

Editorial

Bangladesh Pharmaceutical Industry: Perspective and the Prospects

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Introduction

Propelled by the better health and education, lower vulnerability and an economic boom, Bangladesh, based on a rigorous methodology using a wide range of sustainable development indicators, the largest Least Developed Country (LDC) in terms of population and economic size, looks likely to leave the LDC category by the year 2024¹.

There are a good number of sectors in Bangladesh on which we feel much proud of, and undoubtedly the pharmaceutical sector is one of these best sectors. It is one of Bangladesh's most success stories and one of the most technologically advanced dynamic sectors currently in existence. This industry is a matter of substantial pride to the country. Skillful attitudes, knowledge and innovative ideas from the Pharma Professionals are the key factors why this industry grew in the way it did. Imports are restricted by the Government of the People's Republic of Bangladesh for locally manufactured drugs giving the industry protection from external competition. Drug Policy 1982 played a pivotal role in developing country's own pharmaceutical industries².

The success story of the Bangladesh Pharmaceutical Sector is very pleasant. It had to travel a long way to achieve the present prestigious position in domestic and international markets. By now, 97% of country's demand of medicines is produced locally mainly by national pharmaceutical companies³⁻⁶. The pharmaceutical sector of Bangladesh is expanding rapidly and some companies have already certified by different international regulatory authorities like UK-MHRA, Australia-TGA, EU, etc. for quality management and quality products manufacturing. Moreover, few companies are on the road to achieve

US-FDA approvals.

At present, there are 5 types of medicine manufacturing companies in the country. In a recent Jatiya Sangshad session, Mr. Mohammed Nasim, the Honorable Health Minister of the People's Republic of Bangladesh said, "Local producers are meeting 98% of the country's demand for medicines, and there are 851 factories functioning in Bangladesh for the production of medicines. Of them, 266 are producing allopathic drugs, 26 are producing Unani medicine, 207 Ayurvedic, 79 homeopathic and 32 herbal medicines.^{4, 7-9}"

Many smaller companies are on the verge of entering highly regulated overseas markets. Bearing in mind its' successful past endeavors, the industry has the ability to establish itself in rigorous/mass exportation. "Bangladesh has seen the broad-based gains in health, education, infant mortality and life expectancy," said Daniel Gay, LDC expert in UN DESA's Development Policy and Analysis Division. "These have in turn driven economic growth, and latterly reduced economic vulnerability, so it's really a success story.¹"

Since Bangladeshi products are quality and cost-effective and there is a huge demand for medicine in the global market. We could have exported more but the export process is complex and time consuming. The government should make the process easier. In this regard, Mr. Tofail Ahmed, the Honorable Minister of Commerce of the Government of the People's Republic of Bangladesh opined that "The Pharma sector is exporting high quality medicine after meeting local demands. He also added, we are now exporting to more than 127 countries after meeting 98% of the local demand, and Bangladesh

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is the largest producer of formulated drugs among the Least Developed Countries.⁴⁹

Pharmaceutical export is contributing a lot to the GDP of the country and every year this contribution is positively growing up. In the meantime, Pharma sector has become the 2nd largest potential sector in Bangladesh to earn foreign currency and contributor to the national exchequer. At present, about 30 pharmaceutical companies have started their export activities.

According to industry experts, market size of pharmaceuticals may reach about BDT 330,000 million by 2024. The scenario of pharmaceutical industries of Bangladesh has been pin pointed along with an analysis of its' future prospects and challenges. A recent BMI Research (Business Monitor International is a research firm that provides macroeconomic, industry and financial market analysis founded-1984) suggests, Bangladesh's pharmaceutical market will continue to post relatively the high growth rates in 2017, an estimated +11.1% in local currency terms and +8.1% in US dollar terms from BDT 190 billion (USD 2.4 billion) in 2016 to BDT 211 billion (USD 2.6 billion) in 2017. By the year 2020, the market is estimated to be USD 3.37 billion (approximately)⁵. As per Bangladesh Drugs (Control) Ordinance, 1982 no foreign company could transfer technology to a local manufacturer unless they have their own set up in this country. Moreover, after the amendments of the Drugs (Control) Ordinance in 2006, now there is no restriction to produce any drug under mutual agreement with any pharma companies of the world. These are very timely and appropriate actions undertaken by the government to check misspells as well as misuse of powers.

Pharmaceutical Products Available in the Market
Bangladesh's Pharmaceutical Industry in is a sector of the most challenging developed and golden mining technology. Manufacturers produce the most sensitive drugs such as Insulin, hormones, Cancer, and Vaccines, protecting against 20 bacterial and viral diseases, including Pertussis, Diphtheria, Typhoid fever, Poliomyelitis, Influenza and Mumps, Rabies vaccine, Hepatitis B vaccine, and Tetanus vaccine. The industry also exports medicines to the global markets, including Europe. Pharmaceutical companies are expanding their business with the aim to expand the export market.

The Industry exports active pharmaceutical ingredients (APIs) and a wide range of pharmaceutical products, covering all major therapeutic classes and

dosage forms, to 79 countries. Along with regular forms like tablets, capsules and syrups, Bangladesh also exports specialized products like HFA inhalers, CFC inhalers, suppositories, nasal sprays, injectables, IV infusions etc. These products have been well accepted by medical practitioners, chemists, patients and the regulatory bodies of all of their importing nations. The packaging and presentation of the products of Bangladesh are comparable to any international standard.



Pharmaceutical Industrial Research & Development (R&D)

Research is a very critical thrust discipline in Pharmaceutical Industry because it is foundation upon which the industrialists' strategy to introduce new products and delivering quality products to customers' stand. Some Pharmaceutical companies have built up sophisticated R&D facility equipped with state-of-the-art equipment and facilities with a highly experienced multidisciplinary and experienced world class team. The objective of R&D strength has to develop new drug delivery system and various dosage forms including packaging and marketing.

We haven't at all any doubt for the pharmaceutical industry to aggressively promote products on which huge amounts of money have been invested at the developmental phase. The rigorous testing applied to modern pharmaceuticals has little parallel in other industries. Unlike most other products, pharmaceuticals have the potential to not only improve health but also to cause harm. As such the ethics of promotional activities in the marketing, research & development and then promotion in all sectors of pharmaceuticals has to be clearly identified and should be addressed perfectly. It should not influence doctors' autonomy in making decision although that has been previously showed to be insidiously influenced. Successful pharmaceutical companies realize that they must do more than just

make attractive products. More often than not the 'packaging of a product' is more important than the product itself. To this end, promotional strategies are used to develop persuasive communication linkages between the company and its markets.

Pharmaceutical promotion and advertising can influence not only in the use of a product, but also our (doctors and public alike) belief on medicines. As promotion has the potential to change behavior and because it is a major source of drug information for health professionals, the messages promoting pharmaceuticals should be factual, evidence-based, unambiguous and balanced. One popular way to market a product is to promote it via educational activities. These can range from personalized delivery of educational materials by drug representatives to the doctor's office, company sponsored journal clubs, product presentations during lunch breaks, company sponsored Continuing Medical Education (CME) programs (ranging from one-off dinner talk to a full weekend workshop or seminars), company assisted conferences with industry sponsored symposia (in main program to satellite symposia) as part of the program and sponsoring of doctors (and pharmacists) to attend conferences. Indeed many companies will have their own dedicated "Educational Grants or Funds" for such activities.

Any development program (CME not an exception) requires adequate resources be it is the financial, infrastructural or human resources. Practically every other CME activity is assisted either directly or indirectly by the pharmaceutical industry. In marketing sense, there is no better avenue than that provided by CME activities. Not only is the logistics of addressing a wide audience of potential client achieved, the marketing strategy can be masqueraded by a neutral 'educational platform'. This can take the form of sponsoring the development of 'Evidenced Based Clinical Practice Guidelines (CPGs) to the plainly overt product launch in a desert island resort. While these activities usually have a clearly defined primary educational aim, they may be potentially open to a suspicion of unethical interaction between doctors and the pharmaceutical authority. Doctors involved in organizing or participating in such activities need to have a high level of awareness of this risk. They should ensure they could meet the allegations of unethical behavior, through avoiding any secrecy regarding the source and to the extent of sponsorship, and by ensuring that the provision of food or other attractions at these meetings is not on so lavish a scale as to cast doubt on the primary

educational purpose of the meeting. The cost should not exceed that level which recipients might reasonably be expected to incur for themselves under similar circumstances. Sponsors of such activities must be prepared to accept that not all such activities will generate marketing spin-offs.

So far we notice no effective, strong, committed and dedicated Research & Development (R&D) work on pharmaceutical sector could have been established by the government found in remarkable progress. Right R&D is a must establish to salvage of this sector and executions to be untaken immediately; otherwise the growth and success of the industry may be slow, going down or unexpected or unprecedented might be.

Product Marketing, Promotion and Education

The very nature of the medical practice demands lifelong learning. The need for lifelong learning is never more pressing than in this era of "Information Technology" and "Patient Empowerment". The need to continuously develop on self professionally has given rise to a concept the scope of which is much more than just attending the odd CME lectures. The CME includes a comprehensive approach in personal and professional development of a practitioner to meet ever challenging rewards of modern day medicine.

Some will utilize funds from marketing and sales division because they see it as part and parcel of a common goal; that of promotion and successful marketing of their products. Ideally, marketing should be more than just a promotional or selling effort to increase and satisfy demand for existing products and services. It should also seek to identify and respond to the needs, requirements, expectations and perception of its client; doctors and patients alike. It should lead to better overall performance of a doctor in managing their patients. This in turn should lead to better patient care and clinical outcome. However not all interactions between the medical profession and the pharmaceutical industry end up with positive patient outcomes. The emphasis tends to be more inclined to fulfilling the industry's objectives rather than the educational goals. Indeed a report from an extensive literature review found that doctors are affected by their interaction with pharmaceutical industry. There is evidence to show that doctors prescribing pattern is influenced after attending industry sponsored education programs even when the program is conducted in an academic environment governed by preset ethical guidelines¹⁰⁻¹⁴.

How can education and promotion co- exist in a practical and ethical manner?

To begin with a line must be drawn between what is ethical and what is unethical in terms of the general interaction between doctors and the pharmaceutical industry. There is currently a lack of guidelines issued to doctors in developing countries. In Bangladesh such a guideline has been in existence developed by Ethics Committee of the BMRC (Bangladesh Medical Research Council).

Among the important points to highlight is that doctors should not participate in promotional activities that could in any way damage their public standing or reputation for independence of profession in the eyes of the peers, colleagues and co-workers, media, patients and their relatives and general public¹⁰⁻¹⁴.

Between Promotion and Education - Stick to the Evidence!

The last few decades has seen an exponential increase in our understanding of disease pathogenesis and therapeutics. The science of epidemiology has also evolved from being restricted to the close of public health to that of clinical medicine. Application of clinical epidemiology to daily clinical practice has given rise to a discipline of knowledge called 'Evidence Based Medicine' (EBM).

Unfortunately there is at times too much lip service paid to EBM, when what is really required is for it to be practiced. When there is good evidence that a particular drug is clinically beneficial. Then there should not be any hesitation in its promotion. It can even be argued that once credible evidence has been generated, not applying it is unethical. The argument has always been how really credible is the evidence. Teaching doctors and medical students EBM is now a routine repertoire in many medical schools both at the post graduate and undergraduate levels. The right understanding of EBM will be an important pre requisite for doctors to navigate the sometimes confusing world of medical literature and continuing professional development programs, many of which are directly or indirectly linked to the industry.

This includes doctors who contribute directly to educational program as speakers. Such a vacuum in correct understanding of EBM will be readily capitalized by the industry in the promotion of certain products. In such an environment, promoting and marketing of products of dubious benefits to patients will take precedence over genuine education. Thus it is not the relationship between the industry and the medical fraternity which should be frowned upon. The interaction though fraud with potential ethical

minefields is symbiotic, provided the interest is focused not on the doctors or the industry's interest but that of patients and is strictly evidenced based. In fact eliminating ethical interaction between the industry and doctors may hinder continuing professional developments of doctors which may be a disservice to patients.

Global Marketing- Education:

As a Least Developed Country (LDC), Bangladesh is able to make generic drugs without any intellectual property rights conflicts until 2033. The export earning, around Tk 4 billion, has been increased in recent years with the penetration of costly, regulated markets of the United States and in the Europe.

Two effective policies have accelerated the growth of this sector. One was the Drug Control Ordinance 1982, which banned foreign companies from selling imported pharmaceutical products in the country.

The other was the relaxation of the World Trade Organization's agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which permitted Bangladesh to reverse engineer patented generic drugs. The relaxation of TRIPS for least-developed countries has been extended up to the year 2032.

In fiscal year 2015-16, the annual sales of pharmaceutical products stood at Tk 15,600 crore. "This is a huge jump for the sector as the industry size was only Tk 170 crore in 1982." Bangladesh's pharmaceutical industry is dominated by local players. At present, oncology drugs are imported but some of the local players have heavily invested in the segment.

"Given the fact that local companies can manufacture quality products at affordable price, oncology segment will emerge as an attractive growth segment in future." For instance, A Pharmaceutical Industry has already started exporting to the US, one of the most regulated drug markets in the world, from last year. It shipped Carvedilol, a branded prescription



drug for hypertension.

Bangladesh, however, relies on imports for raw materials. More than 90% of them are imported every year. As a result, the industry is vulnerable to external shocks, according to the report. To address the issue, the government has started the process of constructing an active pharmaceutical ingredient industrial park in Munshiganj. At least half of the companies that got plots in the API Park are expected to go into the operation by this year. Once the API Park is completed, Bangladeshi companies would be able to source at least half of their raw materials from the complex, reducing reliance on imports.

Quality Control

There are two organizations mainly regulate drugs and pharmacies in Bangladesh. The Directorate General of Drug Administration (DGDA) is the national drug regulatory authority which is under the Ministry of Health and Family Welfare. DGDA regulates all activities related to import and export of the raw materials, packaging materials, production, sale, pricing, licensing, registration of all kinds of medicine including those of Ayurvedic, Unani, herbal and homeopathic systems.

The Pharmacy Council of Bangladesh (PCB) was established under the Pharmacy Ordinance Act in 1976 to control the pharmacy practice in Bangladesh. The Bangladesh Pharmaceutical Society is affiliated with the International Pharmaceutical Federation and Commonwealth Pharmaceutical Association. The National Drug Policy (2005) states that the World Health Organization's current Good Manufacturing Practices (GMP) should be strictly followed and that manufacturing units will regularly be inspected by the DGDA. Other key regulation features are restrictions on imported drugs (where these are produced by four or more local firms), a ban on local production of around 1,700 drugs that are considered non-essential or harmful and strict price controls on some 117 principal medicines.

Appropriate actions are timely taken as measures to ensure Quality Products to grasp global markets. The Health Minister of People's Republic of Bangladesh informed the house in a recent JS session that the government had suspended licenses of 86 manufacturers temporarily while 19 other have been suspended permanently for violating the Good Manufacturing Practice (GMP) guidelines. In addition, he added, last year the government also cancelled registration of 61 products and temporarily halted production of 14 others. Legal proceedings have been started against those owners.

According to the Export Promotion Bureau (EPB), Bangladesh earned \$43 million from exporting pharmaceutical goods in the first five month of the 2017-18 fiscal year. The Square, Incepta, Beximco, Eskayef, Opsonin, ACI, Acme, Renata and Ibn Sina are belonging to the Bangladesh's top pharmaceutical companies in authentic management concerns.

Speaking to Outsourcing-Pharma M Chowdhury, founder and CEO of Amretek explained, Bangladesh's educated pharma workforce and costs that undercut India and China will attract multinationals and Contract Manufacturing Organizations (CMO). He also said that the top five Bangladeshi pharma companies account for most of the exports, and also have better quality controls, but there are opportunities for growth. Moreover, Bangladesh represents a "huge opportunity" to pharma sector that CMOs will be attracted by the low costs, which undercut China, and help the industry grow to \$10bn (€6.9m) in 10 years.

From the above facts, as Bangladeshi we feel proud to see "The Pharmaceutical Sector is the pioneer in most successful sectors in Bangladesh."

Trafficking, Reproducing and Marketing of Low Quality Drugs

There is a good number of costly foreign drugs are open available in the local market procured through the improper roots for sale. By taking advantage of the illegal means and ways, some valuable, costly and reputed drugs are suspected-reproduced and/or manufactured locally for black door businesses. To cope up with the existing huge demands in the market, the products are not manufactured maintaining the required quality control measures as whole. Those are just reproduced and marketed for money making purpose only to becoming richest over the night. In many ways, a remarkable and good number of legal actions have been taken against those corrupts by the government of Bangladesh. Country's big whole sale medicine market shoulders the sole responsibility for these irregularities whatever they have been able to prove many times in many ways.

Concerns of the Pharma Leaders on Success to capture Global Markets

The sector leaders came up with individual remarks while addressing a discussion on "Preparedness of Bangladesh pharmaceutical industry for the future potentials and challenges". The discussion was a part of Samson H Chowdhury Memorial Conference 2017 held in Dhaka which focused on the prospect and

problems of Bangladesh's pharmaceutical sector. One of the Pharmaceutical leaders said, "We have already a strong base in domestic market. We need to have presence in global markets, but the government policy is not in favor of the industry." In that meeting another leader opined that "The sector people have to be innovative and focus should be on formulation of generic products having a market worth \$112 billion." For boosting the export, he suggested promotion of products through agents and marketing in the global markets. In July-January period of the current fiscal year, Bangladesh earned \$52.64 million, which is 8.5% higher than that of \$48.50 million in the same period a year before.

Conclusion

Over the past decades, it has seen phenomenal growth, currently contributing to almost one percent of GDP and is expected to grow significantly in the coming years. Bangladesh is experiencing a

consistent increase in healthcare expenditure, mostly out of pocket, which currently stands at almost three percent of GDP. Estimates suggest the domestic market will grow further in the coming years.

Finally, we should not have any concern on the expectations to see the lots of hopes and beliefs, grand successes in the pharmaceutical industry in Bangladesh in near future if its executions are not well operated with high ethical values maintained properly, scientifically as well as strong administrative necks. This overview is prepared based on the available data sources on BMI research, Bangladesh pharmaceuticals, and healthcare report and Quintiles IMS among others.

We apologize for the faults that written permissions could not be obtained for time constraints which might be processed in due course. Also, we are very sorry to quote some other texts may be here but haven't referred inadvertently.

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