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Chapter XI

Bangladesh's Pharmaceutical Exports: Trends, Market Prospects, and Policies

Mohammad Abdur Razzaque, Rabiul Islam Rabi & Hamim Akib

11.1 Introduction

Over the past decades, Bangladesh has seen marked advancements in pharmaceutical production capacities that have contributed to achieving many public health goals through ensuring access to affordable drugs by the mass population. The proliferation in domestic production has generated an enhanced export supply response in recent times. This improved export performance started taking place even without any direct export support (e.g. cash assistance), which was accorded to the sector only very recently. The export dynamism, therefore, shows the sector's genuine export competitiveness. Bangladesh's Export Policy (2018–2021) has recognised the pharmaceutical industry as one of the highest priority sectors given the wide recognition of the industry's huge untapped export potentials. Sustained growth of pharmaceutical exports will be important in attaining the objective of export diversification.

Policy attention to various factors can greatly boost the pharmaceutical industry in expanding further both in domestic as well as international markets. One emerging issue to consider is Bangladesh's upcoming graduation from the group of least developed countries (LDCs) and its likely implications for the relevant policy regime in the country. The least developed countries are granted a transition period until 1 January 2033 to comply with provisions of the World Trade Organization's Agreement on Trade-Related Intellectual Property Rights (TRIPS) concerning pharmaceutical products. However, as Bangladesh's graduation is expected to take place in 2024, the transition period would come to an end almost a decade earlier. Along with addressing any existing supply-side capacity-related issues, establishing a TRIPS-compliant policy regime will also be a task at hand.

This chapter provides an analysis of pharmaceutical exports from Bangladesh. It highlights several major challenges confronting the export growth potential and discusses policy priorities for stimulating the export supply response. The analyses and recommendations provided here can be utilised as inputs for informed policymaking for export promotion and diversification. The rest of the chapter is organised as follows: Section 11.2 provides a brief overview of the industry; Section 11.3 analyses the trends and patterns of pharmaceutical exports along with global market

prospects; Section 11.4 discusses the issues arising from LDC graduation; Section 11.5 provides some policy recommendations to promote the sector's exports and finally, Section 11.6 concludes.

11.2 An Overview of Bangladesh's Pharmaceutical Sector

Evolution of the sector

Confronted with severe development challenges, access to affordable medicines was a prime concern in the post-independent Bangladesh with an average per capita income just above $100 (Reich, 1994). The country's pharmaceutical industry until the early 1980s was largely dominated by multinational corporations (MNCs). This dominance was characterised by heavy imports of medicines and raw materials for drugs. Eight MNCs manufactured almost 75 per cent of all drugs (in value terms), while close to 160 small and medium-sized firms accounted for the rest of the drug production (Reich 1994).

In 1982, Bangladesh adopted its first-ever policy regime on drugs, triggering a massive overhaul of the pharmaceutical industry. The National Drugs Policy (NDP) aimed at disciplining the pharmaceutical industry by initiating drug price controls, reducing market dominance of the MNCs, and prohibiting pharmaceutical patents with the objective of achieving various public health goals. To materialise the NDP objectives, the government also legislated the Drugs (Control) Ordinance (DCO) 1982, regulating various components of the underlying supply chains including production, distribution, importation, and sales. Over time, Bangladesh also adopted two more drug policy regimes: one in 2005 and then more recently in 2016. A summary of the prominent features of the three regimes along with the DCO 1982 is presented in Table 11.1. There is a general recognition that the adoption of the 1982 NDP helped the country's pharmaceutical sector to grow (South Centre, 2019). Besides, the sector also benefitted from the waiver of patent enforcement on pharmaceutical products due to Bangladesh's least developed country (LDC) status (Azam, 2016).

According to industry sources, Bangladesh's robust economic activities, steady population growth with a large consumer base, rising life expectancy, and increased risks of chronic non-communicable diseases have been major growth drivers of the pharmaceutical industry along with the regulatory support measures provided. With the rising income, people tend to spend more on healthcare needs, which, in turn, ensures increased demand for drugs. The health expenditure per capita (in purchasing power parity terms) has increased gradually from less than $30 in 2000 to about $100. Nevertheless, it remains much lower than average corresponding expenditures for South Asian and low- and middle-income country groups (Figure 11.1). This seems to suggest that the demand for pharmaceutical products in Bangladesh is likely to expand at a faster pace in the future. Bangladesh also has one of the lowest public health expenditures (as a proportion of GDP) amongst the global economies (Figure 11.2).[1]

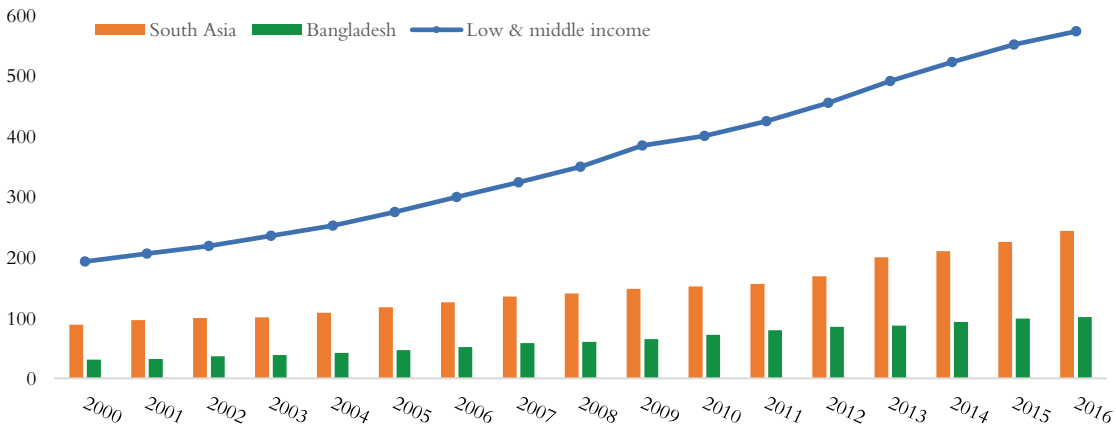
[1] According to some local industry representatives, Bangladesh is perhaps the most competitive producer of generic drugs and this could have contributed to low health expenditures.

Table 11.1: Summary of prominent features of national drug policies

NDP 1982	• Identification of a list of 150 essential drugs and 100 specialised drugs • Promotion of generic drugs by authorising the production and sale of 45 most essential drugs among the list of 150 drugs • Introduction of the National Formulary with formulations of all the listed essential and specialised drugs • Prohibition of pharmaceutical product patents
DCO 1982	• Regulated drug manufacturing companies to employ qualified pharmacists and enforce adequate quality control practices. • Mandated the establishment of an appropriately staffed and equipped national drug control laboratory. • Authorised the government to regulate the price of finished drugs, raw materials, packaging materials, and intermediates. • Restricted the production of vitamins, enzymes, and cough syrups to local drug manufacturers only • Prohibited import of any pharmaceutical products which are locally manufactured by at least three companies or has three close substitutes
NDP 2005	• Lifted the ban on manufacturing under contract or license by Bangladeshi manufacturers • Recommended the idea of setting up a specialised park for Active Pharmaceutical Ingredients (API) production to reduce drug production cost. • Underscored the importance of achieving self-sufficiency, enhancing export competitiveness, and adhering to good manufacturing practices (GMP)
NDP 2016	• Emphasised the preparedness towards TRIPS compliance. • Recommended the establishment of an effective surveillance system for medicines • Proposed regular updating of the Bangladesh National Formulary.[2] • Recommended to update and publish the prices of essential drugs online • Underscored the continuation of current GMP (cGMP) in drug production

Source: Authors' compilation from various government documents: national drug policies of 1982, 2005, and 2016, and the Drugs (Control) Ordinance 1982.

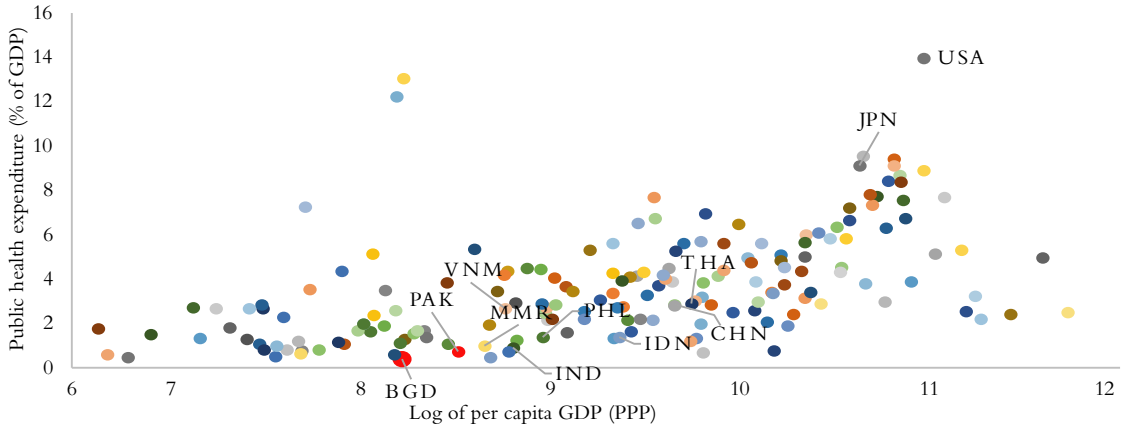
Figure 11.1: Comparison of current health expenditure per capita, PPP (current international $) (2000-2016)



Source: Authors' presentation using World Development Indicators (WDI) data.

[2] The Bangladesh National Formulary (BDNF) is a comprehensive list of all the drugs available in the market. The list, prepared by the Directorate General of Drug Administration (DGDA), helps doctors to know the efficacy, price, risks, and other information about a drug before prescribing it. The last update of BDNF came in 2015.

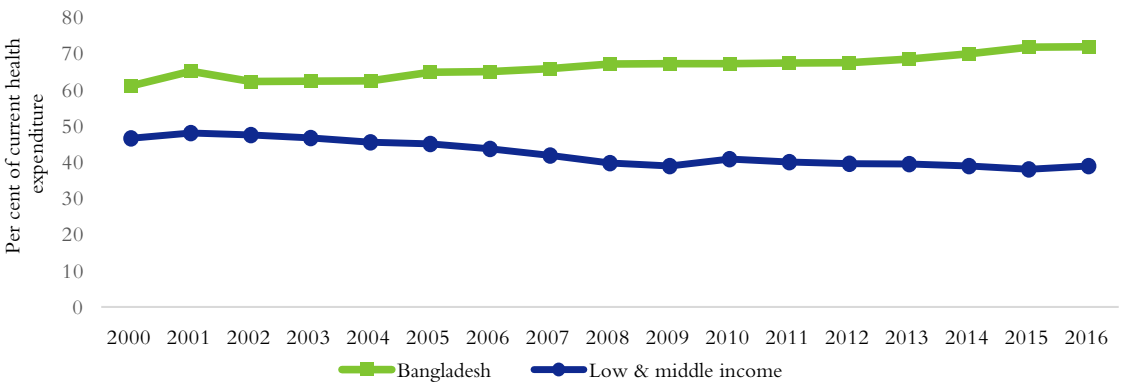
Figure 11.2: Global public health expenditure (% of GDP)



Source and note: Authors' analysis based on WDI data. Countries are indicated as BGD—Bangladesh, CHN—China, IDN—Indonesia, IND—India, JPN—Japan, MMR—Myanmar, PAK—Pakistan, PHL—the Philippines, THA—Thailand, USA—the United States of America, and VNM—Vietnam.

Again, as the country's population increased from 130 million in 2001 to about 164 million in 2018 (Ministry of Finance, 2019b), the consumer base expanded quite significantly. Bangladesh is also characterised by a health financing system in which the out-of-pocket payments (OOPs) are very high (Mollah & Chi, 2017).[3] Almost 65 per cent of OOPs are due to expenditures on various medicines. In Bangladesh, OOPs comprise 93 per cent of private health expenses—much higher than that of low and middle-income country average.[4] Interestingly, with respect to OOPs, Bangladesh is moving in the opposite direction as these expenses are declining in many developing economies (Figure 11.3) due to the emergence of health insurances which are yet to develop at meaningful scales in Bangladesh.

Figure 11.3: Comparison of out of pocket expenditure (as % of current health expenditure)



Source: Authors' presentation from the World Health Organization Global Health Expenditure database.

[3] World Health Organization (WHO) defines out-of-pocket payments (OOPs) as the direct payments made by an individual to the healthcare provider to avail a service.

[4] To reduce high out of pocket expenses to 32 per cent from 65 per cent of total health expenditure and increase health budget as percentage of national budget from 5 per cent to 15 per cent, the Government of Bangladesh has adopted Health Care Financing Strategy (2012–2032) (Ahmed, et al., 2015).

Bangladesh has made impressive progress in health outcomes. The improved life expectancy and reduced infant and maternal mortality rates can partly be attributed to better access to healthcare services and increased awareness regarding health issues. But, the progress in health outcomes is also partially contributed by the growth of the domestic pharmaceutical sector, which provided drugs at affordable prices.

Table 11.2: Comparison of selected indicators in Bangladesh

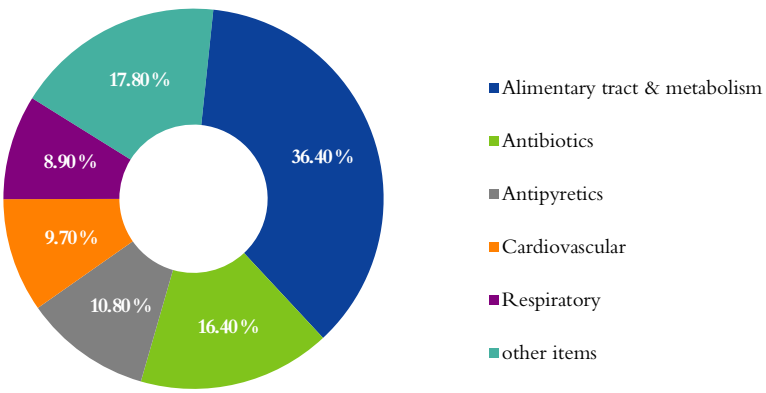
Indicators	2006	2018
Life expectancy at birth	66.5 years	72.3 years
Infant mortality rate	3.37 per thousand live births	1.69 per thousand live births
Maternal mortality rate	48 per thousand live births	22 per thousand live births

Source: Ministry of Finance (2019b).

Notwithstanding the above improvements, Bangladesh has been experiencing a change in disease profile triggered by various factors such as changes in lifestyle, demographic transitions, and widespread urbanization (EBLSL, 2019). Prevalence of non-communicable chronic illness (e.g., diabetes, cancer, asthma, cardiovascular diseases, etc.) is increasing faster than acute infectious diseases. This is reflected in the composition of drugs sold (Figure 11.4).

Over 70 per cent of the sold drugs are mainly related to chronic diseases. In addition, increased life expectancy is associated with a growing proportion of the elderly population being more vulnerable to non-communicable diseases. It has been estimated that about a quarter of Bangladesh's population will be aged 50 or above by 2050 (EBLSL, 2019). Consequently, the demand for medicines is likely to be increased given these recent trends in demographics and disease profiles. The underlying demand for medicines is mostly met by drugs supplied by the country's pharmaceutical sector. In fact, at present, more than 97 per cent of the domestic demand for drugs is sourced from local firms.

Figure 11.4: Composition of medicines sold in Bangladesh

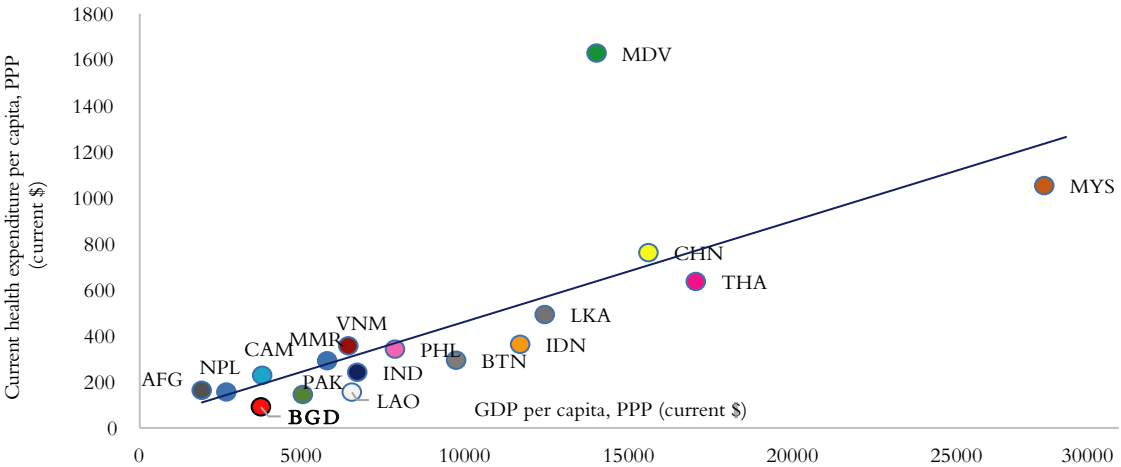


Source: Directorate General of Drug Administration (DGDA) (2018).

Rising per capita income should also boost per capita health expenditure. A cross-country analysis of Asian economies shows that there exists a positive relationship between GDP per capita and per capita health expenditure (Figure 11.5). Given its current GDP per capita, Bangladesh's per capita

health expenditure is somewhat lower than that of the Asian countries' average, as reflected in Bangladesh's location below the regression line in Figure 11.5. With the exception of the Maldives, the relationship between income and health expenditure fits quite closely. Since the rise in per capita income is associated with higher health expenditure, Bangladesh's health expenditure could result in a four-fold rise by 2030. If Bangladesh can close the gap with the Asian countries' average per capita health expenditure, the domestic pharmaceutical market size—even by conservative estimates—would expand to $6.5–$7.5 billion by 2025 (Table 11.3).[5] Under the same assumptions, the corresponding market could be valued at $12–$13 billion by 2030.

Figure 11.5: GDP per capita versus current health expenditure per capita in selected Asian economies



Source and note: Authors' analysis based on WDI data. Countries are indicated as AFG—Afghanistan, BGD—Bangladesh, BTN—Bhutan, CAM—Cambodia, CHN—China, IDN—Indonesia, IND—India, LAO—Lao PDR, MDV—Maldives, MMR—Myanmar, MYS—Malaysia, NPL—Nepal, PAK—Pakistan, PHL—the Philippines, SRL—Sri Lanka, THA—Thailand, and VNM—Vietnam.

Table 11.3: Bangladesh's pharmaceutical market size projections

Year	GDP per capita (current $), PPP	Health expenditure per capita (current $), PPP	Pharmaceutical market size
2017	$3,696	$90.6	$2.5–3.0 billion
2025	$6,300	$215	$6.5–7.5 billion
2030	$8,550	$375	$12–13 billion

Source: Authors' estimation based on WDI data.

The present state of the pharmaceutical sector

Contribution to the economy

The pharmaceutical sector is one of the fastest-growing manufacturing activities in the economy.

[5] By 2030, Bangladesh's GDP per capita (PPP) may reach a level comparable to the current GDP per capita (in PPP dollars) of the Philippines. Domestic market size estimates are based on a conservative assumption of pharmaceutical expenditure being just one-sixth of the total health expenditure. This is much lower compared to the reported proportions of health expenditure spent on pharmaceuticals by the WHO and a study by Mollah and Chi (2017).

The Quantum Index of medium and large-scale manufacturing industries prepared by the Bangladesh Bureau of Statistics (BBS) shows that during 2014–2018, the sector registered an average growth of about 8.3 per cent, which was greater than the country's overall GDP growth rate.[6] However, there seems to be a lack of reliable and consistent information on domestic pharmaceutical production and the sector's share in the GDP. According to BBS provisional Industrial Production Statistics (IPS), the total pharmaceutical production in 2017 was nearly $1.47 billion.[7] However, another study (Rahman & Farin, 2018) mentions the industry size to be at $2.44 billion in 2018, contributing to about 1 per cent of GDP. The information presented in the Bangladesh Economic Review mentions that the allopathic medicine production is worth about $2.6 billion (Ministry of Finance, 2019a).

According to various print media reports, the sector is expected to grow at an annual rate of around 15 per cent over the medium term with domestic sales to grow over $5 billion by 2023. The sector is thought to be the largest provider of white-collar jobs in the country and second-largest contributor to the national exchequer (ACME, 2017). According to the latest BBS Labour Force Survey (2016–17), close to 180,000 individuals were employed in the manufacturing of pharmaceutical and medicinal products. Considering both direct and indirect involvement, the overall employment in the sector is thought to be in the range of 0.5–0.6 million.

Drug manufacturing capacity

Bangladeshi pharmaceutical firms are now manufacturing more than 450 generic drugs covering different therapeutic classes such as oral anti-diabetics, anti-ulcerates, anti-rheumatic antihistamines, non-steroid, nonnarcotic analgesics, and fluoroquinolones.[8] The country imports nearly 3 per cent of drugs to cater to domestic demand. These imports relate to technologically intensive products including biologic drugs (South Centre, 2019).[9] A handful of large companies have recently started producing premium medicines like antiretrovirals (HIV/AIDS), anti-cancer, and epidemic vaccines.

Bangladesh's domestic consumer base has a big demand for branded generics.[10] Of all drugs produced domestically, generic drugs dominate with the share of patented drugs, according to industry insiders, accounting for 10–20 per cent. Few examples of patented products manufactured are Empagliflozin, Linagliptin, Sitagliptin, Sofosbuvir, Rivaroxaban, and Vildagliptin.

Pharmaceutical production can be divided into two technologically distinct parts: (i) manufacturing of active pharmaceutical ingredient (API) and (ii) formulation manufacturing, i.e.,

[6] The Quantum Index of production of mediun and large-scale manufacturing industries prepared by major industry groups prepared by the Bangladesh Bureau of Statistics (BBS)
[7] The provisional estimate of pharmaceutical production was Tk 15.39 billion.
[8] Generic drugs are pharmaceutical drugs having the same chemical composition of an original drug which is patent-protected. Third parties can manufacture and sell generic drugs in markets where there is no patent on the original drug, or where the patent has expired.
[9] Biologic drugs are manufactured from living organisms or are those that contain components of living organisms in contrast to pharmaceutical drugs which are produced from chemical synthesis.
[10] Branded generic is regarded as a generic drug which undergoes abbreviated new drug application (ANDA) process and has a different name from the original chemical substance. A branded generic drug must be bioequivalent to the original brand drug.

processing of active pharmaceutical ingredients into final dosage forms. APIs constitute the raw materials of pharmaceutical production. While Bangladesh has built significant production capacities in formulation manufacturing, API production has been quite limited. At present, eight companies in the country produce more than 40 API molecules.[11] Although few local firms are involved in manufacturing APIs, the pharmaceutical industry heavily relies on imported APIs from various foreign suppliers like China and India. According to the Export Promotion Bureau (EPB) of Bangladesh, approximately 90 per cent of the raw materials required for pharmaceutical production are imported. That is, the domestic pharmaceutical production is still substantially dependent on imported raw materials.

Key suppliers and market shares

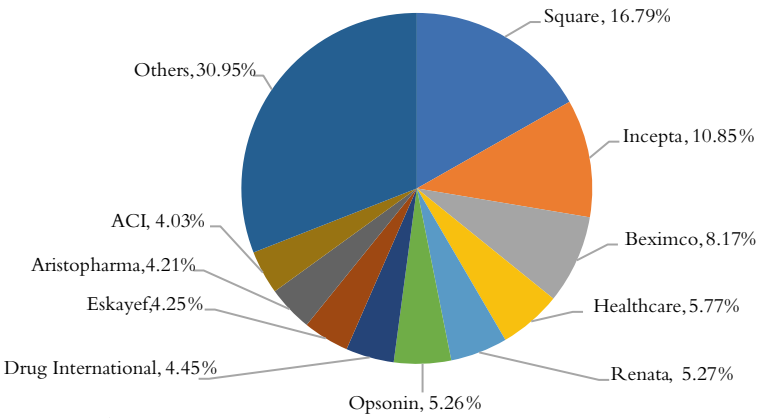
According to the DGDA database, there are 272 allopathic manufacturers and 29,684 registered allopathic drugs (Table 11.4). However, the actual number of firms in active production is around 150 (DATABD.CO, 2019). Strict regulations on imported drugs substantially contributed to the growth of local manufacturing capacity. According to IQVIA data, the top 10 pharmaceutical companies now capture nearly 69 per cent of the domestic market with the top three (Square, Incepta, and Beximco) accounting for almost 36 per cent.[12]

Table 11.4: Registered drug manufacturers, drugs, and retail pharmacies in Bangladesh

Type of medicine	No. of manufacturers	No. of registered drugs	No. of retail pharmacies
Allopathic	272	29,684	116,911
Unani	277	6,573	684
Ayurvedic	202	4,088	407
Homoeopathic	42	2,417	2,406
Herbal	35	549	11

Source: DGDA database (as of October 2019).

Figure 11.6: Market share of pharmaceutical firms in Bangladesh (%)



Source: Based on IQVIA data (2019, Q2).

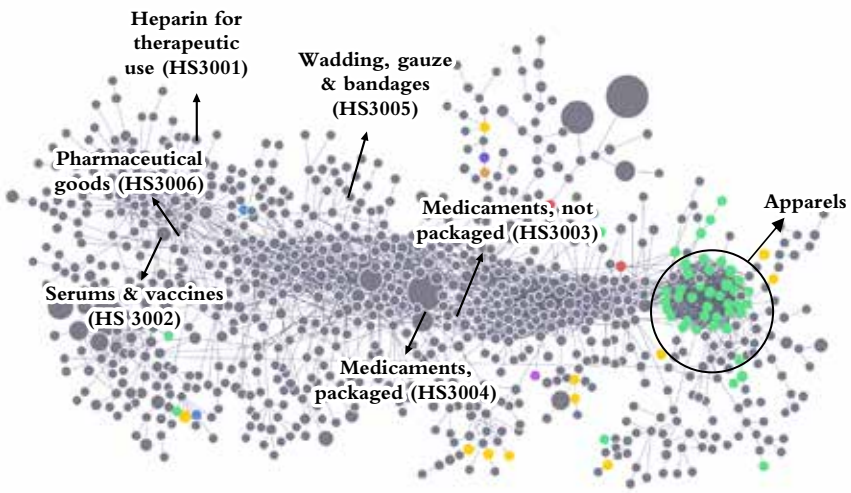
[11] This information is sourced from a report published in the Daily Bonik Barta dated 2 November 2019. According to that report, there are eight domestic API makers and only one manufacturer sells API locally and exports to such countries as Egypt, Nepal, Pakistan, and Vietnam.

[12] IQVIA, an American company, provides various services to the healthcare industry.

Prospect for export diversification

Pharmaceutical products hold a great promise for contributing to export diversification as reflected in the location of the sector in the product space. The product space analysis assesses the prospects for export expansion and diversification. In simple terms, the product space depicts a map of all export items (also known as the economic complexity atlas) to indicate how individual products are linked to one another. Towards the centre of the space, product linkages are dense. This implies that if a country's products lie at or close to the centre, it is easier to expand exports through related products. When products are at peripheries of product space, such as many agricultural exports and mining activities, counties exporting these items find it very difficult to move into other sectors. Therefore, the location of a country's products can determine the nature of its diversification prospects.[13] Bangladesh's product space analysis (Figure 11.7) reflects significant exporting activities in the apparels cluster that provides linkages amongst many potential export items. Pharmaceuticals items—more specifically medicaments, either packaged or not packaged (HS 3003 and HS 3004)—are located at the very core of the economic complexity atlas, indicating that these items have strong linkages with other sectors. This implies that the development of productive capacity in the pharmaceutical sector can lead to the export development of other sectors, contributing to overall export diversification in the long run.

Figure 11.7: Product space analysis for Bangladesh's pharmaceutical items



Source: The Atlas of Economic Complexity (http://atlas.cid.harvard.edu/).

[13] The product space analysis assesses the prospects for export expansion and diversification. In simple terms, the product space depicts a map of all export items (also known as the economic complexity atlas) to indicate how individual products are linked to one another. Towards the centre of the space, product linkages are dense. This implies that if a country's products lie at or close to the centre, it is easier to expand exports through the related products. When products are at peripheries of product space, counties exporting these items find it very difficult to move into other sectors. Many agricultural exports and mining activities are located in the periphery. Therefore, location of a country's products can depict the nature of its diversification prospects.

Key organisations

There are mainly two regulatory organisations for drugs and pharmacies in Bangladesh. Under the Ministry of Health and Family Welfare, the Directorate General of Drug Administration (DGDA) is the national drug regulatory authority. It regulates all activities associated with import and export of raw materials, production, pricing, sale, packaging materials, licensing, and registration of all kinds of medication including those of Unani, Ayurvedic, Herbal, and Homeopathic systems.

The Pharmacy Council of Bangladesh (PCB) controls pharmacy practices in Bangladesh. It was established under the Pharmacy Ordinance Act in 1976. On the other hand, the Bangladesh Association of Pharmaceutical Industries (BAPI) is working as the apex body representing the pharmaceutical companies of Bangladesh since 1972.

Recent policy initiatives for the pharmaceutical sector

In recent years, the Government of Bangladesh has taken several initiatives to support the pharmaceutical sector. In Export Policy 2018–2021, the pharmaceutical, and API and laboratory reagents sectors have been considered as the two highest priority sectors for export diversification. In 2018, the government declared pharmaceuticals as the 'Product of the Year' to recognise the significance of this emerging export sector. At present, the sector is receiving 10 per cent cash incentive for exports of generic drugs while a much higher 20 per cent cash incentive is provided to API exports. In 2018, the 'National API, Laboratory Reagents Production and Export Policy' was announced. The major incentives that would be provided for the production of APIs and laboratory reagents (henceforth referred to as APIs) are as follows:

- Producers will enjoy 100 per cent tax holiday for the first five years from 2016–17 to 2021–22. After the first five years, the same level of tax holiday will be continued until 2032 for those who manufacture at least two molecules every year.
- VAT exemption has been granted to the imports of raw materials of API and reagents for a period until December 2025.[13]
- Producers are exempted from advance income taxes and tax deductions at source until 2032.
- Producers will be provided 20 per cent tax incentives for export of APIs.
- Producers can access various other facilities such as financial facilities including loans from offshore funds; longer tenures of up to 12 years instead of six years for term loans for factories and equipment; back-to-back letter of credit facilities; etc.
- Producers will get priority in getting land in industrial parks and economic zones.

Policy attention is also accorded to infrastructural development to support the industry. Currently, Bangladesh's first API Industrial Park is being developed in Gazaria, Munshiganj, on around 200 acres of land. The park is expected to have 42 plots for manufacturing plants. According to industry sources, Bangladesh can save up to 70 per cent import costs of raw materials from the effective operation of the plants. This should also boost API export supply response in the long run.

[14] The National Board of Revenue attached few conditions with the incentive scheme. API producers will have to manufacture at least two molecules every year, undergo quality audit, and follow good manufacturing practices. Also, API producers should spend at least one per cent of their annual turnover on research and development to avail this benefit and maintain a minimum 20 per cent domestic value addition.

In 2011, the Pharmaceutical Sciences Research Division was approved under the Bangladesh Council of Scientific and Industrial Research (BCSIR) to undertake extensive research on pharmaceutical sciences. In 2017, a project to establish an institute for bioequivalence studies and pharmaceutical sciences was approved and its implementation is currently underway.[15] The five proposed divisions under this institute would be: 1) APIs and Pharmaceutical Excipients Research Division, 2) Quality Assurance Research Division, 3) Drug Discovery and Bioassay Research Division, 4) Dosage form Design Research Division, and 5) Biopharmaceutics Research Division. Successful implementation of this project is expected to expedite pharmaceutical research which includes conducting bioavailability and bioequivalence studies, which will be essential to export to regulated market by local pharmaceutical companies at low cost. Furthermore, this institute is also expected to facilitate clinical research to develop export-quality generic drugs and the development of improved synthetic and semi-synthetic routes of APIs and pharmaceutical excipients.[16]

While these encouraging steps are geared towards the right direction, it is important to fully utilise the currently available advantages due to the absence of patent protection in pharmaceuticals. In this context, Bangladesh can draw lessons from India. Just like in Bangladesh today, Indian firms were not able to manufacture API in large volumes. The Indian government established a large public sector manufacturing facility under the Indian Drugs and Pharmaceuticals Ltd (IDPL) and Hindustan Antibiotics Ltd. Under the Council of Scientific and Industrial Research (CSIR), several government-owned R&D laboratories were also setup. Later, the city of Hyderabad, the headquarters of IDPL, was transformed into a major API manufacturing hub. Founders of many API manufacturing firms once worked for the government owned IDPL or research laboratories. Almost every top pharmaceutical company benefitted from the services of these publicly owned laboratories. In the long run, this resulted in India's advancement in technological capacity to manufacture generic formulations and APIs (South Centre, 2019). Government support in developing start-up infrastructures, investing in R&D, and devising policy initiatives also played a vital role in developing pharmaceutical production capacities and export competitiveness of Chinese firms. China now produces 20 per cent of the global API output (in volume terms) including more than 2,000 API molecules. The Chinese government is reported to have invested $1.6 billion for the development of new drugs. Policy support along with improved infrastructures and low logistics costs helped China's exporters gain significant external competitiveness.[17]

The value chain in the pharmaceutical industry

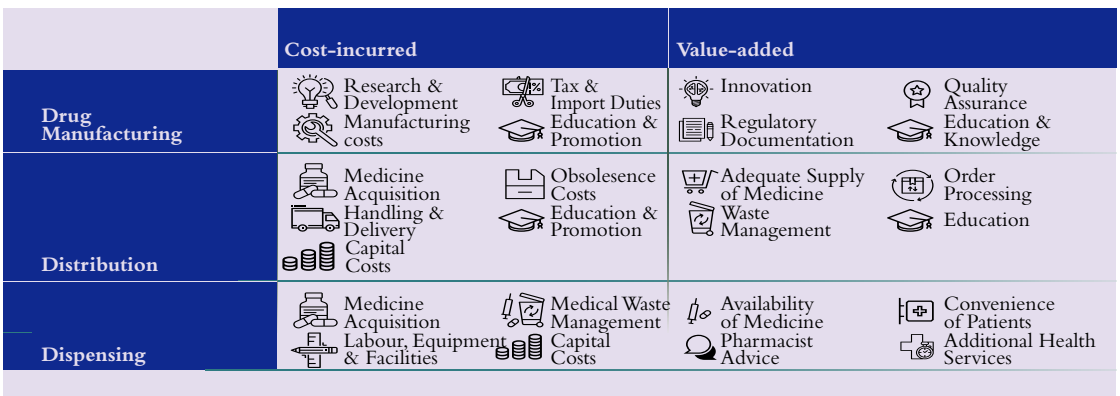
The global value chains (GVC) in the pharmaceutical industry comprise various core components: R&D, product development, manufacturing, exporting, marketing, and retailing. The manufacturing of pharmaceutical items has two separate stages. The first stage is related to API production followed by the making of the medicines. For producers of patented drugs, most costs are incurred in the R&D phase. Generic manufacturers face relatively lower costs and their main means of promotion is through trade incentives or offering larger discounts to secure

[15] This information has been obtained from the BCSIR website.
[16] See https://dhakalab.bcsir.gov.bd/hidden-menu/9-our-services/76-pharmaceutical-research.html.
[17] More discussion on this can be found in IPA (2019).

volume sales. Apart from the transformation of API-raw materials and new medicines, value addition by manufacturers often comes as scientific development or insights about disease control, as well as marketing or promotion of new drugs (Aitken, 2016). In many parts of the world, their profit margins are often limited by regulations.

Distribution is the process that connects manufacturers with retailers. In Bangladesh, most of the distribution is carried out by manufacturers themselves. In a global setting, distribution to retail points is carried out by wholesalers or drug importers. This is also the case for most of the medicines exported from Bangladesh. Local manufacturers export their items to specific importers or distributors. Since there are strict restrictions from the Bangladesh Bank on outward capital flows, Bangladeshi exporters face challenges to undertake marketing or supply operations in export destinations. Therefore, they rely upon the distributors or importers to carry out these key activities. Distributors' costs depend on factors such as logistics and transportation. Although their profit margins are supposed to be thin, when manufacturers are barred from owning their own distribution network due to restrictions, it can be quite significant. As a result, local manufacturers are often forced to share a big portion of their profits generated from the exports, particularly in the developed destinations.

Figure 11.8: Costs incurred and value-added in components of the pharmaceutical value chain



Source: Based on Aitken (2016).

Although seemingly straightforward, retailing or final dispersion of drugs to end-users through pharmacies is a critical point of the value chain. This involves a wide range of activities: from understanding prescriptions to labelling to accurate delivery of medicines and to consumers' awareness building on correct drug usage. Owing to a shortage of medical professionals in rural and remote areas, retailers often act as a source of knowledge about medicines and even act as a prescriber of simple drugs in Bangladesh.

Due to the existing legal framework and TRIPS waiver, Bangladesh's pharmaceutical value chain is relatively insulated from global consolidation. To expand the current base of exports, local manufacturers will eventually require shifting towards the upper stages of the GVCs. This will entail a gradual shift towards producing patented drugs with or without contract manufacturing, exploring opportunities for marketing, and building capacities for sales and distribution of bioequivalent and generic drugs.

11.3 Pharmaceutical Exports from Bangladesh: Trends and Prospects

Trends in exports

Top exported products: Under the Harmonised System (HS) of traded goods classification, the product code 30 (HS 30) at the 2-digit level covers pharmaceutical products. More specific divisions of pharmaceutical items are provided at the HS 6-digit level. Table 11.5 lists the top five exported products according to their share in total pharmaceutical exports in 2018. Clearly, pharmaceutical exports are highly concentrated in HS 300490 as it alone comprises 57.2 per cent of the total pharmaceutical exports. In contrast, products under HS 300320 and HS 300420 account for respectively 11.7 per cent and 10.7 per cent of the total pharmaceutical exports.

Table 11.5: Top pharmaceutical products exported from Bangladesh (2018)

HS Code	Product label	Value (million $)	Share in total pharmaceutical exports (%)
300490	Other medicaments of mixed or unmixed products, for retail sale	74.4	57.2
300320	Medicaments of other antibiotics, not for retail sale	15.2	11.7
300420	Medicaments of other antibiotics, for retail sale	13.8	10.7
300410	Medicaments of penicillins or streptomycins, for retail sale	13.8	8.2
300439	Medicaments of other hormones, for retail sale	0.159	4.5

Source: Authors' presentation using EPB data.

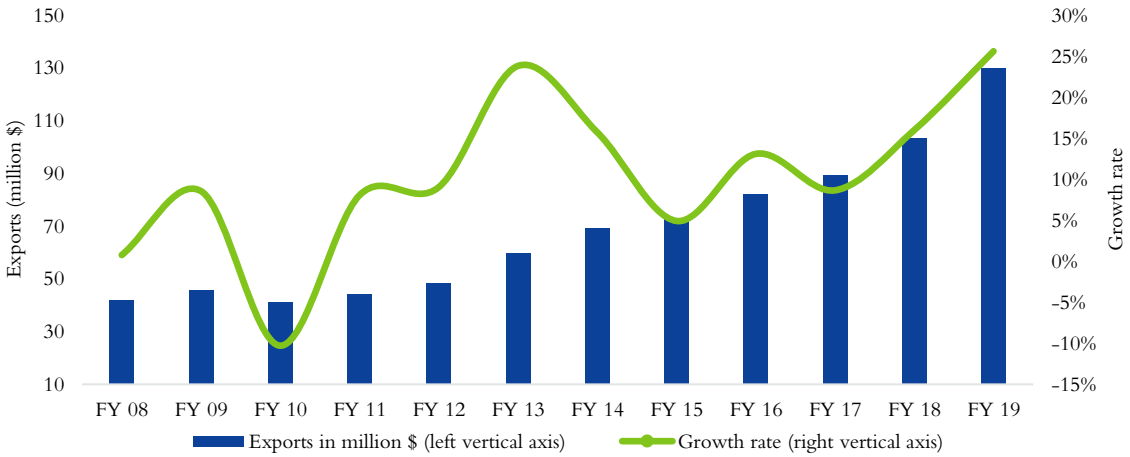
At present, being a least developed country, Bangladesh avails certain privileges that can facilitate its export of pharmaceutical products. It can export patented bioequivalent drug to LDCs or non-WTO members if the destination country has not implemented patent-protection for the products. In addition, Bangladesh can also export to any country where the patent owner has not filed any patent application. However, the sector is yet to fully utilise these flexibilities. According to some industry sources, the relative profitability of the domestic market is higher than that of the export markets. This is accentuated by stringent regulations and costs associated with pharmaceutical exports in foreign countries. In contrast, drug production, marketing, and distribution in the domestic market are much easier and cost-effective.

Export growth

Pharmaceutical exports from Bangladesh registered a steep increase since 2010 (Figure 11.9). It enjoyed an average growth of 12.4 per cent in exports between 2011 to 2018 and reached the record growth rate of 25.6 per cent in 2019. In 2018, Bangladesh's exports of pharmaceutical products crossed the $100 million mark and reached $130 million in 2019. The share of pharmaceutical items in the total export receipts was still quite small: 0.32 per cent. Some leading manufacturers acquired the USFDA (United States Food and Drug Administration), UK-MHRA (United Kingdom Medicines and Healthcare Products Regulatory Agency), and Therapeutic Goods Administration (TGA) certifications enabling them to export to these highly regulated markets. According to industry experts, drug export to the United States has elevated the local industry to a new height.

The high growth of exports has been largely attributed to a cost-effective production line, availability of relatively inexpensive skilled labour, and proliferation in the number of available generics (Gay, 2017). It needs to be pointed out that, pharmaceutical exports were not incentivised until 2018, although the sector benefitted from domestic regulation regarding drug manufacturing and flexibilities accorded as an LDC under WTO's TRIPs agreement.

Figure 11.9: Pharmaceutical exports from Bangladesh and its growth (million $)



Source: Authors' analysis based on EPB data.

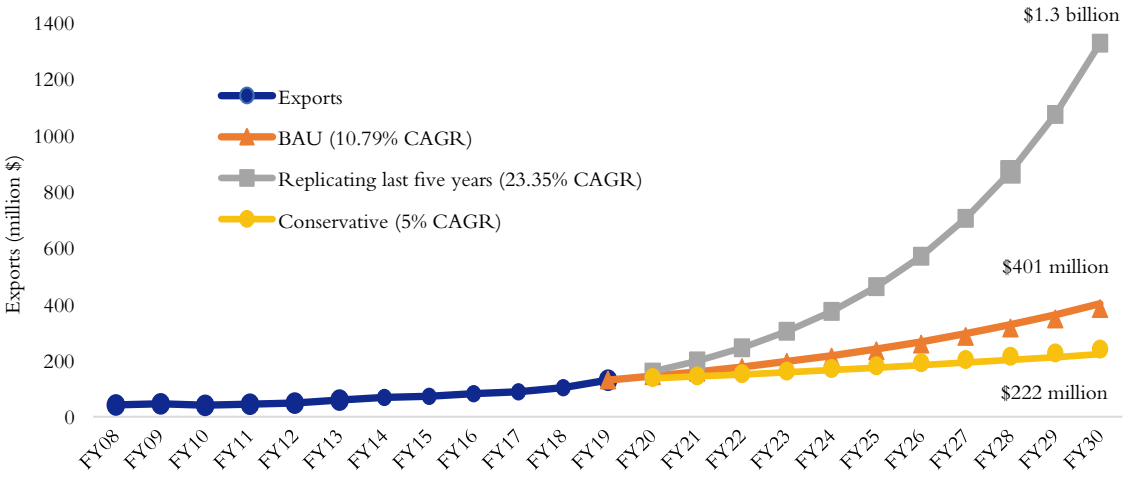
Export growth projections

Over the next few years (by 2024) patented drugs valued about $251 billion is expected to go off-patent (IPA, 2019). As the largest global generic hubs like China and India are losing cost advantage, local firms, particularly the big ones, may enjoy bigger contract manufacturing opportunities.[18] As a result, local exporters are likely to experience growth in export volume similar to the current rate of industry expansion per annum (about 15–16 per cent). Local exporters are upbeat about achieving $1 billion export mark within the next few years. However, the analysis undertaken in this paper reveals that, if Bangladesh manages to continue with yearly growth rate equivalent of the immediate past five years' average export growth rate (of 23.35%), pharmaceutical export receipts will reach $1 billion in 2029 (and $1.3 billion by 2030).[19] Maintaining a slightly lower growth rate of just above 10 per cent (which is the average growth achieved over the past ten years) would result in exports to reach just above $400 million by 2030 (Figure 11.10). A very conservative rate of 5 per cent per annum will take the export receipts to $222 million by 2030.

[18] India and China are thought to be losing cost advantage mostly due to higher labour and research costs (Rahman & Farin, 2018). Contract manufacturing is outsourcing of pharmaceutical production to the developing world with cost advantage. It involves production of goods by local manufacturing firm, under the label or brand of the original firm. By 2021, this feature of pharmaceutical industry is projected to generate contracts worth over $205 billion (Pharma iQ, 2018).

[19] If the industry wants to achieve $1 billion mark by 2025, growth rate will have to be 41 per cent for the next six years.

Figure 11.10: Growth projections of pharmaceutical exports

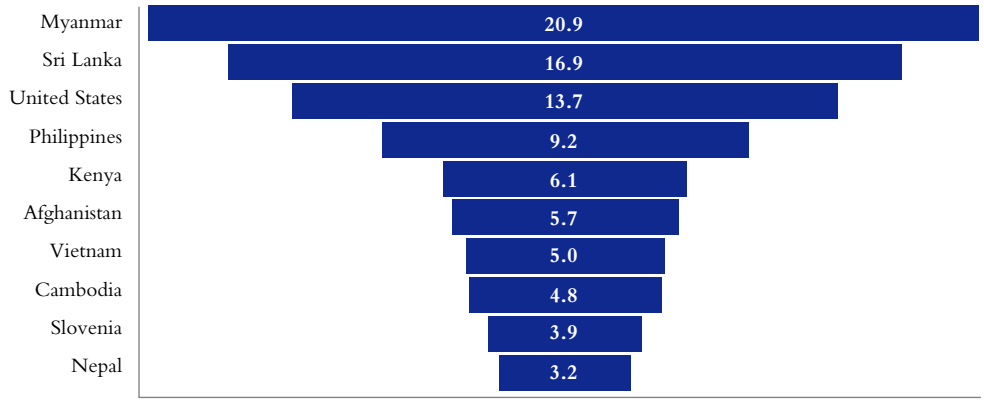


Note: BAU means business as usual situations; CAGR stands for the compound annual growth rate.
Source: Authors' estimation.

Export destinations and market reach

According to Export Promotion Bureau data, Bangladesh is exporting pharmaceutical products to more than 120 countries across the world, which includes 31 LDCs and, as mentioned above, the heavily regulated markets like the United States and the United Kingdom. The top export destinations in FY19 were Myanmar, Sri Lanka, the United States, the Philippines, and Kenya (amongst 120 export markets). These five destinations together capture 51 per cent of the total pharmaceutical exports. Among these, Myanmar was the largest market accounting for $20.8 million export earnings, followed by Sri Lanka ($16.9 million), and the United States ($13.6 million). The top 10 export destinations together comprise 68 per cent of the total pharmaceutical exports.

Figure 11.11: Top ten pharmaceutical export destinations of Bangladesh (million $)



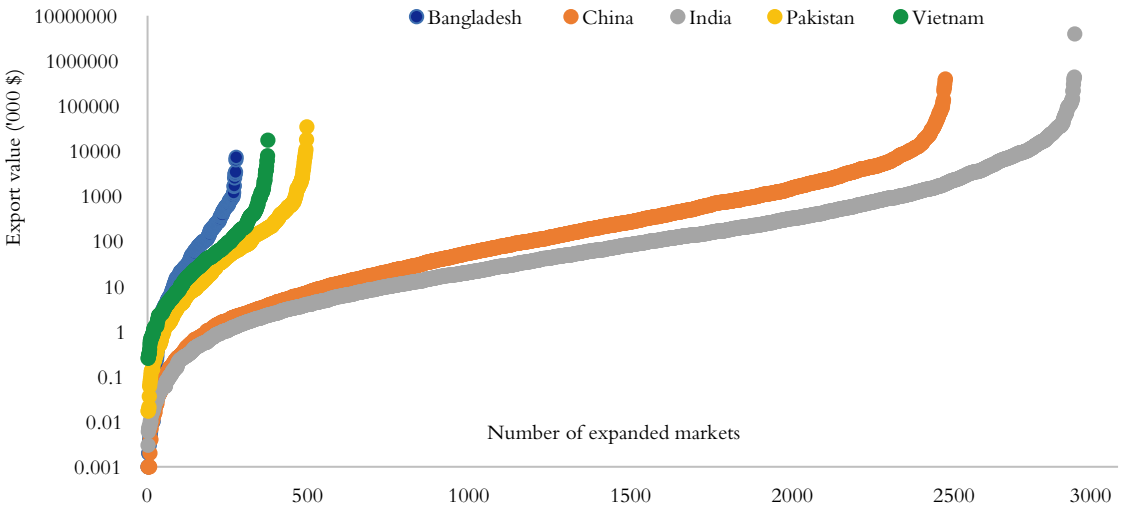
Source: Authors' presentation using EPB data.

Using the expanded market reach analysis for pharmaceutical products, the nature of

Bangladesh's market concentration can be compared with other countries.[20] As part of the analysis, four countries (China, India, Pakistan, and Vietnam) have been chosen as comparator economies. Using the latest available data, this analysis considers the number of all possible export markets based on a country's individual export products and the number of export destinations.

It is found that Bangladesh's pharmaceutical exports are concentrated in fewer markets in contrast with other comparators (Figure 11.12). Considering all individual products and market combinations, Bangladesh managed to reach out to only 274 expanded export market destinations. In comparison, India had 2,866 expanded destinations; China reached out to 2,465 destinations. Vietnam and Pakistan had respectively, 492 and 372 market reaches. Therefore, Bangladesh needs to expand its product base and the market reaches as well.

Figure 11.12: Expanded market reach analysis for pharmaceuticals (HS 30)



Source: Authors' analysis using UN Comtrade data.

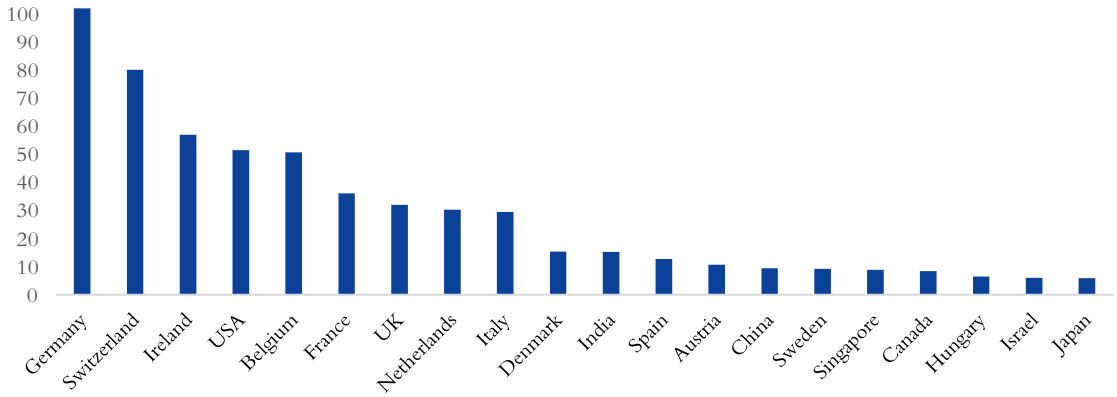
Export market prospects

Export potential

There is a substantial opportunity to enhance export response as the global market for generic drugs is valued at $340 billion and projected to reach $475 billion by 2024 (IMARC, 2019). Developed countries like Germany, Switzerland, Ireland, the United States and Belgium were among the top exporters of pharmaceutical products (HS 30) in 2018 (Figure 11.13).

[20] Expanded market reach is defined as the total number of export relationships. Suppose, if a country sells N number of products in country i, where i= 1, 2, ….., m, then the total or expanded export market reach would be $\sum_i^m N_i$. The higher is the value of this expression, the more diversified the economy is. Here, N has been considered at the HS 6-digit level while m is the number of countries. For example, if a country sells 12 pharmaceutical products in country 1 and 42 pharmaceutical products in country 2, then the expanded market reach/destination for pharmaceutical products would be 12 + 42 = 54. The higher the value, the higher is the number of markets being reached by an exporting country.

Figure 11.13: Major exporters of pharmaceutical products (HS 30) in 2018 (billion $)

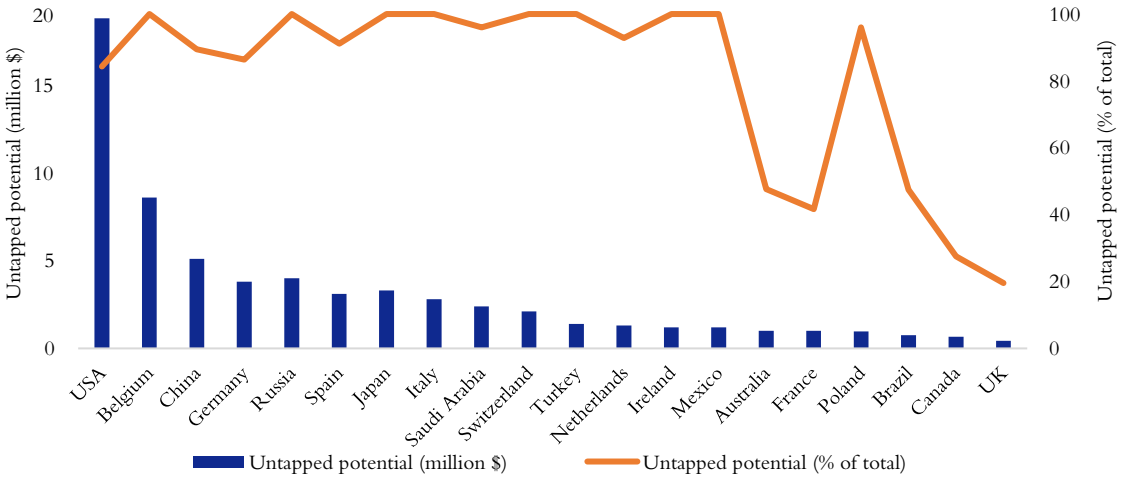


Source: Authors' presentation using ITC data.
Notes: For India, the ITC used India's data until January 2017 ($14.27 billion). This is close to India's Department of Commerce data for HS 30 in 2018–19 ($14.75 billion). The Pharmaceuticals Export Promotion Council of India reports that India's export of drugs, pharmaceuticals & fine chemicals was $19.13 billion in FY19.

The local industry informants are of the view that given the domestic capacity and recent dynamism, Bangladesh can be a major supplier of low-cost generic drugs and vaccines. Therefore, it would be of interest to ascertain any existing unutilised potential of this sector. The International Trade Centre (ITC) has developed a method for estimating the unrealised export potential. It is based on an 'Export Potential Indicator' (EPI) which identifies products in which an exporting country has already proven to be internationally competitive and which is likely to have promising prospects of export success. The EPI comprises three components: exporters' supply capacity of a product, demand conditions, and bilateral easiness-to-trade. An exporter's supply capacity is estimated as a dynamic version of market share where expected economic growth is considered to augment the exporter's capacity; and product-specific trade balance measured by the export-import ratio and global margin of preference, which encompasses information on tariff preference. Demand conditions are captured through partners' projected imports, which are determined by projected GDP and population growth; margin of preference in the target market; and distance advantage, which compares suppliers' geographical distances with the target market. The easiness-to-trade between any two countries is computed based on the actual trade relative to the hypothetical trade estimated by supply and demand conditions. If easiness to trade between countries is greater than 1, countries find it easier to trade between themselves relative to world markets. The ITC export potential is then calculated based on the estimated supply capacity, demand conditions and bilateral easiness-to-trade. A comparison of potential and actual export earnings provides the estimation of untapped export potential.

According to the Export Potential Map of International Trade Centre (ITC), as of January 2020, the markets with greatest potentials for Bangladesh's exports of pharmaceutical components are the United States, Belgium, and China (Figure 11.14). The Export Potential Map suggests that there exists an opportunity to realise additional exports worth $78.2 million, which is about 60 per cent of Bangladesh's total pharmaceutical exports in FY19. This estimated potential is based on a static analysis considering the current situation. The estimated export potential is small when the export base of a country is also small.

Figure 11.14: Export potential of pharmaceutical components



Source: Authors' presentation from ITC Export Potential Map.

Analysis of individual market prospects

Considering one particular market, how a country compares with other rival suppliers in terms of market share and export growth can offer very useful insights in assessing competitiveness and market prospects. The International Trade Centre (ITC) has provided a simple yet perceptive method for undertaking market prospect assessments for individual destination countries. The analysis is based on three primary factors: (i) export growth rates of competing countries in the destination market, (ii) all competing countries' export growth in the global market, and (iii) competing countries' market share in the same destination market. Utilising this methodology, Bangladesh's market prospects are analysed in the current top four export destinations: Myanmar, Sri Lanka, the United States, and the Philippines. A brief assessment of the overall African market is also presented.

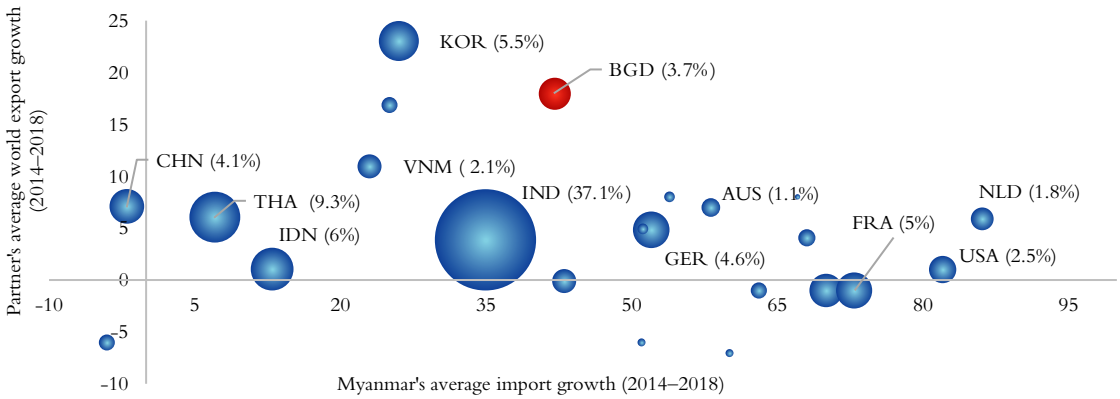
Myanmar

As mentioned earlier, Myanmar is the most important pharmaceutical export market for Bangladesh. In 2018, Myanmar imported $0.54 billion worth of pharmaceutical products. Therefore, the overall market size is not very big. Figure 11.15 summarises the export market prospects in Myanmar, where the horizontal axis indicates Myanmar's average import growth from all partner countries during 2014–2018 while the vertical axis shows the average world export growth of partner countries for the same product during the same period (i.e. 2014–2018). The size of the bubbles represents relative shares of various suppliers in Myanmar's import of pharmaceutical items. As evident, India is the largest supplier in Myanmar, accounting for more than one-third of total imports (37.1%). Among other exporters, Thailand (9.3%), Indonesia (6%), France (5%), Germany (4.6%), and China (4.1%) hold sizeable market shares. Bangladesh's share is 3.7 per cent.

From the position on the horizontal axis, it is observed that during 2014–2018, Bangladesh's pharmaceutical exports to Myanmar grew at an average annual rate of 42 per cent, higher than

most generic medicine exporters such as India (35.4%), Vietnam (23%), and Thailand (7%). But, a closer look at the data seems to suggest that patented drug exporters like the United States (82%), France (73%), Germany (52%) have experienced stronger growth, albeit due to their initial small export base. Overall, Myanmar has seen a very strong import growth of 21 per cent during the reference period.

Figure 11.15: Market prospect analysis for pharmaceutical products in Myanmar



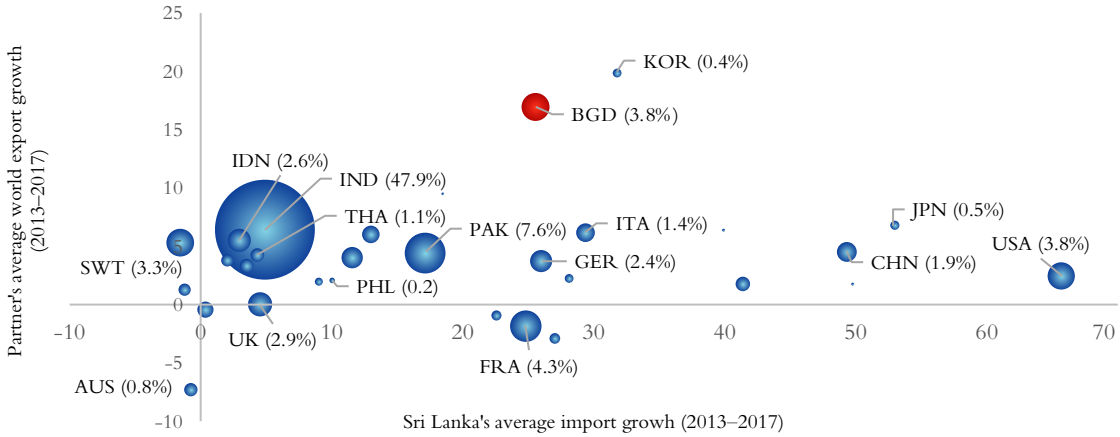
Source and note: Authors' analysis using ITC data. The bubble sizes represent shares of various suppliers in Myanmar's pharmaceutical imports (the numbers within the parentheses indicate the percentage of market share). Countries are indicated as AUS—Australia, BGD—Bangladesh, CHN—China, FRA—France, GER—Germany, IDN—Indonesia, IND—India, KOR—the Republic of Korea, NLD—the Netherlands, THA—Thailand, USA—the United States of America, and VNM—Vietnam.

With a population of nearly 54 million and $1,326 GDP per capita, Myanmar's pharmaceutical market size is expected to grow to $1 billion by 2023 (Invest Myanmar, 2018). Therefore, there will be opportunities for expanded export earnings although Bangladesh's market prospects can be quite challenging given the presence and growth of global suppliers. Bangladesh can consider Myanmar as a niche market, building on the current presence and taking advantage of geographical position as a neighbouring country. However, given the overall small size of the market, it will be difficult to grow exports significantly.

Sri Lanka

Bangladesh accounts for 3.8 per cent market share in Sri Lanka, where India is the largest supplier, occupying nearly half of the market (Figure 11.16). Other major exporters, Pakistan (7.6%), France (4.3%), USA (3.8%), Switzerland (3.3%), and Indonesia (2.8%) hold substantial shares of this market. Reading from the horizontal axis, it can be inferred that over the five years of 2013–2017, Bangladesh's pharmaceutical exports to Sri Lanka annually grew at an average rate of 25 per cent, higher than other exporters such as India, Pakistan, UK, and Switzerland. Indeed, Bangladesh managed to achieve export growth almost four times Sri Lanka's average import growth (6.5%). This is partly because of the fact that Bangladesh had started off with a small export base. With 22 million population and a small market volume, continued export expansion at a brisk pace in this market can be challenging. Similar to Myanmar, however, this market can be considered as a niche market for the future.

Figure 11.16: Market prospect analysis for pharmaceutical products in Sri Lanka



Source and note: Authors' analysis using ITC data. The bubble sizes represent shares of various suppliers in Sri Lanka's pharmaceutical imports, while numbers indicate the percentage of market share. Countries are indicated as AUS—Australia, BGD—Bangladesh, CHN—China, FRA—France, GER—Germany, IDN—Indonesia, IND—India, ITA—Italy, JPN—Japan, KOR— the Republic of Korea, PHL—the Philippines, SWT—Switzerland, THA—Thailand, UK—the United Kingdom, and USA—the United States of America.

The United States

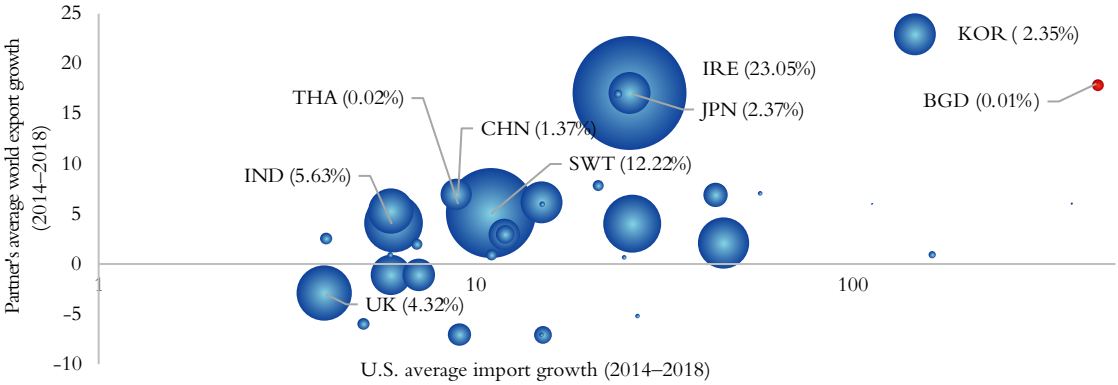
Currently, the United States is the third largest export destination of Bangladesh's pharmaceutical products. Due to high expenditures associated with healthcare, the United States accounts for 45 per cent of the import value for the global pharmaceutical market, making it the biggest import destination in the world. The market is highly regulated by intellectual property rights laws and enforces a very high standard of quality control requirements.

Figure 11.17 portrays market prospects in the United States. Producers of patented drugs (such as Japan, Ireland, Switzerland, the United Kingdom, and the Republic of Korea) hold major shares in the U.S. market. Capturing about a quarter of the market ($115.6 billion in value terms), Ireland is the largest exporter. Among large generic exporters, India has a market share of 5.63 per cent while China has a smaller share of about 1.4 per cent. Bangladesh holds only a meagre 0.01 per cent share in this market.

The U.S. market is witnessing a strong growth as its import of pharmaceutical products grew at 12 per cent per annum. From virtually nothing, Bangladesh's pharmaceutical export to the U.S. has grown rapidly. This market holds an enormous prospect for further export expansion. Currently, two leading pharmaceutical companies (Beximco Pharmaceuticals Ltd. and Square Pharmaceuticals Ltd.) have the approval to export to the United States. In July 2019, Beximco launched its sixth product in this market. According to industry experts, even after obtaining USFDA (United States Food and Drug Administration) approval, it takes time to go through the regulatory requirements imposed by the market. As a result, exports are yet to take off.

Future export growth in this market will require the suppliers' adhering to stringent USFDA regulations and GMP standards along with other factors. According to industry sources, high cost in drug registration and bioequivalence tests are often barriers for the exporters. Nonetheless, securing only a small share in this market can result in huge export earnings.

Figure 11.17: Market prospect analysis for pharmaceutical products in the U.S.

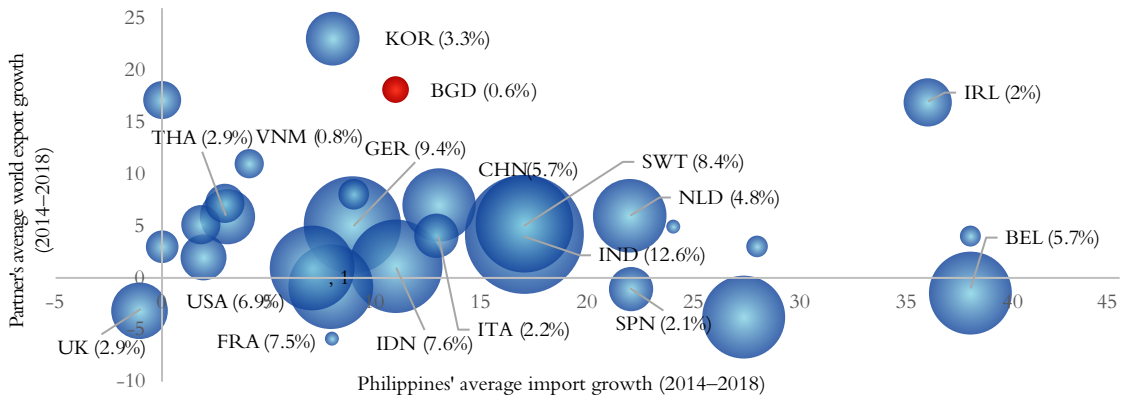


Source and note: Authors' analysis using ITC data. The bubble sizes represent shares of various suppliers in the United States' pharmaceutical imports, while numbers indicate the percentage of market share. Countries are indicated as BGD—Bangladesh, CHN—China, IND—India, IRE—Ireland, JPN—Japan, KOR—the Republic of Korea, SWT—Switzerland, THA—Thailand, and UK—the United Kingdom.

The Philippines

In the Philippines, Bangladesh holds around 0.6 per cent of the import share of pharmaceutical items (Figure 11.18). India is the largest exporter with a market share of 12.6 per cent, followed by Germany (9.4%), Switzerland (8.4%), the United States (6.9%), China (5.7%), and Belgium (5.7%). The Philippines' market grew at a rate of 11 per cent per annum during the period 2014–18. Bangladesh export expansion in this destination matched the exact same rate. In terms of sources of supplies, the market is well-diversified as most established suppliers such as Belgium, France, Germany, the Netherlands, the Republic of Korea, Spain, and Switzerland enjoy comparable market shares. As a result, competition in this market is already quite intense. To capture a sizeable share of this $1.6 billion market, Bangladesh needs to remain competitive in the long run.

Figure 11.18: Market prospect analysis for pharmaceutical products in the Philippines



Source: Authors' analysis using ITC data. Note: The bubble sizes represent shares of various suppliers in the Philippines pharmaceutical imports, while numbers indicate the percentage of market share. Countries are indicated as AUS—Australia, BGD—Bangladesh, BEL—Belgium, CHN—China, FRA—France, GER—Germany, IDN—Indonesia, IND—India, ITA—Italy, IRL—Ireland, JPN—Japan, KOR—the Republic of Korea, NLD—the Netherlands, PHL—the Philippines, SPN—Spain, SWT—Switzerland, THA—Thailand, UK—the United Kingdom, USA—the United States of America, and VNM- Vietnam.

The African market

Another export destination which may hold significant potential in the future is the continental African market. In 2018, the value of imported pharmaceutical items by African countries stood at $15.43 billion. Bangladesh currently occupies only 0.08 per cent of this market. India (18.87%), France (16.93%), Germany (7.46%), Belgium (5.19%), China (4.58%) are the major suppliers. The import growth of pharmaceutical products in Africa (2.2% per annum during 2014–18) appears to be quite slow but is expected to expand fast given the rising per capita income. There is an estimate to suggest that the value of imported drugs by African countries is likely to double (up to $30 billion) by 2030 (Holt, et al., 2016). Although Bangladesh's export base is currently small, proactive initiatives to enhanced market share should be a priority consideration. However, according to some key informants, market prospects are becoming increasingly daunting due to stringent regulations imposed by importers. Nevertheless, several firms are planning to expand their business by setting up plants in African countries. At present, one of the leading pharmaceutical manufacturers is already building its plant in Kenya which is expected to resume operation in 2021 (Box 11.1). More of such initiatives would partly help the export supply, as suppliers can better understand the market demands of the importing countries.

Box 11.1: Square pharmaceuticals: leveraging the Kenyan opportunity

Square Pharmaceuticals Ltd (SPL), one of the pharmaceutical giants in Bangladesh, has been operating since 1958 and is currently exporting to 42 countries across the world. In 2005, SPL started exporting to Kenya. With 117 products registered with Kenya's drug regulatory agency (the Pharmacy and Poison Board), Kenya has been one of the lucrative export destinations for SPL. As Kenyan pharmaceutical firms can supply only 30 per cent of the country's demand, the market remains largely reliant on imports.

In January 2018, SPL launched its subsidiary in Kenya as Square Pharmaceuticals Kenya EPZ Ltd. SPL became the first pharmaceutical firm in Bangladesh to extend its operation abroad. With commercial production expected to commence from the first quarter of 2021, the plant is projected to manufacture two billion tablets and capsules, and sixty million bottles of liquid formulations. Products will undergo pre-qualification from the World Health Organization (WHO) before being released in the market and are expected to be supplied throughout Africa in the future. Equipped with the state-of-the-art manufacturing technology and quality control, Square Pharmaceuticals Kenya EPZ aims to satisfy the unmet demands of various African consumers in Burundi, Kenya, Rwanda, South Sudan, Tanzania, and Uganda.

Source: 'Square Pharmaceuticals begins constructing Kenya plant', The Daily Star (10 January 2018).

11.4 LDC Graduation and Pharmaceutical Exports

International trade regime for the pharmaceutical industry

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides a minimum global standard regime for the protection of intellectual property rights (IPRs). The TRIPS Agreement, which came into force on 1 January 1995, obligates WTO members to align their national IPR regimes in line with the standards set forth by this agreement. Non-compliance of TRIPS standards can be reported to the WTO's Dispute Settlement Body to ensure enforcement of obligations. TRIPS compliance is particularly important for the pharmaceutical sector as new drugs are usually protected by intellectual property rights.

To comply with the TRIPS Agreement, LDCs were initally given a general transition period. After two successive extensions granted by the TRIPS Council, LDCs now enjoy the extended general transition till 2021. In addition, pursuant to the 2001 Doha Ministerial Declaration on the TRIPS Agreement and Public Health, LDCs members of the WTO were exempted from implementing patent protection for pharmaceutical products. The TRIPS council has also extended this waiver for the LDCs till 2033. However, LDC graduation will terminate this extended transition period for graduating countries. Besides these transition periods, the TRIPS provides various flexibilities (broadly referred to as the TRIPS waiver) for the LDCs to develop their IPRs regimes. At present, Bangladesh benefits from these two transition periods and TRIPS waiver as an LDC member of WTO.

In the pre-TRIPS era, Bangladesh's domestic policies focused on the development of national drug production capacity and restricted the market power of multinational corporations (MNCs). These policies, as mentioned earlier, benefitted Bangladesh's local manufacturers to meet the domestic demand for drugs and keep the prices of the medicines affordable for mass population (Reich, 1994). After the adoption of the TRIPS Agreement, Bangladesh continued to boost its drug production capacity under the shield of the TRIPS waiver which grants the right to produce any drug regardless of its patent protection. In fact, nearly one-fifth of the manufactured drugs in Bangladesh are patent protected (Rahman & Farin, 2018). Some of these drugs are priced at a fraction of their internationally patented counterparts, thereby serving the local population with an accessible source of medicine.

Local firms can also export generic versions of patented drugs to any country where those drugs are not covered by patents or where compulsory licenses are issued to treat diseases like cancer or HIV/AIDS. Several pharmaceutical companies like Beacon, Beximco, and Square have already taken advantage of this via collaboration with patenting firms or international financial institutions.

Again, the TRIPS waiver allows local manufacturers to enjoy preferential facilities over multinational corporations operating in Bangladesh and have a regulatory framework in action which is largely otherwise inconsistent with WTO regulations. Another TRIPS flexibility is the issuance of compulsory licensing. By using this instrument, a government allows an external entity to produce a patented product or process without the consent of the rights holder to use the patent-protected invention itself. Article 31(f) of the TRIPS Agreement states that products made under compulsory licensing must be "predominantly for the supply of the domestic market" and included the term "national emergency or extreme urgency" as possible contexts for issuing such compulsory licensing. This led to a sense of ambiguity that countries can only perform it under special conditions, or for the purpose of serving domestic demands.

However, the Doha Declaration, and later the amended TRIPS Agreement which came into force from January 23, 2017, provided further clarifications. Paragraph 5(b) of Doha Declaration of TRIPS on public health acknowledged, "the existence of flexibilities in the TRIPS Agreement with respect to the right to grant compulsory licenses and that each WTO Members has the freedom to determine the grounds on which such licenses are granted.", while paragraph 6 went on to recognise that "members with inadequate pharmaceutical manufacturing capacities could face difficulties in making effective use of compulsory licensing under the TRIPS

Agreement." The Doha Declaration and the WTO's General Council decision (dated August 2003) made it clear that compulsory licensing can be used to supply in the domestic market as well as for imports and exports. While LDCs can use compulsory licensing to import patented bioequivalent from cheaper sources without notification, non-LDC members must notify the WTO if they wish to use it. Developed countries have already declared that they will not utilise this measure. Although some LDCs have used compulsory licensing to import drugs (Bangladesh never did), no LDCs, have been able to utilise this opportunity to export in other destinations. It has been reported that most LDCs find the legal provisions of the WTO to be too difficult or suffer from capacity-constraints to utilise it (UNCDP, 2016).

There exists further opportunity to benefit from the flexibilities embedded in TRIPS article 31bis paragraph 3.[21] According to Article 31bis (paragraph 3), when a developing country (whether or not an LDC) belongs to a regional trade agreement (RTA) where at least half of the membership is made up of LDCs, the limitations on only domestic production under compulsory licensing does not apply and provides an opportunity to export in a RTA-covered area.[22] While Square Pharmaceuticals' recent operations (Box 11.1) in Kenya are expected to make entry into the Common Market for Eastern and Southern Africa (COMESA), other Bangladeshi firms are yet to capitalise on such opportunities (Business Daily, 2018). A wide range of factors including political pressure from some developed countries to comply with the TRIPS-plus agenda, complicated legal frameworks of LDCs, and supply-side constraints can explain such failure to utilise TRIPS benefits (Matthews, 2005).

Graduation implications for the policy regime

LDC graduation would imply termination of the extended transition period to comply with the TRIPS Agreement eight years earlier. The end of TRIPs pharmaceutical waiver is likely to shrink the policy space for Bangladesh.

Updating the Patent Law and IPR Policy

One pressing issue will be updating Bangladesh's existing IPR related legal framework and bringing changes to regulatory bodies to make them WTO-complaint. A broad range of laws and administrative mechanisms will have to be evaluated and updated to ensure conformity with TRIPS regulations. The primary IPR protection law in Bangladesh is governed by the National Patents and Designs Act (NPDA) of 1911, and Patents and Designs Rules 1933. As per the existing provision, patent protection is granted for 16 years, instead of the TRIPS requirement of a minimum of 20 years.

With the assistance of the World Intellectual Property Organization (WIPO), the Department of Patent, Designs, and Trademarks (DPDT) of Bangladesh has already prepared a draft for the new patent act, providing special opportunities for the pharmaceutical sector such as the so-called

[21] The full text can be viewed from WTO analytical index of TRIPS Agreement – Article 31bis. https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf.

[22] The text says: "to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question."

'Bolar provision' and 'Parallel importation' (World Bank, 2008).[23] Incorporation of the 'Bolar Provision' would be helpful as the current business model of top local pharmaceuticals includes extensive use of it which enables them to develop 'bioequivalence' by reverse-engineering of patented drugs that are supposed to go off-patent in near future (Rahman & Farin, 2018).

Although the draft law recognises patent protection for 20 years, it excludes pharmaceutical products from patent protection available under TRIPS waiver (South Centre, 2019). This draft was supposed to come into effect in 2015, but yet to be enacted. Furthermore, it has been argued that, the draft law requires full utilisation of TRIPS flexibilities and adequate focus on public health (Chowdhury, 2018).

In 2018, Bangladesh adopted a new National Innovation and Intellectual Property Rights Policy. It has been suggested that the new IPR policy needs to make proper use of TRIPS waiver to promote the country's public health objectives and support the local generic molecule manufacturers (South Centre, 2019).

Reviewing the 1940 Drugs Act and the National Drugs (Control) Ordinance of 1982

Currently, the 1940 Drugs Act allows regulatory bodies to control how imported drugs are labelled, requiring complete formulaic information to be printed.[24] Under the same act, foreign firms have to provide test data (information on biological subjects during trial periods) to regulatory authorities. However, according to Article 29.1 of the TRIPS, non-LDC members cannot force foreign parties to reveal complete formulaic information (Gay, 2017).

Several provisions of the National Drugs (Control) Ordinance of 1982 will need amending to ensure compliance with the WTO regime. Under this ordinance, multinational corporations (MNC) are prohibited from manufacturing drugs in Bangladesh without the joint collaboration with local manufacturers. In addition, MNCs are barred from importing a drug if the same (or its close substitutes) is manufactured by three local firms. Furthermore, MNCs are restricted from any marketing approval if the product is not locally manufactured. The 1982 ordinance also states that, if a foreign-registered patented drug has not been produced in Bangladesh for four years, the patent can be cancelled in the local market. A TRIPS-consistent regime will not allow for such infringement (Chowdhury, 2014). In the post-LDC period, patented drugs that are exported to other countries will be subject to this infringement. Article 44 of the TRIPS Agreement requires that countries have mechanisms for a party to file for an injunction in the event of an infringement of a patent and that authorities would be able to seize imported goods in such case (Fekuda-Parr & Treanor, 2018).

[23] The 'Bolar provision' (also known as the Roche-Bolar provision) permits non-patent holders to conduct studies, research and test for drug regulatory approvals and other related acts such as drug manufacturing (but not for sale). Under this provision, generic producers can prepare for manufacturing a drug well before the patent expiration so they can start selling it immediately when the drug comes off-patent. 'Parallel importation' involves the import of a medicine in one country and then distribution of that drug from original importing country to other countries.

[24] The 1940 Drugs Act first prohibited the import of a drug unless its complete formula is displayed on the packaging (The Drugs Act of 1940, Act no. XXIII of 1940).

While the product patent of foreign medicines was disallowed by the National Drug Policy 1982, in 2002 process patents were also prohibited (Azam, 2016). The ordinance of 1982 allowed the Directorate General of Drug Administration (DGDA) to effectively regulate prices in the local market and gave authorities to assign compulsory licensing to ensure affordable sources of medication. These regulations rendered substantial advantage to the local pharmaceutical industry. Indeed, within a decade of their implementation, the share of imported drugs was reduced to 20 per cent from as high as about 70 per cent (Reich, 1994).

While the existing law includes the option to activate 'compulsory licensing', Bangladesh never used it (Chowdhury, 2014). The process of compulsory licensing is more stringent for non-LDCs. However, according to the TRIPS agreement, LDCs are not required to enforce these until 2033 or LDC graduation, whichever comes first.

Pricing, competition, and technology transfer

Although an overwhelming majority of the drugs produced in Bangladesh are off-patent, the demand for patented drugs is expected to increase due to changes in the disease profile. After LDC graduation, patented drug production is likely to experience higher cost as it will require acquiring permission from and paying royalty fees to the patent owners. Consequently, the consumers and the public health system in Bangladesh and other LDCs could be affected. According to industry experts, patent protection would adversely affect the country's current effort to reduce import dependency. API manufacturing can also be affected following the enforcement of patents. Also, drug registration procedures might become stringent after LDC graduation. There is a general apprehension that if pharmaceutical firms are required to conduct bioequivalence tests for drug registration, it may increase overall drug prices as well.

Withdrawing import restrictions could result in an intense market competition from major manufacturers like China and India. The local manufacturers could face multifarious effects of stronger patent protection and increased participation of multinationals, which may result in industry consolidation.

Given the country's scant capacity in R&D, the sector's reliance on reverse engineering to imitate drug production could be limited after LDC graduation due to stronger IPR protection. This can impede the sector from the benefits of technology transfer to spur future growth. Article 66.2 of the TRIPS Agreement underscore the necessity for the transfer of technology to LDCs. Although WTO members undertook initiatives in paying attention to capacity building, the focus of donors has been on providing support which favours the right holders through improved IPR enforcement standards (Matthews, 2005; Chowdhury, 2014). According to industry sources, the support received in technology transfer has largely been non-existent.

Although it is quite difficult to ascertain exact implications for the pharmaceutical industry after LDC graduation, drawing from various studies, Box 11.2 outlines major potential implications for the pharmaceutical industry after LDC graduation.

Box 11.2: Potential implications for the pharmaceutical industry after LDC graduation

- Stronger IPR protection
- Higher cost of patented drugs
- Limits on reverse engineering ability
- Increased market competition due to withdrawal of import restrictions
- Stringent drug registration procedure

Source: Based on various sources (South Centre, 2019; Gay, 2017; Azam, 2016).

Export Performance

Bangladesh currently benefits from LDC-specific flexibilities to export drugs. Ideally, the provisions would allow exporting of patented mediciens to those markets where the drugs are not patent-protected or in the markets where compulsory licenses are in use to treat diseases like AIDS, cancer etc. As the current level of pharmaceutical exports, and especially those of patented medicines, has remained rather modest, Bangladesh's exports may not get significantly affected due to cessation of TRIPS pharmaceutical waiver. Table 11.6 provides an overview of the changes in market access conditions for pharmaceutical products in selected countries. Although tariffs can rise in the post-graduation period, it may not be a major concern for the sector. After LDC graduation, the current policy of export subsidy and other support measures to incentivise export performance could be considered non-compliant with the Agreement on Subsidies and Countervailing Measures (WTO, 1994).[25] Again, this should also not be a major cause of concern as the industry has started receiving the cash assistance support only recently. Nevertheless, it shows how the policy space to support the export sector could shrink after graduation.

Table 11.6: Market access conditions for pharmaceutical products after LDC graduation

Country	LDC tariff	Post-graduation tariff	MFN tariff
Australia	0%	No preference.	5% for selected items under HS 3002, 3005 and 3006. 0% for others.
Canada	0%	0% (except HS 30067090)	0% (except HS 30067090)
China	0% except HS 3001 and HS 30049090	No preference	4.74%
EU	0%	0%	0%
India	0%	5.8%	9.9%
Japan	1.78%	4.96%	5.06%
Republic of Korea	0%	4.04% (under APTA)	4.44%

Source: Authors' analysis using WITS data. Note: APTA = Asia-Pacific Trade Agreement.

[25] The agreement defines subsidies as "any financial transfer, tax credits, government purchases of goods, or any income or price support."

11.5 Policy Recommendations

Bangladesh's pharmaceutical export has huge potential given the soaring global demand for generic drugs along with a substantial rise in the number of drugs coming off-patent. However, for such a highly sophisticated sector with extremely challenging global standards and expanding export opportunities, breaking into major import destinations will require addressing various capacity constraints on a priority basis. Bangladesh's impending LDC graduation is also likely to bring in a challenging environment for which appropriate preparedness must be given serious consideration. A positive development is that the industry has already received close policy attention, and it is now important to ensure effective implementation of various support measures to boost the supply response on the back of its recent export dynamism. In this respect, some industry-specific policy recommendations are discussed below.

Enhancing supply-side capacities

Implementation and operation of the API park: Strengthening the backward linkage through domestic production of API is already a policy priority that has been reflected in various supportive measures directed to the industry. As discussed earlier, the API policy does provide incentives for API production and export. However, business enterprises can only reap benefits when they are able to produce and export APIs. The government initiative to establish an API industrial park is, therefore, an apt policy measure. The Bangladesh Small and Cottage Industries Corporation (BSCIC) has been developing the API Park in Munshiganj district and the work is expected to be completed by June 2020. However, after several revisions of the initial project proposal approved in 2008, the project implementation progress was at 63 per cent in August 2019.[26] According to the BSCIC, the API park will comprise 42 plots which will enable pharmaceutical companies to set up their plants and is likely to create 25,000 new jobs. Some industry insiders suggest that, even after setting up the plants, it may take a further five to six years for the API production to take place. This is due to the inherent characteristics of API manufacturing that follows complex chemical preparations and syntheses. Therefore, timely implementation and effective operation of the API park constitutes a policy priority.

Proper implementation and operation of the API park will not only help reduce import dependency but also enable firms to expand their exports. It will support Bangladesh's establishing a footprint in the global API market, which is projected to reach $245 billion by 2024 (Research and Markets, 2019). China is a noteworthy example of specific government interventions developing a thriving API industry. Policies adopted in China and India suggest that achieving API production capacity at a large-scale will require a focused approach in building competency and inducing substantial investment.

Other supporting factors in API manufacturing: API manufacturing is regarded as a high-volume, low-margin business, which is extensively dependent on economies of scale and dedicated manufacturing lines in production. During the consultation with industry professionals, the absence of a vibrant petrochemical industry in Bangladesh came up as a major factor constraining the pharmaceutical supply response. To achieve cost-leadership in API manufacturing, it is

[26] Information obtained from project progress report of BSCIC.

essential to have a strong petrochemical industry, which can help strengthen the backward linkage of the pharmaceutical sector. It is also important to ensure that API manufacturing facilities have adequate infrastructure to achieve economies of scale. Some industry experts are of the view that the size of the plots being allotted to firms in the API park are inadequate to build full-fledged manufacturing units. Uninterrupted utility supplies and availability of central effluent treatment plants (CETP), amongst others, will have to be ensured to enable firms in minimising production costs and maintaining global standards. For future API production, opportunities in various industrial parks and special economic zones (SEZs) should be explored.

Strengthening synthetic chemistry skills: Industry representatives have also pointed out that for export success in regulated markets, the use of drug master file (DMF) grade API in medicines is a prerequisite.[27] India, the major generic drug supplier, has more than 4000 DMF approvals for API whereas Bangladesh has none.[28] Besides, there is a need to develop domestic capabilities to produce high-value patented API molecules which will help reduce dependency on external markets. To achieve these, the government and BAPI can collaborate in developing institutional capabilities to strengthen synthetic chemistry skills. Improved capacities will enable the country to manufacture the API of newly patented drugs and thus enhance the generic drug exports as soon as the as the API comes off-patent.

A special economic zone (SEZ) for the pharmaceutical industry: Developing a dedicated special economic zone (SEZ) for the pharmaceutical industry can help improve supply-side capacities for export success. Infrastructure and business environment within such a SEZ should be of global standard. It is also important to ensure that the SEZs offer faster permitting, reduced taxes or duties and relaxed control over movement of capital and goods. Experiences of China and India suggest that numerous SEZs boosted pharmaceutical exports.

Infrastructure for exporting high-end pharmaceutical products: Pharmaceutical products are extremely sensitive to storage and handling conditions. For enhanced export of high-end products, creating a dedicated cargo storage and handling zone exclusively for sensitive pharmaceutical products (such as biologics, insulins, vaccines etc.) which require cold chain system thus constitutes an important consideration. Bangladesh can learn relevant lessons from India which has 'Pharma Zone' for such products. In addition, Bangladesh can seek assistance from the World Health Organization (WHO) to make such facilities complaint with international standards.

Reducing the cost burden of bioequivalence testing

Reducing the cost burden on test fees: Bioequivalence (BE) testing is essential to examine whether the generic version of a drug is identical to the originator brand or not. This test is mandatory for product registration in any moderately and well-regulated foreign market. The test requirements vary across countries and involve clinical trials of the drug on human volunteers

[27] A drug master file (DMF) is a document containing complete information on an active pharmaceutical ingredient or finished drug dosage form. The document is prepared by a pharmaceutical manufacturer and submitted to an appropriate regulatory authority in the intended drug market. The document provides factual and detailed information regarding facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drug products.

[28] This information has been obtained from the industry professionals.

to ascertain the effectiveness of the medicines set for export. At present, Bangladeshi pharmaceutical companies resort to foreign countries to carry out bioequivalence testing, which is expensive (in the range $50,000–$200,000 per product) (Rizwan & Kathuria, 2016; KIIs). According to pharmaceutical manufacturers, the test fees are sent as outward remittances and are subject to a 20 per cent tax and another 15 per cent value added tax (VAT). Such taxes exacerbate the cost burden. There exists a scope to alleviate the additional cost burden on exporters by relaxing the currently imposed taxes. It needs to be pointed out that BE tests are often undertaken without any guarantee of future sales. Removal/reduction of these taxes can encourage domestic manufacturers to look for external markets by making their products export-ready.

Fast-tracking the implementation of fully functional bioequivalence testing facilities: At present, Bangladeshi manufacturers are largely dependent on bioequivalence testing facilities of India, Malaysia, and several other countries. India boasts having a number of privately-owned laboratories. Such availability of homegrown facilities has helped India keep their export costs low.

In one positive policy direction, the Government of Bangladesh has already undertaken a project to establish an institute so that the tests can be undertaken in the country. The Institute of Bioequivalence Studies and Pharmaceutical Sciences (IBSPS) under the Bangladesh Council of Scientific and Industrial Research (BCSIR) was expected to be completed by June 2020. However, the progress made on the project is reported to have been quite sluggish. At present, only 2 per cent of the project work has been completed.[29] Therefore, fast-tracking the implementation of this project should be given utmost priority. It is also important to make it fully functional in compliance with global standards so the test results are globally acceptable. India's experience shows that its pharmaceutical companies often face difficulties in performing clinical trials in such government facilities (IPA, 2019). The relevant lessons should be learnt in better developing testing facilities here in Bangladesh.

Attracting FDI through joint ventures in contract research organisations (CROs)

Full-fledged BE tests are undertaken by internationally accredited contract research organisations (CROs). Such organisations are absent in Bangladesh. Industry experts are of the view that Bangladesh can become an emerging hub of BE testing facilities because of the existing manufacturing capacities in the country and due to its large population as these tests require human volunteers. Along with establishing the IBSPS, it is also a good idea to attract globally accredited contract research organisations (CROs) through joint ventures in Bangladesh. This is an area which can attract substantial FDI. This can also help develop technical know-how and earn foreign exchanges. In this regard, the Ministry of Commerce, Bangladesh Bank, DGDA and BAPI can collaborate to explore the possible options including the scope of any policy support.

Incentivising R&D expenditure

Revamping R&D activities of research institutions: R&D activities are a critical precondition for pharmaceutical manufacturers to innovate new products. Bangladesh largely relies on reverse engineering to manufacture drugs. New drug development is extremely research-intensive and

[29] See Annual Report 2018–19, BCSIR (page 25-26).

takes time. Investment in capacity development can help firms introduce product differentiation in export markets as well as manufacture new drugs. To do so, government support can boost R&D spending across the sector. In this context, India provides an example of its entrepreneurs benefiting from the publicly owned manufacturing facilities and research laboratories. For Bangladesh, while setting up large-scale public research facilities might not be a pragmatic option but providing incentives to private-sector research projects could comprise an important initiative. There are public sector entities such as the National Institute of Cancer Research and Hospital, Bangladesh Medical Research Council, Bangladesh National Research Council that are not involved in drug manufacturing but revamped activities of these institutes can help expand R&D activities, benefiting the pharmaceutical industry. (South Centre, 2019) Since providing export subsidy may not be possible after LDC graduation, the scope for supporting R&D activities should be proactively explored.

Developing biosimilar capabilities: Valued at more than $250 billion, the biologic drugs market is a major component of the global pharmaceutical market (GlobeNewsWire, 2019). Biosimilar or generic versions of these biologic drugs are increasingly becoming a key focus for pharmaceutical companies across the globe. As the number of drugs coming off-patent in this category is rising, this offers a huge opportunity for generic manufacturers (GlobeNewsWire, 2019). Enhancing the industry's biosimilar capabilities should thus receive due attention. This will not only result in improved access to biosimilar drugs in Bangladesh but also help achieve diversified exports of pharmaceutical products. In this context, the DGDA, Ministry of Finance, and BAPI can work together to encourage and incentivise the development of biosimilar capacities.

Setting up an R&D fund for the sector: Given the high cost of drug registration and approval procedures, the sector requires special attention to alleviate its financial constraints. A possible option to encourage R&D can be the creation of a special fund, especially for high-end generic drugs targeting the most lucrative but highly regulated markets. A portion of the R&D support could be made available for exporters to undertake bioequivalence tests. Such fund can be also used to incentivise companies focusing on research in the areas of biosimilar drugs, early-stage drug development, novel drug delivery system (NDDS), etc.[30] This support measure would promote entrepreneurship in the sector and support the development of a self-sustaining environment for R&D in the country.

Forging public-private partnerships and industry-academia ties to develop skilled human capital

A shortage of skilled professionals is also a major constraint facing the pharmaceutical sector. According to industry insiders, although Bangladesh enjoys the benefit of low-cost white-collar workers, pharmaceutical companies require foreign professionals for management and export market-related activities.[31] Every year nearly 2,500 pharmacy students graduate from more than 40 public and private universities.[32] However, their academic knowledge and training in many

[30] According to Jamshaid (2015), "Novel Drug delivery System (NDDS) refers to the approaches, formulations, technologies, and systems for transporting a pharmaceutical compound in the body as needed to safely achieve its desired therapeutic effects."
[31] See "Lack of skilled professionals challenge for pharma export", http://www.newagebd.net/print/article/9462.
[32] Data obtained from the Bangladesh Pharmacy Council.

cases do not match with the industry needs. Pharmaceutical firms also require graduates from various disciplines such as business, engineering, microbiology, biochemistry, chemistry, and law. Equipping these graduates with the necessary skillsets should be given due policy consideration and engagements between the industry and academia should be facilitated. There is also a critical need to update the university curriculum to meet the new requirements in pharmaceutical industry. In addition, degrees such as Bachelor of Technology (B. Tech.) and Master of Technology (M. Tech.) should be introduced to help strengthen API and drug manufacturing skills. Bangladesh can draw lessons from the experiences of India and China (Box 11.3). Through public-private partnerships, training institutes can be set up to assist graduates with job-oriented training. In addition, following China's examples, non-resident Bangladeshi skilled and specialised professionals can be attracted to the local industry. Also, regular training and exchange programmes with global regulatory bodies should be arranged to equip the industry professionals with the skills and knowledge required to manage export markets. These initiatives are likely to address the current shortage of skilled professionals, which is a major capacity constraint.

Box 11.3: Developing and retaining skilled human resources: lessons from India and China

India offers various examples of developing skilled human resources for the pharmaceutical sector through public-private partnerships. For instance, in a joint venture with Cipla Limited, an Indian multinational pharmaceutical and biotechnology company, the provincial government of Goa established the Cipla Technical Academy. The academy imparts an initial six-month training followed by an onsite in-depth training for students with the relevant background (undergraduates or graduates holding B.Sc., M.Sc., and B. Pharm degrees or diplomas). After completion of the training, Cipla assesses the candidates' acquired knowledge and abilities to absorb the trainees into their workforce. Otherwise, the Labor and Employment Department assists the trainees to obtain suitable appointments in other organisations.

India also established the National Institute of Pharmaceutical Education and Research (NIPER) which was the first national-level institute in pharmaceutical science with the objective of becoming a 'centre of excellence' for advanced studies and research in pharmaceuticals sciences. Besides, there are 2,000 PhD students enrolled in Pharmacy education in India, according to All India Survey on Higher Education 2018.

China adopted 'Thousand Talents Plan' to attract China-born scientists. Through substantial funding support (up to $75,000/year), the plan attracted nearly 50,000 PhDs. The returning talents' work ranges from forging partnerships between transnational biotechnology firms and Chinese universities, to developing cancer research partnerships and to negotiating and facilitating company-to-company deals.

Source: Authors' compilation from IPA (2019).

Exploring markets to maximise export earnings

Given the existing capacity constraints and the industry's overwhelming specialisation in generic drugs and dependence on some small markets (such as Myanmar and Sri Lanka), opportunities for expanded exports are limited. Industry sources are of the view that exporters aim for less regulated countries to minimise costs. However, even many of these countries (e.g., Ethiopia, Uganda) are increasingly adopting more demanding regulations to ensure quality medications. This emphasises the need for strengthening the supply-side capacity of compliance-certified domestic production. Nonetheless, Bangladesh can certainly explore several large untapped markets. For example, the United States imports pharmaceutical products worth close to $120 billion. As discussed above, Bangladesh's share in this market is quite small. Capturing just a 0.1 per cent share in the United States will generate $100 million exports from Bangladesh. The

analysis undertaken as part of this chapter suggests that to fetch $1 billion from the export of pharmaceuticals, aiming for such a large market should be an important strategic consideration. Bangladesh can also consider exploring markets in such countries Brazil, Saudi Arabia, South Africa, Kenya, and Nigeria that are becoming major consumers of generic drugs. According to ITC data, pharmaceutical imports of these countries in 2018 were Brazil ($7.2 billion), Saudi Arabia ($5.5 billion), South Africa ($2.5 billion), Kenya ($0.55 billion), and Nigeria ($0.51 billion). At present, China and India are two of the largest exporters in these markets. Breaking into these markets would be a significant boost to the export sector. At the same time, to reap the maximum benefit, it is important to move up the global value chains by exploring options for expanded activities in such areas as marketing, logistics, consultation, and distribution. In addition, positive branding of products along with compliance with required standards can help establish the country as a responsible source of supplies, attracting reputed importers.[33]

Moving towards full-fledged contract manufacturing

Having considerable cost advantages in manufacturing, Bangladesh is well-positioned to offer contract manufacturing services to global clients as the country has a sound track record of partnerships with a number of major multinational companies. But, the industry's involvement in contract manufacturing has been so far limited to the final stage formulation of drugs that requires minimal technological expertise. To take full advantage of contract manufacturing opportunities, the industry must go beyond the current focus on final stage formulation to establish collaboration in each stage of drug formulation, R&D, clinical trial, and API synthesis. Collaborating with MNCs for full-fledged contract manufacturing will help develop the country's capacity in research, clinical trial, and custom synthesis. The domestic industry will also benefit from technology transfer and capacity building. A proactive initiative in this regard may encourage MNCs operating in Bangladesh as well as in other countries (preferably in LDCs) to source their supply of low-priced generics from Bangladesh, eventually resulting in enhanced export supply through contract manufacturing.

Policy flexibilities for further export drives

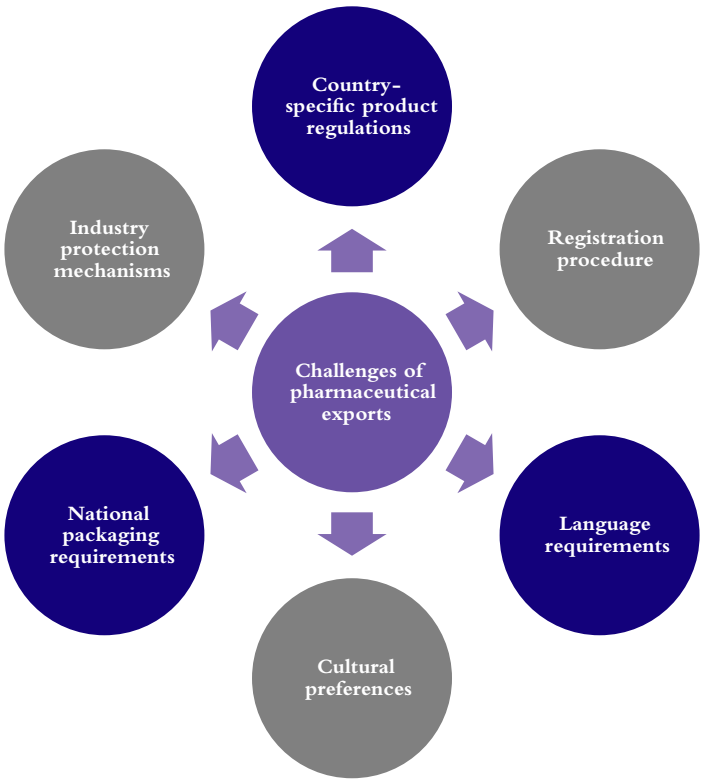
Flexible foreign exchange regulations: As mentioned above, countries are increasingly updating and adopting more demanding regulations to address their public health needs. At the same time, in many LDCs and developing countries, there are strong regulatory obstacles and technical restrictions against imported drugs. Although Bangladeshi producers have established their presence in many of these markets, increased export earnings will require expanding the product range in existing markets and exporting to newer destinations. Each country's own industry protection mechanism, product registration requirements, language requirements, cultural preferences, and national packaging requirements make the export of pharmaceuticals a challenging task (Figure 11.19). Registering drugs, receiving certifications from regulatory bodies of target destinations, and ensuring best manufacturing practices are major areas in which exporting firms incur huge costs. Given the capital intensive and technologically demanding

[33] It was revealed during the key informant interviews of this study that, Bangladesh's medicine has started to gain popularity in the export destinations. However, with respect to major generic suppliers like China and India, Bangladesh's medicine requires further promotion from the branding perspective.

nature of the industry, exporting firms face difficulties in accommodating further costs in the export destinations.

Current regulations in Bangladesh allow exporting companies to remit money on a case-by-case basis to manage their operation costs abroad. The central bank authorises to remit a maximum of $30,000 in a year to maintain overseas office expenses for commercial purposes (Bangladesh Bank, 2018). Payments for the company and product registrations; product dossier (ANDA) purchase; consultant fees; office establishment, staff and maintenance costs; marketing and promotional activities; and miscellaneous export-related expenses are usually much higher than the current limit. To help export expansion further, this ceiling can be increased for the pharmaceutical sector to ease business operations required for export activities. To encourage overseas expansion, measures to relax regulations could be undertaken on a case-by-case basis for the pharmaceutical firms with proven supply-side capacities. Although there is a general apprehension about capital flight in allowing such overseas transactions, policy enforcement could be relatively easier for pharmaceutical enterprises due to their significant domestic presence.

Figure 11.19: Major challenges of pharmaceutical exports in target destinations



Source: Authors' presentation based on Rizwan and Kathuria (2016).

Policy flexibilities for outward FDI flow: As mentioned earlier, one major Bangladeshi firm's future operation in Africa by setting up its own plants would likely to help understand the market

needs of Africa. Such subsidiary or transnational venture can help diversify the export markets particularly in countries which can be used to utilise regional exceptions of TRIPS 31bis waiver for bundled demand to LDCs and developing countries in a regional trade agreement' (e.g. Southern African Development Community, Economic Community of West African States, Common Market for Eastern and Southern Africa, etc.). In fact, Indian companies like Ranbaxy, Cipla, Dr Reddy's and Lupin have already set up production units in Southern and Eastern African markets. Multinational companies like Novartis and Pfizer have production units across Africa. In this context, export expansion in these markets will require large investments. In addition, acquiring certifications and registering drugs in regulated or semi-regulated markets take time. Existing regulations allow domestic companies to invest overseas through individual applications that are evaluated on a case-by-case basis only. This is reportedly an involved and lengthy process.

According to industry experts, some pharmaceutical firms in developed countries are willing to sell their product licenses due to lack of their own adequate manufacturing units and cost disadvantages. In contrast, many Bangladeshi firms have manufacturing facilities for commercial production and supply at very competitive prices. There exist opportunities to acquire such product licences and increase exports further. This requires outward fund transferring akin to outward FDI flow. Again, while capital flight could be considered a challenge facing many developing countries like Bangladesh, business practices in today's world need policy flexibilities for firms' export drives. Consideration of approvals for purchasing such licences/companies on a case-by-case basis can be a way forward.

Streamlining the import approval of sensitive chemicals: According to industry representatives, getting approvals for imports of sensitive compounds (like acid, ethanol, etc.) from multiple government bodies can be quite challenging. As different ministries and departments deal with the approval of various chemical compounds, it is often a cumbersome process. The problem gets worse given the occasional rise of untoward incidents with the use of these chemical substances. While the significance of regulations in addressing public health and safety concerns is clear, there is also a need to streamline the approval process so that it does not unnecessarily affect the pharmaceutical manufacturing and the industry competitiveness.

Deepening policy support prior to LDC graduation

As mentioned earlier, the Export Policy (2018–2021) puts both pharmaceuticals and API under the category of highest priority sectors. Currently, pharmaceutical items are eligible for a 10 per cent export subsidy (cash assistance), while APIs are eligible for a 20 per cent cash incentive on exports. The incentives are available upon fulfilling the requirements of ensuring a minimum of 30 per cent value addition for pharmaceutical products and at least 20 per cent value addition in the cases of API.

While the incentives are a helpful policy instrument for stimulating export response, such support measures after LDC graduation are unlikely to be compatible with the WTO Agreement on Subsidies and Countervailing Measures (SCM). Article 3 of the SCM Agreement prohibits any subsidy based on export performance or the use of local content.[34] Article 6 defines the usage of

[34] See the WTO Agreement on Subsidies and Countervailing Measures, https://www.wto.org/english/tratop_e/scm_e/subs_e.htm.

industry, region, enterprise-specific subsides that will be subject to countervailing measures or other retaliatory actions from other countries. Therefore, it is unlikely that in the post-LDC graduation period, it would be possible to continue with export subsidies. It is high time to adopt well-planned strategies to embrace future changes in the policy regime. There exists the scope for re-evaluating and expanding direct policy support now. While VAT on API imports have been waived until 2025, pharmaceutical manufacturers are incurring various additional costs including duties on machinery imports, and charges for bio-equivalence tests and foreign approvals from regulatory authorities like USFDA and UKMHRA. Despite these challenges, pharmaceutical exports have shown dynamism. Raising the level of assistance can encourage further export expansion until Bangladesh's LDC graduation when such policy support will have to be discontinued. One option could be to keep the existing level of cash assistance while increasing the rate to a higher level for any yearly incremental exports. This will help keep the pressure on the exchequer in check and at the same time encourage additional exports. This enhanced incentive scheme can be put in place for a limited duration (for example, 5 years or until LDC graduation) with the objective of expanding the export base. Support measures for exporting to highly regulated markets such as the EU, UK, and U.S. should also be given careful consideration since export success in these markets will result in huge gains. In short, Bangladesh should try to make the most of the policy space that is currently available.

Providing assistance for services-related activities associated with the pharmaceutical industry can be yet another option to strengthen policy support. There are arguments that regulations about providing subsidies on services are not well defined in the WTO's General Agreement on Trade in Services (GATS).[34] Many analysts suggest that services used in the manufacturing supply chains can be subsidised (Mukherjee et al., 2018). For the pharmaceutical sector, subsidies can be provided to export-oriented units in areas such as human resource development, utility services, training and skill enhancement, technology accumulation, product promotion, marketing, etc. Administering such incentives can be difficult and thus should be carefully designed to make the policy support effective. The private sector can also undertake research to design and demand WTO-consistent incentives to improve exporters' competitiveness.

Proactively engaging in WTO processes to withhold the early termination of the TRIPS-pharmaceutical waiver

As an LDC, Bangladesh is exempted from implementing the provisions of the TRIPS agreement related to pharmaceutical products until 1 January 2033 or the graduation from the LDC status, whichever comes first. Bangladesh's imminent LDC graduation and the subsequent loss of LDC-specific TRIPS-pharmaceutical waiver could put the local drug manufacturers under pressure. Although it is difficult to provide a precise and quantitative assessment of any adverse consequences, it is generally recognised that a much earlier termination of the waiver (in 2024 rather than in 2033) would constitute a drastic change for local exporters in an unprecedented manner as no other previously graduated country had a pharmaceutical production base like Bangladesh. It is in this context that there may be options for Bangladesh to proactively engage in WTO processes to request for an extension of the transition period.

[35] Article XV of GATS only says, "Members shall enter into negotiations with a view to developing the necessary multilateral disciplines to avoid such trade-distortive effects." But WTO is yet to prepare a discipline about subsidy in services.

According to Article 66.1 of the TRIPS Agreement, any graduating LDC may submit a 'duly motivated' request to the TRIPS council with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce special rights provided for under those sections until 1 January 2033 (South Centre, 2019). Bangladesh can submit such an application before graduating out. In doing so, Bangladesh can seek support from other LDC members and other sympathetic developing and developed country partners to strengthen the case for an extension.

As per the provisions of the TRIPS agreement, the TRIPS council can consider a 'duly motivated' request from an LDC member to allow extension of its transition period. It has been suggested that there are no specific definition or guidelines on what can be considered as a 'duly motivated' proposal (South Centre, 2019). The Doha Declaration's paragraph 7 only instructs the TRIPS council to provide an extension for the waiver to address public health concerns in LDCs and developing countries. To make a persuasive case for such a duly motivated request, it needs emphasising that there is precedence that the TRIPS council granted Maldives an extension of the general TRIPS transition period in 2005. The Maldives submitted a request for an extension well before the due date of its LDC graduation.

Apart from citing public health concerns, Bangladesh can also include the pitfalls of abrupt policy discontinuity resulting from LDC graduation. The early termination of the waiver will disrupt the policy continuity that was envisaged by the industry to plan ahead taking advantage of the transition period. At the same time, Bangladesh can argue about not being benefitted from technology transfer as committed in Article 66.2 of the TRIPS agreement as insignificant API production, absence of bio-equivalence testing facilities and inadequate R&D continue to constrain the supply-side capacity for a sector that is so inextricably linked to public health issues.

Devising strategies for the pharmaceutical industry

Preparing an action plan to ensure a smooth LDC graduation for the industry: LDC graduation may require Bangladesh to make some policy adjustments towards its pharmaceutical sector. Having a strong drug manufacturing base, preparing for such adjustments needs to be well planned with a focused approach to promoting competitiveness of the industry while ensuring access to affordable medicines. As discussed above, some currently available LDC-related privileges will cease to exist as a result of LDC graduation. Amongst others, the major areas of concern for the sector include, among others, (i) likely changes in the intellectual property regime and legal frameworks; (ii) regulations regarding patented drug production and registration after LDC graduation; (iii) pricing of patented and generic drugs; (iv) operation of foreign companies in the post LDC graduation period; and (v) distribution and sales of imported drugs.

While preparing for any impending changes in the trade and intellectual property regime, it is of utmost importance to develop an action plan backed by a comprehensive study on the sector. The DGDA can undertake such an in-depth analysis in assessing the areas of necessary reforms to make the existing regime compatible with the WTO system and in considering any potential implications. It should also include the option of becoming a member of the Patent Cooperation Treaty (PCT) and carrying out the necessary consultations with the industry to better appreciate any consequences.

The study can be conducted in collaboration with the Department of Patents, Designs & Trademarks (DPDT) and the Export Promotion Bureau of Bangladesh (EPB), and the Ministry of Commerce. Consultations with all relevant stakeholders should be carried out to gather the necessary inputs, helping develop practical recommendations that can be implemented as part of the action plan to support a smooth LDC graduation process for the sector. The DGDA should also engage with the global community and regulatory bodies to learn any lesson and ask for technical assistance. The action plan should comprise forward-looking objective of addressing industry-specific needs to enhance supply-side capacities in relation to growing international compliance requirements related to pharmaceutical exports. The action plan should be made available to the industry well before the country's LDC graduation to avoid any abrupt policy reversal.

Updating the list of essential drugs: There is also a need for updating the country's list of essential drugs, which was published in 2016. An updated drugs list can help address the emerging health challenges, improve access to medicines and prioritise most effective therapeutics for better treatment outcomes. Furthermore, change in disease profiles requires that the essential drug list is being regularly updated. Therefore, the DGDA should work to update the essential drug list at regular intervals.

Revamping the existing export expansion roadmap of the sector: As mentioned earlier, globally about $251 billion drug sales are expected to go off-patent by 2024. In addition, the world is also experiencing a shortage in medicine supply which appears to be a widespread and persistent problem (WHO, 2016). Bangladesh can take advantage of the worldwide rising demand for drugs. However, under the existing supply-side constraints, expressed policy support to propel the industry with a timebound plan cannot be overestimated. In this context, the existing roadmap for the sector should be revamped with concretely defined output and outcome indicators to assess the implementation and effectiveness of any intended support measures. The roadmap should articulate implementation strategies to gather information on a regular basis to monitor any progress made. Implications for LDC graduation, possible adaptation strategies, specific industry support measures for the development of the skilled workforce, promotion of R&D activities, exploring export market opportunities, etc. should be an integral part of this roadmap. While some of these issues are mentioned in the current plan, the implementation and evaluation frameworks of the roadmap need strengthening.

The Ministry of Commerce and EPB, in association with BAPI, can work to make improvements and track the progress of a revamped roadmap. Within government processes, the General Economic Division of the Ministry of Planning has developed expertise in formulating and undertaking independent evaluations of the implementation status of various economywide programmes. It can assist with updating the pharmaceutical sector roadmap and monitoring the implementation progress. Such an initiative is very much needed in transforming this sector into a billion-dollar export-earning industry and help Bangladesh's pursuit of export diversification.

Capacity building of the regulatory bodies

Capacity building in intellectual property-related regulatory and legal affairs: As mentioned earlier, the country's existing IPRs related legal framework will require updating to make them

WTO-compliant. There is a critical need to enhance the domestic capacities to deal with intellectual property related regulatory and legal affairs. To keep pace with the evolving landscape of international trade and IRPs regime, the key regulatory body for patents and trademarks—the Department of Patents, Designs, and Trademarks (DPDT)—needs to be strengthened. In this context, increasing the number of patent examiners and IPRs professionals with appropriate training should be given serious consideration.

Furthermore, to operate in regulated markets (like Australia, the European Union, the United Kingdom, the United States), it is essential that a generic drug company has sufficient knowledge and expertise to deal with important regulatory and legal issues including patent litigations. In this area, Bangladesh's pharmaceutical industry is still at a nascent stage. Addressing this capacity constraint should also be regarded as a priority. Among others, creating research facilities on intellectual property-related issues and arranging regular training and exchange programmes with global regulatory bodies can help develop domestic capacities in this aspect.

Capacity building of the DGDA: Capacity building of the DGDA is important for improving and harmonising quality standards. In this context, becoming a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) can provide the DGDA with a significant boost in its regulatory function.[36] Membership in PIC/S will facilitate improved quality standards as preparing for accession to the scheme compels the interested regulatory authorities to improve good manufacturing practice (GMP) inspection systems and procedures. Besides improved quality standards, reduced duplication of inspections, cost-savings, export facilitation and enhanced market access in all the member countries are major benefits of PIC/S membership.

The accession process to PIC/S is preceded by a 'pre-accession' phase when a gap analysis is undertaken to identify the differences between PIC/S membership requirements and the system used by the interested regulatory body. In April 2019, the DGDA submitted the pre-accession application to the PIC/S. It is important to note that during the pre-accession procedure, PIC/S do not follow up on the corrective actions to overcome the identified gaps. In addition, the procedure is a time-consuming exercise. Therefore, it is imperative to ensure a regular follow up of the pre-accession procedure and implement corrective actions promptly.

Standardising the drug testing laboratories: To ensure quality standards for the export market, serious attention should be given to transform the DGDA drug testing laboratories into internationally accredited ones. With the help of the World Bank and WHO, the sole laboratory in Dhaka was modernised. However, Bangladesh is yet to have an internationally accredited drug testing and quality control laboratory. Making the drug testing laboratories compliant with the recommended standards under the WHO Prequalification Programme can provide a significant impetus to improve the quality control procedures of the existing laboratories.[37] According to

[36] To become a member of PIC/S, a regulatory authority has to undergo a comprehensive assessment of its good manufacturing practices (GMP) inspection system, licensing system (or equivalent), legislative requirements, inspector training and so forth. The applicant authority may need to undergo various improvements as recommended by the PIC/S committee.

[37] Under the prequalification programme, the WHO lists the quality control laboratories that express their interest in participating in prequalification procedures and comply with the standards recommended by the WHO. To list a lab as prequalified, the WHO ensures compliance with the Good Practices for National Pharmaceutical Control Laboratories (GPCL) and relevant parts of WHO good manufacturing practices.

official sources, efforts are underway to enlist the drug testing laboratories of the DGDA as the WHO's prequalified quality control laboratories (QCL). These initiatives should be meticulously pursued to raise the standards of local laboratories.

11.6 Conclusion

The growth of a sophisticated industry like pharmaceutical, catering for almost the entire demand of the local market, has been an impressive success story of Bangladesh's industrial development. It is also a case of using policy instruments to develop the sector with the public health objective of ensuring medicines at affordable prices for the mass population. Bangladesh's pharmaceutical sector is gradually establishing its footprint in the global generic medicine market by delivering quality drugs at competitive prices. Despite the recent dynamism in pharmaceutical exports, the sector is far from realising its export potential. The industry can grow further by capitalising the tremendous untapped opportunities in various export markets. Bangladesh has just started exploring the high-value and highly regulated markets. Even a very small increase in the share of these markets could generate large export earnings. The global generic drugs market is going to expand fast as patent protection of hundreds of billions of dollars' worth of medicines will expire over the next few years.

Concerted efforts from all stakeholders (including Government regulatory bodies, pharmaceutical companies and their association) are needed to achieve the aspiration of transforming the industry into a billion-dollar export sector. In this respect, strengthening the supply-side capacity is an utmost priority for the sector. Developing the country's API manufacturing capacity will lead to reduced dependence on the import of basic ingredients used in manufacturing. It should also help firms access raw materials at a lower cost, thereby improving their export competitiveness. Therefore, the initiative of setting up an API park and its effective implementation within a shortest possible time is an important issue. Furthermore, streamlining the import approval processes of sensitive chemicals can help with disruption-free pharmaceutical production and promote industry competitiveness.

Establishing bioequivalence testing facilities that comply with international standards will be another important boost for expanded export supplies. Before that to happen, reducing the cost burden by removing/reducing taxes and VAT on the charges for bioequivalence testing in foreign laboratories will constitute an important policy support measure. Flexible foreign exchange regulations should be given due consideration so that the firms can manage their export market operations. Attracting FDI to setup contract research organisations (CROs) through joint ventures should be proactively explored. How to incentivise research and development, which is inextricably linked to the pharmaceutical sector, is another serious matter for policy attention. A shortage of skilled human resources is a constraint that can be addressed effectively through a collaboration between the private sector and academia with the support from the government. Bangladesh needs to proactively aim for highly regulated markets to increase export earnings. It is in this context that trade policy options and supportive measures should be recalibrated to support the exporters.

There is a need for a renewed policy attention for helping the pharmaceutical sector adjust with any abrupt policy changes arising from the imminent LDC graduation. This will involve

exploring negotiation options for obtaining any favourable terms including the possibility of any extension of the transition period to comply with the TRIPS regime; making the most of any policy space available prior to graduation; devising and executing support measures complying with the WTO regime, and securing an enabling domestic environment for the sector to sustain its growth performance. The list of essential drugs needs to be updated on a regular interval to address the evolving health challenges, provide better access to medicines, and prioritise most useful therapeutics to ensure better treatment of the mass population. The DGDA's pre-accession procedure for PIC/S membership should not lose the sight of priority. Current efforts to achieve international accreditation of DGDA testing laboratories should be strengthened to improve quality standards for export markets. Revamping the existing pharmaceutical sector road map to make it outcome-oriented should also help realise the promising export prospects.

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