

As of 5 September 2019

Australia Bangladesh Trade Conference, Sydney, 2019

Date: 14 November 2019
Session: 03:30 am ó 05:30 pm
Theme: Prospects of greater Collaboration on the Pharmaceutical Sector

A. Background

Bangladesh's pharmaceuticals are a high-tech industry. Not only does the industry meet the demands of 98 per cent of the population, it currently exports to over 100 countries, including the US, the UK, the EU and Australia. The relaxation of the World Trade Organisation's agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which permitted Bangladesh to reverse engineer patented generic drugs, facilitated growth of the industry that started emerging with essential drugs policy of early 1980. The relaxation of TRIPS for least-developed countries has been extended to 2032.

Around 1,200 pharmaceutical products got registration for export, which is likely to result in a massive jump in earnings within the next few years. The Industry has now a turnover of about US\$ 2 billion and total exportation was of US\$ 135 million in 2018-19.

Bangladesh pharmaceutical producers are one of the lowest-cost producers of drugs in the world. Bangladesh manufactures can produce drugs at a significantly lower cost than any other pharmaceutical industry in the world. Most of the companies have their own premises and large factory base, many employing state-of-the-art technology. Bangladesh local manufacturers can now produce insulins, hormones, cancer drugs, vaccines against over 20 bacterial and viral diseases, much beyond production of generic drugs. They global standards of HFA/CFC inhalers, IV infusions and various supplements. The industry boasts good packaging and can meet international standards.

The government has started the process of constructing an active pharmaceutical ingredient industrial park (API Park) near Dhaka- in Munshiganj. At least half of the companies that got plots in the API Park are expected to go into operation by the end of 2019. Once the API Park is completed, Bangladeshi companies would be able to source at least half of their raw materials from the complex. However, there is a clear need for greater focus on R&D and product marketing.

Backward linkage of the Pharmaceutical industry of Bangladesh relatively weak and still heavily dependent on imported raw materials for manufacturing drugs. 15 companies of Bangladesh including Square Pharma, Beximco Pharma, Active Fine, ACI Limited, Globe Pharma, Gonosastha Pharma, Oponin Pharma, Drug International and Eskayef produce 40 APIs. Ganashastha Pharmaceuticals Limited (GPL) alone accounts for about 60% of the raw materials manufactured in Bangladesh. In 2015, the demand of API & Excipient was BDT 60,000 million (about US\$750 million). Leading suppliers of raw material are India, China, Italy and Germany. As such, API is a vast area for foreign investment.

B. Bangladesh's greater capacity and trade in pharmaceuticals

The pharma industry of Bangladesh is now on the verge of entering highly regulated overseas markets like the USA, Europe and Australia. In this connection, several pharma manufacturers have already made huge investments in their new state of art manufacturing

facilities. Several companies have already obtained or in the process of getting UK MHRA, EU, TGA, AUSTRALIA and GCC certifications. Approximately 1200 pharmaceutical products received registration for export over the last three years and are being exported to more than 100 countries.

Some certification in the highly regulated market by major pharma players:

Company	Details
Square Pharmaceuticals Limited	US FDA, UK MHRA
Beximco Pharmaceuticals Limited	US FDA, TGA Australia, AGES Austria (for European Union), Health Canada, ANVISA Brazil, INVIMA Colombia and TFDA (Taiwan)
Incepta	UK MHRA, Health Canada, Germany, Taiwan

However, Bangladesh and Australia could not take advantage of their respective markets in the pharmaceuticals and bio-tech products. Better engagement can help the two countries identify opportunities for further trade and investment in this important and growing sector.

Trade between Australia and Bangladesh
Pharmaceutical products- HS code 30

Particulars	Value in 2016	Value in 2017	Value in 2018
Australia's imports from the world	7,7899	7,868	8,173
Australia's imports from Bangladesh	0.994	1.252	1.342
Australia's exports to the world	2,369	2,529	2,968
Australia's exports to Bangladesh	2.92	1.53	0.26
Bangladesh's export to the World	92.69	105.78	86.17
Bangladesh's Import from the World	231.19	244.79	233.88

C. The regulatory requirement on registration for the Australian Market:

Before a prescription medicine can be made available in Australia, the company legally responsible for supplying the product must lodge a submission with the Therapeutic Goods Administration (TGA), a Division of the Australian Department of Health. The TGA then evaluates the safety, quality and effectiveness of the product to determine if the benefits to people taking medicine outweigh the risks. If a company wants to change something about the medicine once it is available, they also need to lodge a submission for the TGA to evaluate.

D. Requirements of Investment of Bangladesh

The Government of Bangladesh encourages foreign companies to partner with local companies in producing drugs, and high-tech and specialized products. Regulations have eased, allowing foreign companies to export medical products to Bangladesh.

The market for biotech products are on the rise. The market size is over \$100 million and growing fast. Imperatives for biotech products are compelling local Pharmaceutical companies to turn to biotech and high tech products. However, given limited access to high and cutting edge technology, lead time, tie-up with foreign biotech companies is a strong

possibility in this market segment. Such joint ventures may then export such biotech products to advanced economies like Australia.

Human insulin market is dominated by Novo Nordisk (Denmark), GSK and Aventis are leaders in vaccines. Roche, Sanofi-Aventis are leading suppliers of anti-cancer drugs, though some local manufacturers are there. Anti-HIV/AIDS drugs are produced locally by Beximco Pharma.

Bangladesh also offers opportunities for foreign exporters of high-end medical equipment, surgical instruments, diagnostic equipment, and services. Anti-cancer drugs, vaccines, hormonal contraceptives, and others can be imported without any tax, while others are subject to applicable duty. Policy for medical device sector awaits approval. The established Bangladesh research entities like ICDDR, BCSIR, biotechnology, microbiology and genetic engineering department of Dhaka University and other Universities could be tied up for the development of biotech molecules and enzymes at lower cost.

To enter in the healthcare sector in Bangladesh, pharmaceutical companies are required to submit applications to the Directorate General of Drug Administration (DGDA) for necessary license. Beyond pharmaceuticals, investment could yield good returns in sub-sectors like medical devices; clinical lab trials; waste management; sanitation coverage; dietary supplements; pharmacovigilance; cosmetics; veterinary and human Vaccines; hormonal therapies etc.

E. The session is expected to allow an interactive discussion on all relevant issues regarding Pharmaceutical product export to Australia.

Major points of discussion:

- a) Relative advantages/strength of Bangladesh Pharmaceutical Industry.
- b) Registration requirements in Australia and challenges/ inadequacies.
- c) Barriers in entering the market-importers perspectives.
- d) Investments opportunities in Bangladesh with particular emphasis on biotech products and APIs.

F. The organisation of the Industry Session Prospects of greater Collaboration on the Pharmaceutical Sector: 03:30 pm ó 05:30 pm

1.	Moderator/ speaker to introduce the topic and discussants- Name (Aided by Rapporteur)	10 Minutes
2.	Lead Discussants (names or entities represented)	
a)	Bangladesh Association of Pharmaceutical Industries One Presentation	20 Minutes
	Discussants	10 Minutes
b)	Discussants from Australia (Austrade/ Importers etc.) Two persons	20 minutes
3.	Open discussion	40 Minutes
4.	Summation by the Moderator/ Chair	10 Minutes
