

R. *Local Drug Dissemination:* Bangladesh's drug 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). Although there were approximately 200,000 private pharmacies in Bangladesh, reported back in 2010, the government lists officially only 76,000 pharmacies. The rest were illegal, without a license or a licensed pharmacist on staff. The top 20 pharmaceutical manufacturing firms have established extensive sales and distribution networks. A significant number of end users obtain drugs without a prescription. Prescription errors no further discussions, as only 13% drug in Bangladesh is sold under

prescription and 97% (approx.) of the pharmacist recommend medicine taking inadequate history. An estimated half of all antibiotics being sold without prescriptions. Also, the quantity of drugs purchased often depends more on the customers' finances of than on the recommended dose. ⁽²⁾

S. *Most Pharma Companies Entice Physicians with Bribe:* Most pharma companies convince doctors with bribe in the name of gift, free samples and donation. The DGDA is more often careless in this aspect. Pharmaceutical companies boost sales with drug promotion, a huge ratio from their profit which is clearly unethical. It is reported that the gifts could be simple pen, freeze, TV, Clothing's, chamber decoration, common utilities, showpieces, ornaments etc. The bribe amount surely higher in urban area than rural. Absenteeism commonly reported with drug prescribers as they maintain dual practice or even more. Bangladesh Legal Aid and Services Trust (BLAST) working for regulatory authorities, as they say but violation of Code of Pharmaceutical Marketing is still a common practice, that nobody controls. ⁽⁹⁾

T. *Crying Necessity of Pharmacovigilance:*

1. *Diethylene glycol tragedy in Bangladesh:* A death of 26 children (11 months to 3 years of age) reported in 2009 due to altered paracetamol syrup formulation, where diethylene glycol (severe nephrotoxic) was added instead of propylene glycol as co-solvent. Arrest warrant issued by the accused Temset (Paracetamol suspension, Rid Pharmaceuticals) selling company. Same incidence reported in 90's with contaminated Paracetamol syrup caused death of nearly 340 children.
2. *Rancid Vitamin A Cap Tragedy in Bangladesh:* During 90' a huge campaign raised against Vit A deficiency induced night blindness and measles. These maladies concluded to over 33% of deaths among children aged 0-5 years in Bangladesh

(UNICEF- Bangladesh media center, 6 June 2009). Bangladesh government, in response started conducting Vit A campaign on a yearly basis. Rancid Vit A capsules supplied by Olive Healthcare (Indian Company) reported sudden but revocable sickness and vomiting of children in Noakhali, Cox's Bazar, Chittagong ⁽¹⁰⁾.

3. *Consequences of Aberrant Drug Promotion:* Doctors are prescribing more costly antimicrobials, leaving behind old tested and trusted Metronidazole for amoebiasis and Azithromycin for diarrhea and PID. Benzodiazepines, sex hormones, steroids, Terbinafine, Butenafine, Crotamiton etc. reported direct promotion in newspapers with separate advertising sheet on Dukoral, a Swedish company for diarrhea prevention. Other misused drugs are Diclofenac, caffeine with paracetamol, Irrational vitamin preparations with several minerals that are not detected by drug testing laboratories, violating the principles of the NDP. Aggressive promotion often leads to irrational prescriptions and so is applicable to counterfeit version of costly drugs that surface progressive mismanagement ⁽¹¹⁾.

4. Hospitals found selling counterfeit drugs, keeping expired reagents: At different time periods from 2017 to present RAB fined United Hospital for selling 30 counterfeit drugs, United Hospital for using date expired reagents in their lab along with selling unlicensed drugs. 2 fake doctors with seven other hospital associates were sentenced to jail for taking high charges and providing forger reports. A lack of proper monitoring reported in private clinics. They were found to run OT with expired reagents and medicines. Patients lose faith on these reporting and choose to go abroad for remedy that causes loss of foreign currency by the economy. However, non-compliance also reported by several shops of Bangladesh Medical Association (BMA) market, namely EM Surgicals, Bhuiya

Surgicals, SA Surgical, Midland, Lotus and Atlanta Medica etc with selling expired insulin and diagnostic lab reagents or not maintaining the thermal control during preservation. Also 2 distributors of pharma items in Shyamoli caught red handed with expired drugs and diagnostic reagents. None of them were stored at their proper temperatures, which caused denaturation; the warehouses kept no record of where and when they were manufactured ⁽¹²⁻¹⁶⁾.

U. *Contract manufacturing brings new hope for pharma companies:* To make good return on fixed investments, pharma companies are in constant effort to outsourcing i.e. utilizing unused facilities/capacity without further or very less investments. The NDP also fixed conditions for this toll manufacturing, greatly favoring the national companies (82' ordinance 12 (I, II and III). Beximco, Popular, Renata including 30 companies are processing raw materials or semi-finished goods with specialized machineries for the last decade. Foreign companies and local companies using the facility of others to keep focus on their core issues, which ultimately created a win-win situation. Some of the toll manufacturing companies made a strong position. Incepta, Popular, Renata, Radiant also working with technology transfer ⁽¹⁷⁾.

V. *Emerging business of herbal medicines:* Herbal medicines are becoming increasingly popular in local market. More than 20 companies seeking licenses. DGDA received nearly two dozen of applications seeking approval for herbals. Of the applicants, four got licenses.

Among them Square, Acme, Modern, Radiant and a few others are making huge business with allied products. The complimentary medicines are almost one forth of the total allopathy market. The market size is 1000 times bigger compared to 80's and expected to be a volume of Tk 2,500 crore by 2020, herbalists predicted. A nearly 650 medicinal plant species have been

identified to be in use in Bangladesh with around 25 plants having high value. And herbalist also claim that these are different from other complimentary medicines ^(18,19).

W. MNCs are in a Great Ruffle: MNCs are always ahead of technology and compliance to drug authorities' home and abroad. During 70's, right after liberation war, Bangladesh market was solely dominated by the MNCs, three forth of the total industry sales. After NDP taken into effect, the sales of antacid, Vitamins, all these volume sale product market captured by the national companies, leaving options of high-tech, injectable vitamins and single ingredients patented products for the MNCs ⁽¹¹⁾. No multinational company without their own factory in Bangladesh are allowed to market their products after manufacturing them in another factory in Bangladesh on a toll basis. No foreign brands are no longer allowed to be manufactured in Bangladesh under third party license. Imports are also prohibited if similar products are manufactured locally. And if the International patented trade name of the brands is allowed if their raw materials are brought from the patented companies, which make MNCs to price their products higher then the national companies in this generic market. The impact of 82' ordinance was dramatic. Total number of registered products, both locally produced and imported from more than 120 foreign companies of 22 countries; more than 4300 of which 1750 were found to be harmful, inappropriately formulated or therapeutically ineffective. Out of 1742 harmful and /or ineffective drugs, more than 170 were imported. GSK Bangladesh has convened a meeting to conclude its operation from Bangladesh. A huge shortage of their patented vaccines causing sufferings of people from a little ago. The demonstration began after the GSK Bangladesh board proposed to shut down the plant, saying it was making losses ⁽²⁰⁾. Earlier, Beximco completes Nuvista (formerly

Organon) acquisition in a first for Bangladesh pharmaceutical industry ⁽²¹⁾. 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. Phizer Bangladesh started its operations in 1972 as Pfizer (Bangladesh) Ltd, transferred the ownership of its Bangladesh operations to local shareholders and the name was changed to Renata Ltd in 1993 (Renata LTD. Website). Sales of SK + F claimed to be a successor of SmithKline & French in Bangladesh, was acquired by Transcom in 1990. The company was renamed Eskayef Pharmaceuticals Limited ⁽²²⁾. "In 1973, the UK based MNC, ICI plc, established a subsidiary in Dhaka, known as ICI Bangladesh Manufacturers Limited", another claim by a national company to give an MNC flavor in pharma market. However, in 1992, ICI plc divested its share to local management, and the company was renamed Advanced Chemical Industries (ACI) Limited ⁽²³⁾. Apollo Hospitals Dhaka organized a joint campaign with Roche Bangladesh Limited and Sanofi Bangladesh Limited inside the to increase awareness against the disease in the community ⁽²⁴⁾. 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 Banning Accused Pharmaceutical Companies: **A petition filed by Human Rights and Peace for Bangladesh (HRPB) approved by high court justice and ordered) to stop production and marketing of substandard medicines.** The court constituted committee for examination with a WHO representative, Bangladesh Drug Regulatory Authority, Dhaka University's Pharmacy department and the Health Ministry to scrutinize newly submitted applications of pharma companies whose license was not cancelled. 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. and others. Fourteen companies banned from producing antibiotics, namely Ad-dwin Pharmaceutical Ltd, Alkad Laboratories Ltd, Belsen Pharmaceuticals Ltd, Bengal Drugs and Chemicals (Pharma) Ltd, Bristol Pharma Ltd, Crystal Pharmaceuticals Ltd and others. ^{(26), (27)}.

Y. *The PCB Has Abrogated the Registration Examination System:* The PCB has revoked the registration examination system for the evaluation of graduate pharmacists 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. Practically this option may lead pharmacy professionals to challenge in the long run. Recently, many intellectuals raised questions about the educational status and quality of some of the private universities. Whatever the private or public universities, the examination systems are maintained in all the developed countries like USA, UK, Canada, Australia, Japan, etc. in order to obtain the registration for pharmacy practice. The same is not maintained in countries like Uganda because of lack of educated and qualified pharmacists. 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 ⁽⁴⁾.

Z. *Job Crisis in The Pharmaceutical Industries for The Pharmacists:* 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. However, some 20 years ago, students of pharmacy used to get jobs during final year of their bachelor degree. The number of pharmacy graduate increasing day by day. The number of graduate Pharmacists coming out from private universities is 6 times greater than that of public universities. Now a days, number of pharmacy students became so high that no degree can assure a job for them at all. 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. Today's new job area for Bangladeshi pharmacist is Hospital Pharmacist and Clinical Pharmacist.

Future Challenges

- *Lack of API Support:* The dependency of imported raw materials is resulting in increased production cost of the finished products. Ultimately the competition to offer export prize is becoming tough, which is one of the major challenges of pharmaceutical sector of Bangladesh. 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. Again, API can also be exported to other countries. Currently, Global API market stands at USD 238 billion.

Bangladesh Government also has declared pharmaceuticals as thrust sector, has announced Pharmaceuticals “The product of the year 2018.” It’s a great opportunity for Bangladesh to export APIs to foreign countries.

- *Bioequivalence Test Facility*: Bioequivalence study of a product is mandatory in many of the moderately regulated and well-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 are less interested to register in foreign countries that require Bioequivalence study. In fact, BAPI and pharmaceutical exporters first felt the necessity of having Bioequivalence test facility in Bangladesh and demanded Bioequivalence test center to the govt. for the export promotion
- *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*: Registration of pharmaceutical products in regulated markets requires highly standardized documents. There are possible directions of registration in US, EU, Australia and Japan along with other highly regulated and semi regulated countries. To meet all their requirements sophisticated and accredited

manufacturing plant required along with standardized manufacturing process, proper quality control and above all highly skilled professionals. It’s tough but not impossible to small pharmaceutical companies of Bangladesh.

Recommendations

The following g proposal may ease to Bangladesh pharma sector in reducing their complexities in different arena:

- Promotional cost curtails through information-oriented knowledge-based promotion and avoid unethical cash or undue privileges. steps should be taken by all the companies together with a mutual understanding between them.
- The quality production should be ensured by the companies with better raw materials and excipients, which can help them to acquire a quality image in front of prescriber’s end users and foreign buyers.
- Pharmaceutical companies should be more export oriented, through several achievements (UK MHRA, TGA Australia certification).
- The companies may offer better compensations to medical representatives to decline turnover
- They should stop violating the law imposed by the government, which can hamper the trust of the people of the country.
- Organizations should hire more foreign delegates on audits and observation to maintain highest standard.
- Government should impose more strict rules to abate the foreign pharmaceutical organizations to practice the concept of dumping in this country. Backward integration into APIs could reduce import cost.
- Providing incentive scheme by the govt. to the medicine exporters.
- International fair/exhibitions arrangement by Export Promotion Bureau (EPB) could

be a very effective way to bring more buyers and to establish business in a new horizon. More initiatives should be taken by BAPI like as before, high level pharmaceuticals delegation team visit to foreign countries to explore more export.

- E-commerce is a new concept in Bangladesh. Again, trust and security issues in electronic money transaction and sensitive items like medicines and medical equipment are likely to provoke doubts in the customer minds. In this context, renowned pharma companies can have an option of ordering online in the already existing websites on a trial basis.

Conclusion

Two tales told by the philosophers that improvement is a continuous process and quality is working when no one is looing. The tales are very true for thriving pharma sector of Bangladesh. Definitely other successful economies with well regulated pharma sectors are not devoid of paybacks from their moral and ethical aspects of costly and well managed state of the art technologies. Medical pluralism and a mixed economy surely a challenge after costly investments. But also, there are options to grow bigger through export-oriented sales, as achieved by few companies. So, it's time for the companies to adapt think global, act local concept. Last but not the least, the sector is highly promising, looking for more government support and also financial and technology support from abroad.

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