TECHNOLOGICAL READINESS OF BANGLADESH'S PHARMACEUTICALS INDUSTRY

Preparing for LDC Graduation

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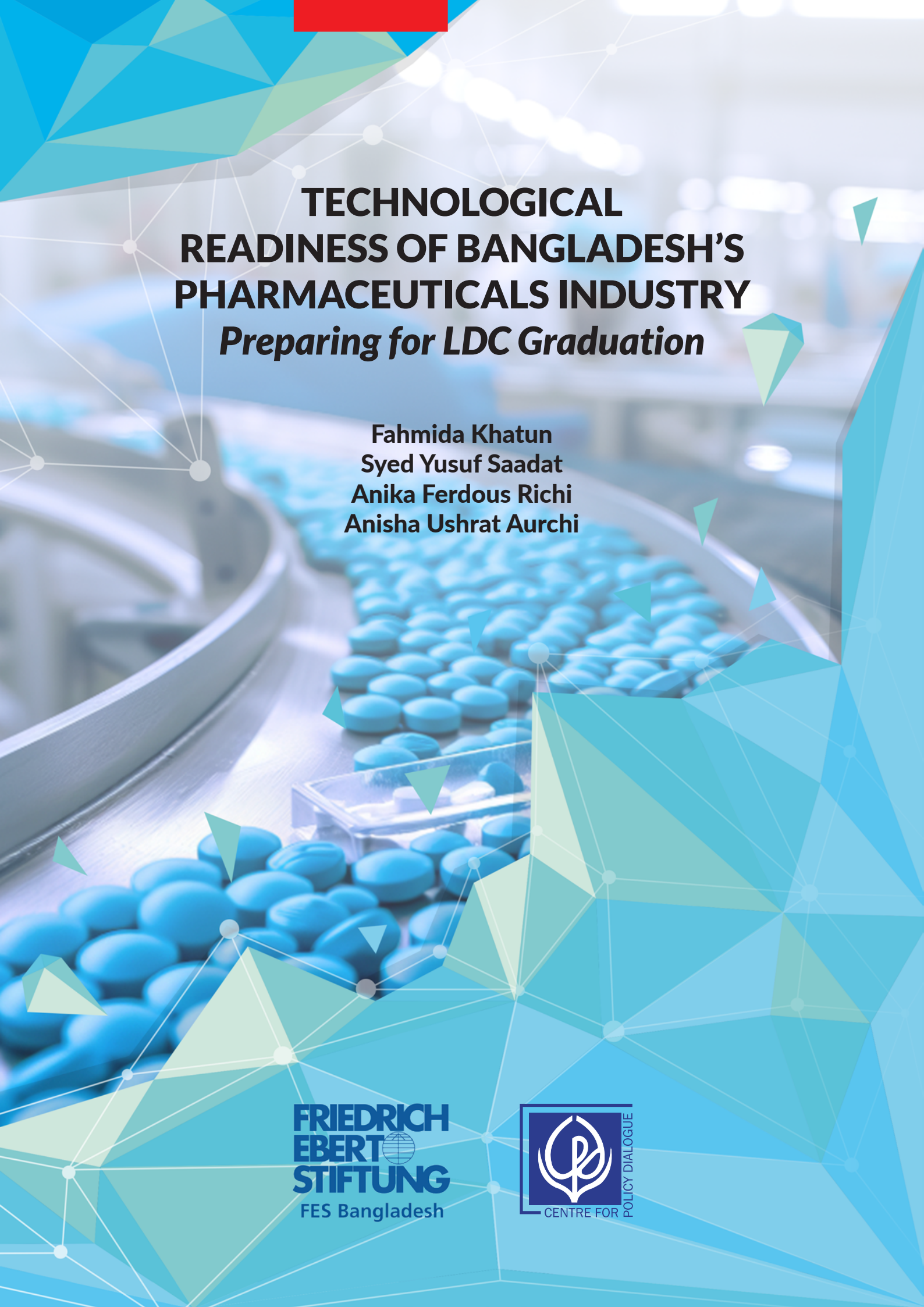

FRIEDRICH EBERT STIFTUNG
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Abstract

The pharmaceutical industry of Bangladesh is one of the most technologically advanced sectors in the country, contributing significantly to domestic healthcare and exports. Despite its strengths, the industry faces technological limitations, particularly in producing active pharmaceutical ingredients (APIs) and investing in research and development (R&D). Bangladesh's pharmaceutical sector also benefits from a Trade Related Intellectual Property Rights (TRIPS) waiver, which allows it to produce generic versions of patented drugs. However, with Bangladesh's imminent graduation from the Least Developed Country (LDC) status in 2026, the industry is at a critical juncture where it must enhance its technological capabilities to stay competitive in the global market. This paper explores Bangladesh's pharmaceutical industry's preparedness to overcome these challenges. A survey conducted as part of this study found that most APIs are still imported into Bangladesh, and investment in R&D is very low. This paper recommends that pharmaceutical firms develop their R&D capabilities, and that the government emphasise their investment in building the API park.

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Acronyms

ADB	Asian Development Bank
AI	Artificial Intelligence
AIDS	Acquired Immunodeficiency Syndrome
AIT	Advance Income Tax
ANDA	Abbreviated New Drug Application
ANVISA	Agência Nacional de Vigilância Sanitária
APIs	Active Pharmaceutical Ingredients
BAPI	Bangladesh Association of Pharmaceutical Industries
BBS	Bangladesh Bureau of Statistics
BDT	Bangladeshi Taka
BIDA	Bangladesh Investment Development Authority
BPA	Bangladesh Patent Act
CDP	Committee for Development Policy
CEOs	Chief Executive Officer
CETP	Common Effluent Treatment Plant
CFC	Chlorofluorocarbon
CGMP	Current Good Manufacturing Practice
COVID-19	Coronavirus disease 2019
CPD	Centre for Policy Dialogue
DAAs	Direct-acting Antivirals
DGDA	Directorate General of Drug Administration
DPM	Drug Management
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration
FY	Fiscal Year
GATT	General Agreement on Tariffs and Trade
GCC	Gulf Cooperation Council
GDP	Gross Domestic Product
GMP	Good Manufacturing Practice
GRIPS	National Graduate Institute for Policy Studies
HFA	Hydrofluoroalkane

HIV	Human immunodeficiency virus
HS	Harmonized Commodity Description and Coding System
IIP	Index of Industrial Production
IPR	Intellectual Property Rights
ISIC	International Standard Industrial Classification
ITC	International Trade Centre
IV	Intravenous
KIIs	Key Informant Interviews
LDC	Least Developed Country
MHRA	Medicines and Healthcare Products Regulatory Agency
MNCs	Multinational corporations
NAFDAC	National Agency for Food and Drug Administration and Control
NBR	National Board of Revenue
NCEs	New Chemical Entities
NDDS	New Drug Delivery Systems
NDP	National Drug Policy
NPRA	National Pharmaceutical Regulatory Agency
PPB	Pharmacy and Poisons Board
PPE	Personal Protective Equipment
RDIs	Research and Development Institutes
RMG	Readymade Garments
SAHPRA	South African Health Products Regulatory Authority
SDG	Sustainable Development Goal
SEIP	Skills For Employment Investment Program
SMME	Small, Medium & Micro Enterprise
TGA	Therapeutic Goods Administration
TRIPS	Trade-related Aspects of Intellectual Property Rights
TTI	Total Tax Incidence
UK	United Kingdom of Great Britain and Northern Ireland
UN	United Nations
UNICEF	United Nations Children's Fund
UNU	United Nations University
US	United States of America
USA	United States of America
USD	United States Dollar
VMD	Veterinary Medicines Directorate
WHO	World Health Organisation
WIPO	World Intellectual Property Rights Organisation
WTO	World Trade Organization

1. INTRODUCTION

The pharmaceutical industry in Bangladesh is not just a cornerstone of the nation's economy but also a global player, crucially supplying affordable medication to both the domestic market and other Least Developed Countries (LDCs). This makes it a vital contributor to public health on both local and international levels. The industry meets a significant portion of the nation's demand for medicines and pharmaceutical products and exports to other LDCs, playing a crucial role in shaping the global public health landscape and driving national economic growth.

The success of Bangladesh's pharmaceutical sector, partly attributed to the World Trade Organization's (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) pharmaceutical waiver for LDCs, has allowed the industry to thrive by producing affordable generic versions of patented medicines. As Bangladesh prepares to graduate from the LDC status and this waiver is withdrawn, this transition presents challenges and opportunities for the country's pharmaceutical sector. However, the industry's past successes reassure us of its potential to maintain and enhance its competitive edge in the global market even after Bangladesh graduates from the LDC category in 2026.

The transition after LDC graduation will subject the industry to more robust intellectual property regulations and increased costs associated with patent compliance, which could potentially impact the affordability and accessibility of medications, especially for the marginalised low-income groups in Bangladesh and the LDCs to which it exports medicine. It may also pose a significant threat to the country's pharmaceutical industry's competitiveness and potentially result in a substantial loss of the export revenue earned from this sector. This underlines the urgent need for strategic planning and policy adjustments to mitigate these potential threats.

In light of this, it is crucial to evaluate the technological preparedness and innovation necessary for Bangladesh's pharmaceutical industry to sustain its growth and global competitiveness. The strategic evaluation in this paper aims to assess the current state of technological readiness, identify potential gaps, and propose strategies to enhance the sector's innovation capacity. Through this, it seeks to ensure a smooth transition for the pharmaceutical industry as Bangladesh graduates from LDC status so that the industry continues to thrive and support public health efforts in Bangladesh and other LDCs.

1.1 Background and Context

In the global pharmaceutical industry, innovation can be divided into two major categories: the introduction of new chemical entities (NCEs), which is heavily reliant on extensive research and development (R&D) efforts, and incremental innovation activities, commonly known as 'imitative R&D' or 'me-too' medicines (Bottazzi et al., 2001). The discovery of NCEs involves substantial risk because the results are erratic and the effects are highly unpredictable (Petrova, 2014). Pharmaceutical innovation follows a technology-push model heavily impacted by technological breakthroughs, rigorous medical research, and market demands (Petrova, 2014). Much pharmaceutical innovation falls under imitative learning (Kale, 2017). Firms must shift from imitative innovation to process innovation to sustain the profits

gained through innovation (Doha et al., 2018). In the case of firms from developing countries, economic, political, and social complications make the capacity transformation from imitation to innovation quite challenging (Kale, 2017). Intellectual property rights are essential to any government's economic and industrial strategies. The implications of such regulation are crucial, especially in knowledge-based industries like pharmaceuticals (Kale & Wield, 2008). The withdrawal of patent exemptions post-LDC graduation due to TRIPS compliance will present a substantial institutional change for pharmaceutical industries in Bangladesh and other similar developing countries.

In the Bangladeshi pharmaceutical industry, 80 per cent of the drugs manufactured are non-patented, while 20 per cent are patented drugs (BAPI, 2024b). The process of non-patented medicine manufacturing can be broken down into several stages. Active pharmaceutical ingredients (APIs) are crucial in the whole process. API is the critical component that stimulates the drug's intended effect on the patient. The API is combined with the inactive ingredients to make the medicine stable, safe, and deliverable (Narayan, 2011).

Pharmaceutical manufacturing can be broadly separated into two phases. The first is the production of APIs, which require chemical synthesis abilities. The second step is the final formulation, which constitutes manufacturing activities that involve mixing API with other non-active ingredients to manufacture pharmaceutical products such as pills, tablets, or other forms of administration (American Pharmaceutical Review, 2024). Innovation is driven by technology. Technological capabilities can be mapped along a spectrum that begins with simple manufacturing skills required for formulation activities and progresses to the acquisition of chemical synthesis skills for reverse engineering the APIs, to more sophisticated generic competition in terms of new drug delivery systems (NDDS) or inventing molecules, and ultimately having the capacity to conduct NCE research at the frontier (Sampath, 2007). Pharmaceutical enterprises in Bangladesh are primarily engaged in formulating APIs that require only manufacturing capabilities (Chaudhuri, 2020). Bangladesh's pharmaceutical industry should now strive to build the capacity to participate in the more knowledge-intensive procedures of reverse engineering APIs.

How much and how quickly firms in any sector transition to build technological capabilities to compete at the frontier is determined by how well the institutional framework promotes coordination among the various parts of the domestic knowledge system, such as universities, financial institutions, industries, and entrepreneurial associations. Pharmaceutical industries, specifically in developing countries, face several micro, meso, and macro-level limitations that limit the sector's innovative and technological capacity (Belousova et al., 2020). Micro-level constraints in firms include the intellectual isolation of researchers and a lack of incentive or motivation for joint or individual research (Belousova et al., 2020). Meso-level limitations include a lack of access to information and technology inputs, a lack of scientific support infrastructure for universities, public research organisations, and businesses, insufficient human capital generation, and institutional instability (Belousova et al., 2020). The disjunction between the demand for health research and the current output, a lack of scientific mindset among scientists and researchers, bureaucratic rigidity and corruption, as well as a weakened public support system, are some forms of constraints that the pharmaceutical sector faces at the macro level which impede innovation (Belousova et al., 2020).

Bangladesh has an inadequate knowledge infrastructure at secondary and post-secondary levels, and the country also has very low R&D investments (Sampath, 2007). Lack of scientific infrastructure includes a lack of human resources as well as a shortage of domestic research and development institutes (RDIs) and universities to assist firms in developing these chemical synthesis skills due to research underfunding and discouragement of scientists and researchers (Sampath, 2007). This lack of coordination between various parts of the knowledge systems exemplifies a prevalent problem in most LDCs that hampers effective learning and absorption of knowledge by the entrepreneurial sectors and is also one of the significant obstacles to developing API capabilities in Bangladesh (Sampath, 2007). Technology development and the production of pharmaceutical raw materials, particularly APIs, necessitate advanced engineering skills and an understanding of chemistry, which LDCs like Bangladesh often lack. As a result, pharmaceutical companies rely heavily on imported raw materials (Sampath, 2007). Bangladesh has very few scientists per million of the population (Sampath, 2007). In FY2021, Bangladesh had 107 total researchers per million of the population (BBS, 2024a). Lack of coordination between university and state-funded research and the industrial sector is one of the significant obstacles to developing API capabilities in Bangladesh (Sampath, 2007).

The need for nations with great pharmaceutical potential to establish local manufacture of medicines and vaccines to build resilience was emphasised by the COVID-19 pandemic. During that time, low- and middle-income countries, like Bangladesh, experienced delays in receiving vaccinations and therapies due to limited supply (ADB, 2024). R&D of drugs and vaccines is essential to develop self-sufficiency and supply chain security in Bangladesh. Clinical trials are an important part of the discovery of new pharmaceutical products as they are required by the regulatory authorities to maintain the effectiveness and safety of new drugs or vaccines (ADB, 2024). However, Bangladesh is underrepresented in the clinical research due to a shortage of skilled researchers and a lack of financial viability (ADB, 2024). Although Bangladesh has a few clinical trial facilities with experience in conducting studies for infectious diseases, overall activity has remained modest and corporate participation has been low (ADB, 2024).

Bangladesh imports over 90 per cent of the raw materials required annually for the pharmaceutical sector from foreign countries, mainly India and China, which is equivalent to BDT 47 billion (Mitsumori, 2018). Bangladesh's pharmaceutical companies lack the technological and manufacturing capacity to produce APIs (Mitsumori, 2018). Thus, APIs are mostly imported from India and China. The Bangladesh government intends to establish an API Industrial Park at Bausia in Munshiganj, around 40 kilometres from Dhaka, to expand its API production capacity (Mitsumori, 2018). Once the park is established, over 40 pharmaceutical companies intend to develop API production factories there (Mitsumori, 2018).

Over-reliance on imported APIs is a vulnerability of Bangladesh's pharmaceutical industry and a threat to the country's economic security. Developing a scientific and technological base for resolving import substitution issues and enhancing technical security from adverse global shocks is essential for any country (Golova & Sukhovey, 2015). Even though imports give people access to pharmaceutical breakthroughs, the absence of imported raw materials could prevent the creation of necessary medications, increasing healthcare risks, particularly during pandemics (Baimakova & Trofimova, 2020). The vulnerabilities of countries which are heavily

dependent on imported vaccines were revealed during the COVID-19 outbreak. Thus, import dependence on APIs, vaccines, or other pharmaceutical products could threaten Bangladesh's economic security.

1.2 Justification and Policy Relevance

The WTO Doha Declaration on the TRIPS Agreement and Public Health, signed by WTO members in 2001, aided in framing the intellectual property system's health policy framework (WTO, 2023). It emphasised the need for TRIPS as part of broader national and international action to address public health issues affecting poor countries (WTO, 2023). Under Article 66.1 of the TRIPS Agreement for LDCs, Bangladesh's pharmaceutical industry enjoys patent waiver benefits (WTO, 2023).

Bangladesh is currently an LDC, so it is not required to recognise pharmaceutical patents. This enables the Bangladeshi pharmaceutical industry to manufacture generic versions of medications patented elsewhere for domestic consumption without prior authorisation from the developer. One of the advantages of the Bangladeshi pharmaceutical industry is its ability to export to any country if the drug is not patentable in that country (BAPI, 2024b). Bangladesh can also export to other LDCs and non-WTO member countries without patent protection on the exporting drug (BAPI, 2024b). The country can also export to countries where patent holders have yet to file for a patent (BAPI, 2024b). Bangladesh also has the unique opportunity to export to countries that have issued compulsory licenses and designated production contracts for Bangladesh (BAPI, 2024b).

Pharmaceutical manufacturers in Bangladesh benefit immensely from the TRIPS waiver and the extended transition period, as they can produce any patented drug and learn from it through imitation and follow-on innovation (Rahman & Farin, 2018). This allows Bangladesh to accumulate experience producing these medicines, which require significant technological understanding through reverse engineering and follow-on innovation (Rahman & Farin, 2018). It also inspires research ideas for making new drugs. Under the Drug Control Ordinance 1982 regulations, Bangladesh's pharmaceutical industry is protected from import penetration (Rahman & Farin, 2018). Most LDCs rely on imported medicines partially or entirely (Rahman & Farin, 2018). Bangladesh is the most export-oriented LDC in terms of the global share of pharmaceutical exports and the least import-dependent in terms of the domestic consumption of medicines (Rahman & Farin, 2018).

The growth rate of Bangladesh's pharmaceutical industries was 17 per cent from 2014 to 2020 (BIDA, 2023). The sector has exported USD 169 million in Fiscal Year (FY) 2021 (BIDA, 2023). One unique advantage of Bangladesh's pharmaceutical industry is its capacity to produce at lower prices than its international competitors (BIDA, 2023). Production costs in the pharmaceutical sector of Bangladesh are estimated to be around 15 per cent lower than those of China and India (BIDA, 2023). The TRIPS exemption for LDCs is crucial to Bangladesh's pharmaceutical industry's remarkable expansion (Mitsumori, 2018). Bangladesh's export-oriented pharmaceutical industry is well-positioned to meet a significant portion of the rising demand for LDC markets due to its TRIPS flexibility and strong supply-side capacity (Rahman

& Farin, 2018). Bangladesh can produce generic versions of patented and non-patented medications, increasing its exports to other LDCs and low-income nations with limited or no manufacturing capacity (Rahman & Farin, 2018). Bangladeshi pharmaceutical firms have the potential to become global players (Mitsumori & Kubo, 2022). TRIPS grants LDCs a unique exemption from pharmaceutical patents until 2033 (WTO, 2023). However, LDC graduation will terminate this extended transition phase for graduating countries (WTO, 2023). Bangladesh is expected to graduate from the LDC group in 2026. When the country graduates from LDC status, the TRIPS waiver for pharmaceutical products will expire, slowing down the country's pharmaceutical industry growth (Mitsumori & Kubo, 2022).

Bangladeshi firms have expanded their technological capabilities through technology imitation and reverse engineering because of the TRIPS waiver (UN, 2017). Economic catch-up in various industries, including the pharmaceutical industry, involves copy-pasting and reverse engineering (UN, 2017). Businesses in emerging nations can benefit from what others have learned rather than starting from scratch (UN, 2017).

Strong intellectual property rights regulations can drive up costs, preventing imitation and subsequent innovation and thus restricting access to crucial technological resources for R&D (UN, 2017). LDC graduation risks slowing down the technological learning process that has fuelled development in Bangladesh's pharmaceutical industry (UN, 2017). As a prospective middle-income nation, one of the biggest challenges for Bangladesh is climbing the technology ladder, creating value, and dismissing low-cost production (UN, 2017).

Restricting the pharmaceutical industry's operations by withdrawing the TRIPS waiver may result in higher costs for global consumers in other LDCs and Bangladeshi consumers who would not otherwise be able to afford essential medications (UN, 2017). The impoverished population of Bangladesh and other LDCs and developing nations would no longer have access to life-saving medicines at affordable prices (UN, 2017).

Although the vast majority of medications produced in Bangladesh are off-patent, the demand for patented medicines is likely to rise due to changes in illness prevalence (Razzaque et al., 2020). Patented medicine production is anticipated to be more expensive after LDC graduation since royalty payments must be made to patent owners (Razzaque et al., 2020). As a result, consumers and the public health system in Bangladesh and other LDCs may be affected (Razzaque et al., 2020). According to industry experts, patent protection would negatively impact the country's ongoing efforts to reduce import dependency (Razzaque et al., 2020). Following the enforcement of patents, API manufacture can also be affected.

One of the significant implications of LDC graduation for Bangladesh will be the increase in prices of essential medicines. As strict intellectual property rights (IPR) protection schemes must be implemented post-LDC graduation, prices of essential pharmaceutical products such as insulin will increase, creating a public health concern (Islam et al., 2020). A modelled estimate was used to examine the impact of the TRIPS waiver withdrawal and the subsequent effects on welfare and poverty levels (Islam et al., 2020). The results show that without any adjustments to the policy framework, withdrawal of the TRIPS waiver will trigger a significant increase in

insulin prices, which will reduce the overall welfare of Bangladeshi households with one or more members living with diabetes by up to half, alleviating their poverty levels by up to 40 per cent which will further worsen national inequality levels (Islam et al., 2020).

As non-communicable diseases continue to increase, withdrawing a vital international support mechanism such as the TRIPS pharmaceutical waiver will make it challenging to attain the Sustainable Development Goal (SDG) 3.8, 'access to safe, effective, quality and affordable essential medicines and vaccines for all' (WHO, 2024). Bangladesh's pharmaceutical sector is effectively a global good, providing low-cost medicines to poor nations in Asia, Africa, the Americas, the United States and Europe (Gay & Gallagher, 2020). Bangladesh's pharmaceutical industry exports to 120 countries, including 31 LDCs (Gay & Gallagher, 2020). As several LDC economies are rapidly expanding, they require low-cost drugs, which they can import from Bangladesh (Gay & Gallagher, 2020). As the world's main generic hubs, including China and India, lose their cost advantage, Bangladeshi manufacturers can capitalise on this trend by applying what they have learned from manufacturing the patented medications under the TRIPS waiver (Gay & Gallagher, 2020).

In the contemporary data-driven world, big data and artificial intelligence (AI) have been combined in the pharmaceutics industry to create computational pharmaceutics, which uses multiscale modelling techniques to improve drug delivery systems (Vora et al., 2023). In the pharmaceutical industry, NCEs are chemical compounds that emerge from the process of drug discovery. Computational pharmaceutics analyses big data sets and forecasts drug activity using AI algorithms and machine learning approaches. Moreover, supervised learning algorithms can be used to forecast the activity or characteristics of novel drug candidates, predict clinical trial results, and diagnose illnesses or forecast patient outcomes based on medical data (Vora et al., 2023). Among the popular AI model tools used for drug discovery, DeepChem is an open-source library with a wide range of tools and models for drug discovery, and IBM RXN for Chemistry is an AI model designed to forecast chemical reactions, helping in the discovery of new synthetic routes and chemical compound synthesis (Vora et al., 2023). The development of AI-based computational methods would also help to reduce the need for human clinical trials (Vora et al., 2023). Pharmaceutical firms in Bangladesh are moving towards modernising and automating processes in the industry, such as using AI and robotics. However, a significant number of companies still depend on traditional methods of production (Hossain & Shila, 2024).

1.3. Research Questions

The proposed study will address the following research questions:

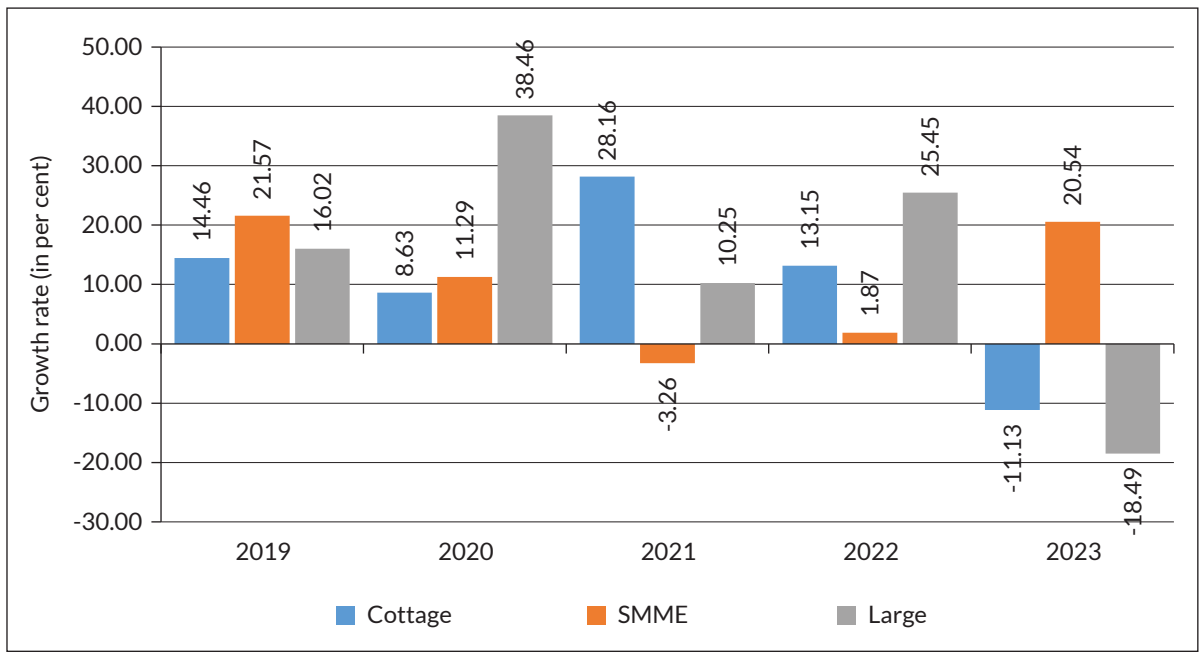
i) To what extent does the pharmaceutical industry depend on the TRIPS waiver to generate its sales revenue and profits?
ii) What strategies are pharmaceutical manufacturers taking to prepare for the post-LDC withdrawal of the TRIPS waiver?
iii) Apart from TRIPs, what other barriers are pharmaceutical manufacturers in Bangladesh facing regarding technology adoption?

2. OVERVIEW OF THE PHARMACEUTICAL INDUSTRY IN BANGLADESH

Among 70.46 million of the employed population in Bangladesh, 0.24 million are employed in manufacturing basic pharmaceutical products (BBS, 2023). Workers in the pharmaceutical sector constitute about 0.34 per cent of the total number of employed people in the country (BBS, 2023). The pharmaceutical industry is considered capital-intensive, and the scope of employment in this sector is limited compared to Bangladesh's readymade garments (RMG) sector. Nevertheless, the opportunities for white-collar jobs are relatively prominent in the pharmaceutical industry, compared to the RMG sector, given that it is the largest white-collar employment sector in Bangladesh (BAPI, 2024d).

The Index of Industrial Production (IIP) of 2023 explains how the volume of pharmaceutical goods produced changed over time in Bangladesh. Figure 1 below shows the growth rate of large-scale, small, medium & micro enterprise (SMME) scale and cottage-scale pharmaceutical industries from FY2018 to FY2023 (BBS, 2024b). According to the International Standard Industrial Classification (ISIC) class code of 2100 (4-digit level), which includes the manufacture of pharmaceuticals, large-scale industries' production growth rate increased from 16.02 per cent in 2019 to 38.46 per cent in 2020 (BBS, 2024b). However, the growth rate decreased from 25.45 per cent in 2022 to 18.49 per cent in 2023 (BBS, 2024b). On the contrary, only SMME scale industries faced increasing manufacturing growth in 2023, with a growth rate of 20.54 per cent after a series of slower production growth rates from 2019 to declining production in 2021 (BBS, 2024b). Cottage-scale industries also experienced a decrease in the production

Figure 1: Growth rate of pharmaceuticals industries



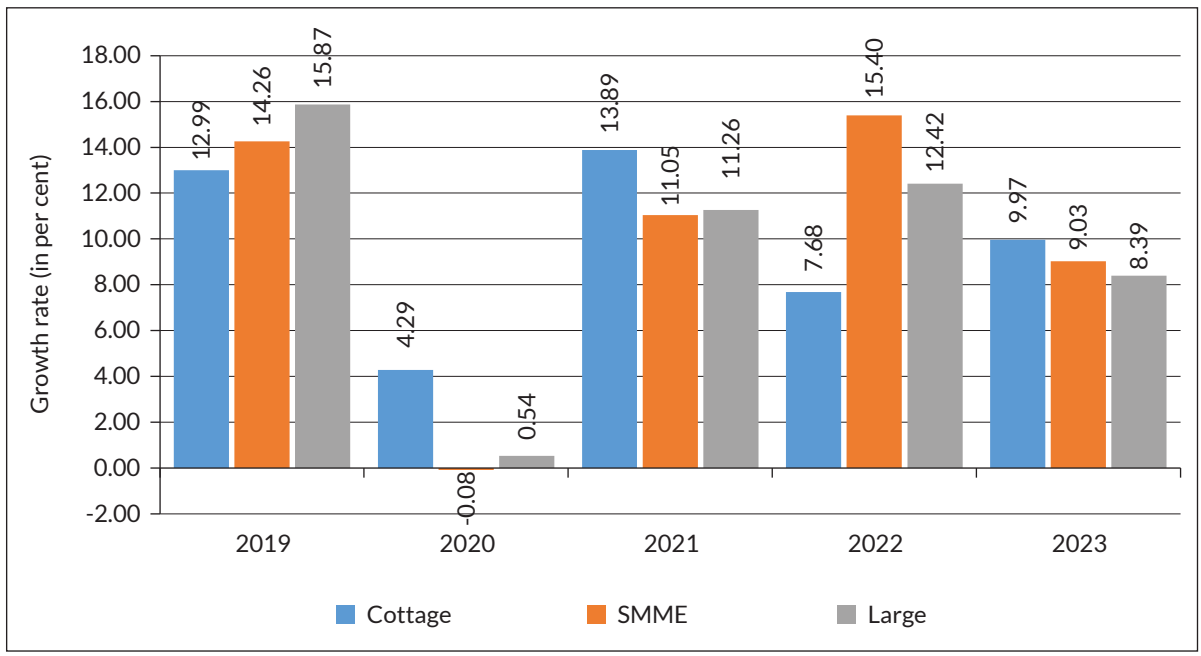
Source: Authors' illustration based on the data from the Bangladesh Bureau of Statistics (BBS, 2024b).

growth rate of pharmaceutical products, similar to large-scale industries. Their growth rate decreased from 13.15 per cent in 2022 to 11.13 per cent in 2023 (BBS, 2024b).

Figure 2 depicts the industrial production growth rate of manufacturing industries of all sectors in Bangladesh. The highest growth rate of 15.87 per cent was achieved by large-scale industries in 2019 (BBS, 2024b). In 2020, large-scale and cottage-scale manufacturing industries had the slowest production growth, 0.54 and 4.29, respectively, from 2019 to 2023 (BBS, 2024b). In contrast, SMME-scale industries faced a drastic fall of 0.08 per cent in their manufacturing growth rate in 2020 from 14.26 per cent in 2019 (BBS, 2024b). Bangladesh's industrial output in 2019 was valued at USD 74.49 billion, an increase of 11.42 per cent from 2018 (Macrotrends, 2024). However, the manufacturing output in 2020 amounted to USD 77.02 billion, a 3.39 per cent rise over 2019 (Macrotrends, 2024). From 2021 onwards, the manufacturing growth rate of all manufacturing industries in Bangladesh increased compared to the production growth of 2020. SMME-scale industries achieved their highest growth rate of 15.4 per cent in 2022 (BBS, 2024b).

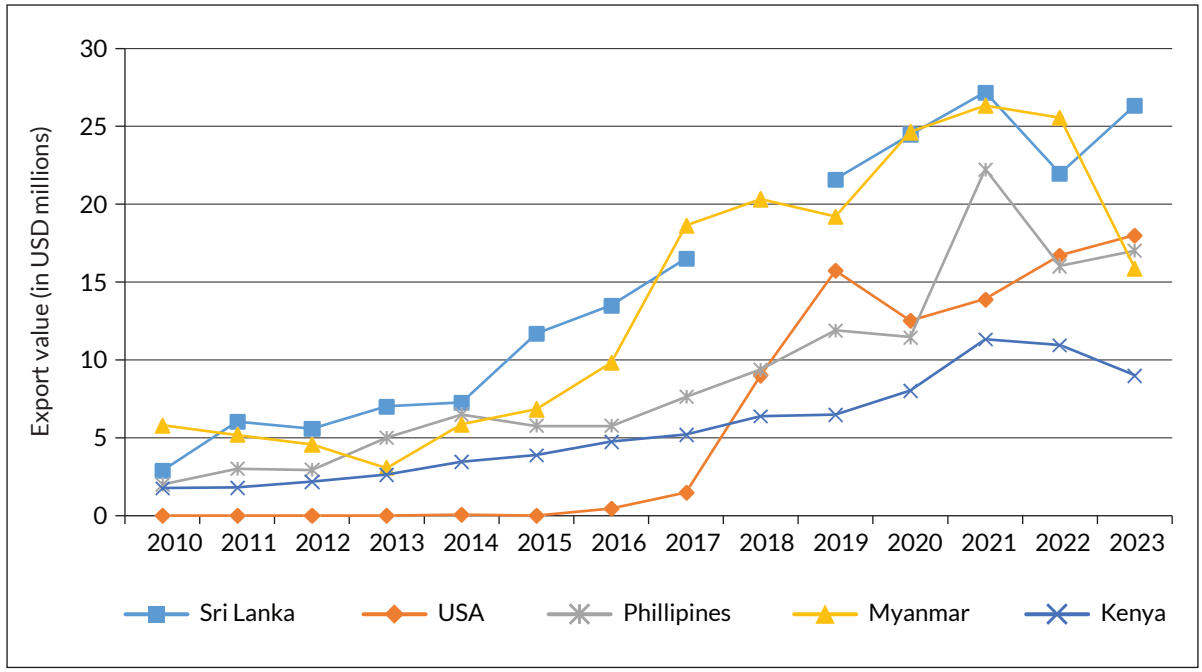
Compared to the aggregate growth rate scenario of all manufacturing industries in Bangladesh, pharmaceutical industries have had a higher but unstable growth rate in the last six years. Comparing Figure 1 and Figure 2, when all large-scale manufacturing industries faced the slowest growth rate of industrial production in 2020 during COVID-19, large-scale pharmaceutical industries achieved the highest production rate of pharmaceutical products in the last five years.

Figure 2: Growth rate of all manufacturing industries



Source: Authors' illustration based on the data from the Bangladesh Bureau of Statistics (BBS, 2024b).

Figure 3: Bangladesh's top 5 export destinations



Source: Authors' illustration based on the data from the ITC Trade Map (ITC, 2024).

Bangladesh exported USD 134 million worth of pharmaceutical products to the rest of the world in 2023 (ITC, 2024). According to the latest data of 2023, most of the pharmaceutical products from Bangladesh were exported to Sri Lanka, the USA, the Philippines, Myanmar, Kenya, Cambodia, Pakistan, Australia, Jamaica, Canada, Nepal, South Africa, and Vietnam (ITC, 2024). The highest share of exports, 19.6 per cent, went to Sri Lanka (ITC, 2024). Figure 3 illustrates the top 5 export destinations of Bangladesh's pharmaceutical products in 2023: Sri Lanka, USA, Philippines, Myanmar, and Kenya. Since 2010, there has been an upward trend in the value of pharmaceutical products exported to most countries. Bangladesh exported USD 2.9 million worth of pharmaceutical products to Sri Lanka in 2010, significantly increasing to USD 26 million in 2023 (ITC, 2024). There were negligible or no pharmaceutical exports to the USA until 2016, when Bangladesh gradually started exporting its pharmaceutical products, finally leading to a sharp increase in exports of USD 15.7 million in 2019 (ITC, 2024). Bangladesh's export of pharmaceutical products to the Philippines and Myanmar had an upward trend from 2010 to 2023. However, exports to Myanmar fell drastically from USD 25.6 million in 2022 to USD 15.9 million in 2023. Moreover, pharmaceutical exports to Kenya have remained low and steady, between 1.8 million and 11.3 million from 2010 to 2023 compared to other countries.

The pharmaceutical industry of Bangladesh exports a wide range of pharmaceutical products that include all main therapeutic classes and dosage formats, as well as APIs. Bangladesh exports goods such as hydrofluoroalkane (HFA) and chlorofluorocarbon (CFC) inhalers, suppositories, nasal sprays, injectables, intravenous (IV) infusions, and other forms in addition to standard forms, including tablets, capsules, and syrups (Islam et al., 2018). Almost 90 per cent of the raw materials used in the production of pharmaceutical products are currently imported, placing a heavy burden on the industry (Mohiuddin, 2019).

The Directorate General of Drug Administration (DGDA) of Bangladesh regulates all activities related to the import of raw and packaging materials (Mohiuddin, 2019). Some packaging materials used for pharmaceutical products include bottles, jars, packing containers, aluminium foil, boxes, bags, amino resins, etc. Aluminium foil, whether printed or backed with paper, with HS code 7607, has a total tax incidence (TTI) of 43 per cent (NBR, 2024). The TTI of bottles and jars (HS code 70109000) is 89.32 per cent, and cartons, boxes and cases (HS code 48191000) is 73.96 per cent (NBR, 2024). Bangladesh's pharmaceutical industries also have to pay taxes on imports of pharmaceutical products. Medicaments containing penicillin or derivatives (HS code 30041000), medicaments containing vitamins (HS code 30045000), and medicaments containing Homeopathic, Biochemic, Ayurvedic, Unani medicine, Anaesthetics (HS code 30049020) have TTI of 10 per cent (NBR, 2024). Placebos and blinded clinical trial kits for a recognised clinical trial (HS code 30069300) have a higher TTI of 31 per cent (NBR, 2024). Customs duties on 14 goods used in anti-cancer medications have been removed, while customs duties on 40 basic raw materials used in drug manufacture have been lowered from 10-25 per cent to 5 per cent (Mohiuddin, 2019).

3. THE GLOBAL CONTEXT

A few companies in the USA, China, India, and Europe dominate the global medical supply chain, making up over 70 per cent of the manufacturers of personal protective equipment (PPE) and APIs during the COVID-19 pandemic (Rahman et al., 2021). The COVID crisis has highlighted the perils of centralising manufacturing and economic power inside global health value chains. The total value of the world exports of pharmaceutical products stood at USD 836 billion in 2023, a 0.96 per cent fall from the world export value of USD 844 million in 2022 (ITC, 2024). The top 5 countries exporting pharmaceutical products worldwide are Germany, Switzerland, USA, Belgium, and Ireland, where Germany covers 14.6 per cent share of world exports of these products (ITC, 2024). Alongside the top exporters, as of 2024, the leading companies around the world that manufacture pharmaceutical products are Pfizer, Jhonson & Jhonson, AbbVie, Merck, Roche, Sanofi, AstraZeneca, Novartis, Bristol-Myers Squibb, and GSK. Pfizer ranked number one among all the pharmaceutical companies in the world by earning a total revenue of USD 58.5 billion in 2023 (Burke, 2024b).

Novartis, Allergan, Takeda, Axsome, and Gilead Sciences Inc. are the pharmaceutical companies with the greatest number of active patents. (Drug Patent Watch, 2023). Globally, the leading countries that registered pharmaceutical patents between 2010 and 2017 were China, the USA, Japan, Germany, Switzerland, the Republic of Korea, France, the UK, the Russian Federation, and Italy (WIPO, 2019). China had 215,000 patent registrations, and the USA had 205,000 between 2010 and 2017 (WIPO, 2019).

Big Pharma is one of the most influential sectors, consisting of the world's biggest pharmaceutical companies, which make significant annual contributions to the U.S. Food and Drug Administration (FDA) budget. Johnson & Johnson, Pfizer, Merck, Gilead, Amgen, and AbbVie are six of the top 10 pharmaceutical firms in the world with headquarters in the United States as of 2017 (Compton, 2024). In 2021, the pharmaceutical industry generated over USD 1.42 trillion in revenue globally (Compton, 2024). The pharmaceutical market has been steadily increasing demand

for novel treatments, which is good news for the long-term dynamics of the sector. The global pharmaceutical sector faces several obstacles, including ongoing patent expiration, regulatory barriers, access, pricing, reimbursement, and R&D productivity. To be competitive in this new business environment, big pharmaceutical corporations have started reworking their strategy, where the major players are quickly forming two distinct camps. First, diversified businesses, like Bayer, Eli Lilly, Merck, and Sanofi, which combine diagnostics, generics, medical devices, innovative drugs, consumer health, and animal health businesses under one organisation, and second, pure-play biopharma companies, like AstraZeneca, Novartis, Pfizer, and Roche, which are primarily focused on innovative drugs (Gautam & Pan, 2016). The companies in both groups have implemented a variety of business-evolution strategies, including the pursuit of biologics and speciality medicine, asset-swapping to exit non-aligned portfolios and focus on leadership businesses, geographic expansion and regional consolidation, R&D restructuring, and bolt-on acquisitions and partnerships (Gautam & Pan, 2016).

Pembrolizumab (sold under the brand name Keytruda) was first approved by the FDA in 2014 for cancer treatment. It has since expanded its uses, including non-small cell lung cancer, head and neck cancer, gastric cancer, cervical cancer, etc. By 2023, it accounted for 40 per cent of Merck & Co's pharmaceutical sales. With its patent expiring in 2028, sales are expected to decline by 19 per cent to USD 27.4 billion in 2029 (Burke, 2024a). Additionally, The FDA authorised Eylea, a medication made by Regeneron, in 2011 for treating wet age-related macular degeneration, diabetic retinopathy, and diabetic and non-diabetic macular oedema. The Eylea franchise brought approximately USD 5.9 billion in sales to the US in 2023 (Burke, 2024a).

Direct-acting antivirals (DAAs) like sofosbuvir, which were first introduced to treat hepatitis C, have a high rate of cure, but they come at a high cost. Sofosbuvir can run up to USD 84 thousand for a 12-week course, which results in higher healthcare costs and restricted access in the USA. The expense is still a hardship even with firms like Gilead and AbbVie competing and lowering costs somewhat. These exorbitant charges are not due to production or research expenses but rather patent protections (Kapczynski & Kesselheim, 2016). The same medication is offered for significantly less in nations like India, and increasing competition may drive down costs even more to treat more patients. Important patents allow holders to make as much money as possible by setting prices that do not consider the costs associated with research and development or producing the drug, as with the new hepatitis C virus medicines.

After Bangladesh's independence in 1971, eight multinational corporations (MNCs) supplied 75 per cent of all medications, with the remaining 25 per cent coming from 158 small and medium-sized local businesses (Sarkar & Plahe, 2021). Restrictions on MNCs in Bangladesh in 1982 (Ministry of Law, Justice and Parliamentary Affairs, 1982) made it impossible for them to produce even basic medications, inadvertently blocking the local manufacturing of essential drugs under licensing, which left the nation dependent on imports. The National Drug Policy (NDP) removed this prohibition in 2005 (Ministry of Health and Family Welfare, 2005) to promote technology transfer. These regulations were designed to stop MNCs from advertising non-essential medications and incentivise them to focus on domestic production and technological advancement. The MNCs have not made much headway in producing innovative products in Bangladesh. Since 2012, Novo Nordisk, a leader in treating diabetes worldwide, has started

manufacturing human insulin in vials with the local company Eskayef. Nevertheless, pen-filled contemporary insulin was still imported from Denmark (Chaudhuri, 2020). This technology had been utilised outside of Denmark for the first time when Novo Nordisk and Eskayef inked a technology transfer deal in January 2018 to manufacture enhanced insulin in Bangladesh. Due to local enterprises' competitiveness, the MNCs in Bangladesh gradually abandon simpler medicine formulations to import advanced technology items. For instance, GSK discontinued producing drugs in 2018 because of financial difficulties but kept its consumer healthcare division. Sanofi intends to stop making drugs and concentrate on imports instead. Large MNCs like AstraZeneca, Johnson & Johnson, and Merck Sharp & Dohme mainly serve the market through imports or joint ventures with regional businesses (Chaudhuri, 2020).

The pharmaceutical sector in Bangladesh is dominated by the top 10 producers, who account for over 70 per cent of the local market (BIDA, 2020). The top 10 manufacturers in Bangladesh's pharmaceutical market, comprising a market share of 72.3 per cent in 2023, are Square, Incepta Pharma, Beximco, Healthcare Pharma, Renata, Opsonin Pharma, Aristopharma, Eskayef, Radiant Pharma, Acme (Pharma Specialists, 2023) (Manik, 2023). In 2022, Square Pharmaceuticals had the highest market share of 18.7 per cent (Manik, 2023). In Bangladesh, the price of patented medications has decreased due to competition. Businesses must publicise their market entrance plans and notify the DGDA before API imports. After Incepta introduced a generic form of the Hepatitis C medication Sofosbuvir (brand name Sovaldi) for USD 10 in 2015 (as opposed to USD 1,000 in the USA), Bangladesh emerged as a significant substitute provider of Sofosbuvir and eleven other regional companies started offering it for even less (Chaudhuri, 2020). Incepta is exporting Sovaldi to Mauritius, Togo, the Republic of Congo, Ivory Coast, East Timor, Myanmar, Cambodia, Uzbekistan, Vietnam, Moldova, Nigeria, Nepal, and Mauritius (Sarkar & Plahe, 2021). Moreover, Incepta attracted attention from around the world in 2001 when it started offering HIV/AIDS therapy for USD 350 per patient yearly, as opposed to USD 10,000 in the USA (Sarkar & Plahe, 2021). Bangladesh has profited from selling India cheap cancer medications like osimertinib and ibrutinib after India became TRIPS compliant in 2005 (Sarkar & Plahe, 2021). At home, Bangladeshi businesses like Eskayef, Renata, and Beacon have begun manufacturing 80 different kinds of cancer medications, and throughout the last 10 years, the local market has grown by 30-35 per cent yearly (Sarkar & Plahe, 2021).

4. EXTENT OF DEPENDENCE ON TRIPS PHARMACEUTICALS WAIVER

As a member of the WTO, Bangladesh must follow the rules of trade, which are built on the principles of non-discrimination and market efficiency. One of WTO's main goals is to assist developing countries and LDCs in utilising international trade to boost their economies. Bangladesh's status as an LDC has allowed it to benefit from market access to its fellow WTO members while also enjoying exemption from several important agreements and regulations (Rahman et al., 2021). TRIPS is one agreement that lessens trade barriers and distortions by providing sufficient and adequate protection of IPR (Koul, 2018). Additionally, the TRIPs agreement ensures that laws and processes about intellectual property enforcement do not obstruct lawful trade interests. Under the TRIPS agreement, the WTO has extended its exemption from patent protection for Bangladesh and other LDCs until 2033 (WTO, 2024).

The output of the pharmaceutical industry approximately comprises 1 per cent of the gross domestic product (GDP) of Bangladesh (Gay, 2018). Bangladesh's pharmaceutical industry is expected to bring in USD 2.3 billion in revenue by 2024, with oncology drugs expected to be the largest segment, with a predicted market volume of USD 129.90 million (Statista, 2024). Using the TRIPS waiver, any patented medication can be produced in Bangladesh without the inventor's consent, aiding Bangladeshi pharmaceutical companies in producing 20 per cent of patented and 80 per cent of non-patented medications (BAPI, 2024b). Bangladesh also benefited from USD 46 billion in pharmaceutical export revenue in 2011, a 16.1 per cent rise from USD 39.6 billion in 2010 (Azam, 2016). Currently, 98 per cent of local demand is satisfied by the domestic pharmaceutical sector, which exports raw materials and medications to more than 150 nations (BAPI, 2024d). The addition of anti-coronavirus medications to the export basket, alongside policy assistance and continuous quality improvement, has contributed to a 25 per cent increase in pharmaceutical exports of Bangladesh from USD 136 million in FY2020 to USD 169 million in FY2021 (Ministry of Foreign Affairs, Bangladesh, 2022). Moreover, because of Bangladesh's current LDC status, patented products imported into the country are re-exported to other developed countries at far lower prices than in many countries (Pharmexcil, 2020).

According to paragraph 5 of Article 66.1 of the TRIPS Council decision on 29 November 2005, all LDCs must make sure that any modifications they make to their laws, regulations, or practices during their transition period do not cause them to become less compliant with the terms of the TRIPS Agreement (WHO, 2024). This 'no-rollback' clause significantly affects LDCs because it prevents them from taking advantage of the comparative advantage of reverse engineering and many other TRIPS flexibilities due to their IPR regime. The 'no rollback' clause also impacts LDCs' ability to enact policies. If their current IPR regime permits such protection, they cannot forbid actions like 'evergreening' patents, which is the extension of the patent period by minor modifications which research companies tend to use to extend patent life. However, under the Bangladesh Patent Act (BPA) 2022, a novel version of a known material is not eligible for patent protection if the invention does not advance the known expected result (Ministry of Law, Justice and Parliamentary Affairs, 2022). This provision aims to stop the evergreening of existing drugs that do not show improved efficacy and addresses 'patent layering', a type of evergreening where companies secure patents on different components or enhancements of the same drug in sequence (Islam & Apurbo, 2023).

5. BARRIERS TO TECHNOLOGY ADOPTION APART FROM INTELLECTUAL PROPERTY RIGHTS

Alongside intellectual property rights being a constraint to technology adoption in Bangladesh, there are other obstacles to the smooth take-up of new technology. Bangladesh's human capital is weak, given country's poor quality of higher education. None of the universities from South Asia ranked in the top 100 in the Times Higher Education, one of the most credible sources for global university rankings (Rabbani & Chowdhury, 2014). Bangladesh's higher education is not up to international standards in terms of quality. Moreover, labour mobility from multinationals into Bangladesh's local pharmaceutical industries would augment the chances of acquiring and transferring skills and technology in Bangladesh's pharmaceutical sector. In 2013, 32 out of the 148 top managers in the pharmaceutical industries in Bangladesh had prior experience working

at a pharmaceutical multinational firm, rendering a more extensive knowledge base and superior skill level (Amin & Sonobe, 2013). Compared to other developing nations, Bangladesh has provided favourable access to higher education related to pharmacy and has extended the potential for such education quickly (Amin & Sonobe, 2013). Due to labour mobility and higher education provision, this sector has evolved to have a solid manufacturing base with a skilled workforce (BAPI, 2024d). However, pharmaceutical industry workers lack training, highlighting the necessity for the sector to prioritise capacity building (Raihan et al., 2022).

Additionally, universities, pharmaceutical companies, and the public sector in Bangladesh collaborate in an uncoordinated and ineffective manner to apply the knowledge to produce new products (Karim et al., 2023). Academia and industrial collaboration have a positive impact on drug discovery (Takebe et al., 2018). The success rates for projects that started in academia appeared to be even greater when working with the industry than those observed in drug discovery and development as a whole (Takebe et al., 2018).

Biotechnology is the body of knowledge and methods for utilising living things in a specific process of production where a variety of technologies from industries like medicine, chemicals, pharmaceuticals, and agriculture are involved (Staropoli, 1998). Biotechnology's introduction into pharmaceutical R&D has brought significant organisational and technological changes. Programmes for advanced technology, like 'Biotechnologie', promote biotechnologies and seek to foster collaboration between private businesses and public or quasi-public research institutions to advance biotechnologies in the conventional pharmaceutical sector.

Bank financing was frequently used to finance machinery purchases in the pharmaceutical industry. When bankers saw that the NDP (Ministry of Health & Population Control, 1986) offered significant profit-making opportunities for local pharmaceutical companies, and highly skilled human resources were accessible, they were ready to support fixed capital expenditures made by local pharmaceutical companies.

After the liberation war in 1971, the pharmaceutical sector in Bangladesh has been dominated by multinational companies. In addition to manufacturing vitamins, enzymes, and cough syrups domestically, eight prominent multinational corporations accounted for 75 per cent of the domestic market (Rizwan & Kathuria, 2016). These companies also imported additional critical medications from their overseas units. The NDP (Ministry of Health & Population Control, 1986) of 1982 and the Drugs (Control) Ordinance of 1982 (Ministry of Law, Justice and Parliamentary Affairs, 1982) played a significant role in the development and growth of the domestic pharmaceutical industry, establishing favourable conditions for the growth of domestic pharmaceutical enterprises and implementing measures to secure access to essential drugs for all. Multinational corporations could no longer manufacture vitamins, enzymes, or cough syrups under NDP. However, they could only produce vitamin injectables for local distribution (Rizwan & Kathuria, 2016). Only the Bangladeshi local businesses were permitted to make vitamins, enzymes, or cough syrups, and these businesses were restricted to manufacturing goods on contract for global corporations (Rizwan & Kathuria, 2016). As an industrial policy, the 1982 Ordinance (Ministry of Law, Justice and Parliamentary Affairs, 1982) and the NDP of 1982 (Ministry of Health & Population Control, 1986) sought to end MNC cartelisation in the

nation's pharmaceutical industry and foster an atmosphere encouraging local business owners and pharmaceutical firms to join the market (Rahman et al., 2021).

The main goal of the NDP 1982 was to ensure that all drug acquisition, local manufacturing, quality control, distribution, and utilisation were subject to unified legislative and administrative oversight (Ministry of Health & Population Control, 1986). The NDP was designed to be a crucial component of national health policy, advancing universal access to reasonably priced medication and medical care.

6. STRATEGIES FOR THE POST-LDC PERIOD

6.1 Measures taken by the Government of Bangladesh

Few pharmaceutical companies in Bangladesh can produce APIs. Thus, Bangladesh currently imports the API required for the domestic production of drugs from China, India, Germany, Switzerland, and other EU suppliers (BAPI, 2024a). To promote API production in the country, the government provides a 100 per cent tax waiver to producers of 5 API molecules and a 75 per cent tax waiver to producers of 3 API molecules (BIDA, 2023). API and laboratory reagent manufacturers based in Bangladesh were exempt from corporate taxes until FY2022. After this period, they will also enjoy a tax holiday (from 2023-2032) if they can continue to produce API domestically (BIDA, 2023). Advance income tax (AIT) will not be applicable for API producers on the import of chemical compounds (BIDA, 2023). Firms established between 1 July 2019 and 30 June 2024 are eligible for a 5 to 10-year phased or partial tax exemption (BIDA, 2023). Bangladesh's government actively promotes the production of APIs through different fiscal and export subsidies (BIDA, 2023). The government developed the API Policy in 2018, aiming to attract USD 1 billion in investment in API manufacturing and reduce import dependence to 80 per cent by 2032 (BIDA, 2023). The government also seeks to increase API export income and generate 500,000 jobs by 2032 (BIDA, 2023).

One of the policies of the government of Bangladesh was to create an industrial park that complies with environmental regulations for domestic manufacturing of API. On 200 acres of land, the government is constructing an API Industrial Park in Munshiganj, where 42 plots will establish API manufacturing industrial units, providing about 25,000 jobs for the project's participants (BAPI, 2024a). The project will include all necessary infrastructure, including a waste dump and a common effluent treatment plant (CETP). Bangladesh government's incentive to boost local production of API will lower the cost of domestic pharmaceuticals and increase the cost advantage for exports, given APIs are easier to export than pharmaceutical items (BAPI, 2024a). Therefore, export prospects for the future lay in constructing a cost-effective API park for Bangladesh. Apart from creating a special API Park, which would attract more investment in the API field, another favourable government policy is export subsidy. Bangladeshi companies that export API enjoy a 20 per cent export subsidy whereas companies exporting pharmaceutical products enjoy a seven per cent subsidy (BIDA, 2023). Therefore, the pharmaceutical industry has grown over time due to the resources and assistance that the government provides.

6.2 Measures taken by pharmaceutical companies

Prominent pharmaceutical companies in Bangladesh emphasise exploring and extending their businesses in heavily regulated markets like the European Union (EU), United States of America (USA), United Kingdom (UK), Canada, Australia, and Germany (BAPI, 2024c). Over the past few decades, many pharmaceutical enterprises in Bangladesh have exported their goods to LDCs (Mitsumori & Kubo, 2022). Large pharmaceutical companies have exported their goods to regulated markets. Nowadays, only a few of these businesses export medications to nations with strict regulations, such as the US, UK, Canada, Australia, Germany, and Europe (BAPI, 2024c). Moreover, nearly all significant good manufacturing practice (GMP) accreditations, including those from the United States Food and Drug Administration (FDA), UK Medicines and Healthcare Products Regulatory Agency (MHRA), EU GMP, Health Canada, Therapeutic Goods Administration (TGA) Australia, the national health surveillance agency (ANVISA) Brazil, and Gulf Cooperation Council (GCC) are held by top companies in Bangladesh (BAPI, 2024c). In 2015, the U.S. Federal Drug Agency (FDA) approved the first Abbreviated New Drug Application (ANDA) in Bangladesh, granted to Beximco Pharmaceuticals, the third-largest pharmaceutical firm in Bangladesh. Since then, the business has released four medicines in the US and received six ANDAs from the FDA (Mitsumori & Kubo, 2022).

Significant investments are required for R&D operations in the pharmaceutical industry, although success is not assured. Stakeholders claim that this is one of the main reasons regional pharmaceutical firms are reluctant to participate in research and development (Karim et al., 2023). However, some Bangladeshi companies have cutting-edge R&D facilities that make it easy to develop novel and challenging products, with a focus on enhancing and bolstering their capacity to formulate technologically complex products like oral thin films, metered dose inhalers, multi-layer tablets, sustained-release formulations, dispersible tablets, prefilled syringes, sterile ophthalmics, and so on (Beximco Pharmaceuticals Limited, 2021). Additionally, Bangladeshi pharmaceutical companies are exploring research partnerships with domestic and international institutions and biotech firms to improve their expertise in particular areas. Some Bangladeshi pharmaceutical companies boast state-of-the-art research and development centres with 35 scientists working around the clock to develop products that rank first and best in their respective classes and lab spaces for producing novel vaccines (Incepta, 2024).

Targeting new types of medicines is another strategy that the pharmaceutical industries in Bangladesh are using to prepare for the post-LDC situation. A few major corporations in Bangladesh have created biomedicines and value-added medicines, including insulin analogues and monoclonal antibodies (Mitsumori & Kubo, 2022). The biomedicine industry has been growing quickly and is anticipated to present many opportunities.

7. METHODOLOGY

This study used data and insights collected through a semi-structured questionnaire administered through an online survey. All companies listed as members of BAPI were approached for this survey.

The online survey questionnaire was structured into several modules, each focusing on different aspects of the pharmaceutical industry in Bangladesh. It collected general information about the firm's legal status, ownership structure, management experience, and political affiliations or female ownership. It then gathered details about the establishment's operational history, including the number of employees, quality certifications, export activities, and the origin of material inputs. The manufacturing module explored the types of medicines produced, compliance with international regulatory agencies, and the number of patented products. The sales and revenue section focused on the firm's financial performance, including revenues from both domestic and international markets, with a particular emphasis on patented products. The technical preparedness and R&D module examined the firm's involvement in R&D activities, including using imported APIs, API production, and reverse engineering efforts. It also assessed plans for future R&D activities, such as new drug delivery systems and research on NCEs. The questionnaire then addressed barriers to R&D, identifying key obstacles like financial constraints, regulatory issues, and workforce skill gaps while also probing the relevance of university curricula to industry needs and the availability of internships. It further investigated innovation and R&D activities, including collaborations with universities and other research organisations, investments in government-supported initiatives, and perspectives on government support as Bangladesh graduates from LDC status. The final module solicited recommendations from firms on how the industry and government can better support the sector's growth and competitiveness considering the impending LDC graduation, aiming to gather suggestions for future strategies and policy measures.

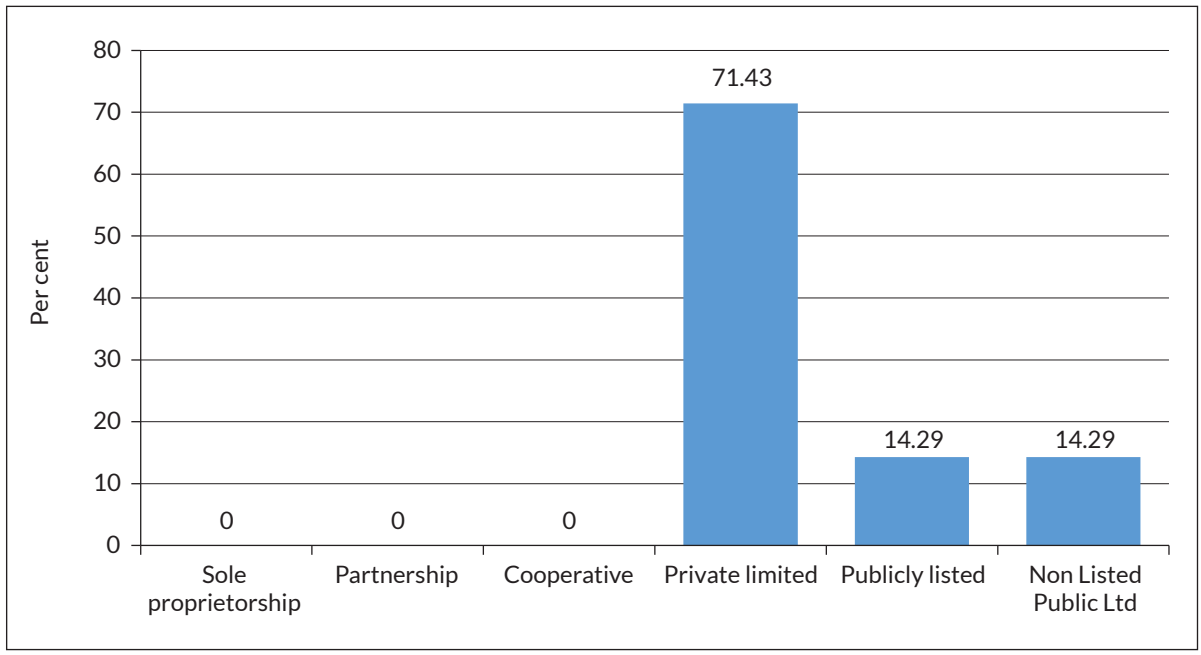
To analyse this survey's data, appropriate statistical tools were utilised based on a review of the existing economic theory and empirical literature. Key Informant Interviews (KIIs) were conducted with industry leaders, representatives from the private sector, and industrial technology experts to validate the findings further and obtain a deeper understanding.

8. FINDINGS FROM THE SURVEY

The survey from the study began with several general information questions regarding the pharmaceutical establishments of Bangladesh exhibiting their current scenario in the pharmaceutical industry. In Figure 4, we can see that 71.43 per cent of the pharmaceutical companies of Bangladesh are private limited companies, whereas only 14.29 per cent are publicly listed. Publicly listed firms can raise capital by selling bonds or stock, giving them access to the financial markets (Banton, 2023). Since most firms are private limited companies, the availability of investment finances is expected to be limited. Private Bangladeshi individuals, companies, or organisations own 100 per cent of the firms in the survey that are non-listed public limited companies.

Moreover, 71.43 per cent of the pharmaceutical firms mentioned that their largest owner is also the top manager of their company. Separating ownership and management ensures business sustainability by allowing a skilled professional team to manage operations, ensuring continuity even if future heirs are not involved (Botha, 2020). Having their largest owner as their top manager could disadvantage for firms, creating conflict among themselves. Nevertheless, the top managers, on average, had 30.3 years of experience in the pharmaceutical

Figure 4: Current legal status of the pharmaceutical firms of Bangladesh



Source: Authors' illustration based on the data from the survey conducted as part of this study.

sector, which manifests their expertise in this sector. Furthermore, none of the surveyed firms' owners, CEOs, top managers, or board members were elected or appointed to a political position in Bangladesh.

The CPD survey found that all the firms have at least one female owner in their establishment, demonstrating that gender plays a vital role in this sector. A recent study found that the pharmaceutical industry of Bangladesh places a high importance on women's representation on boards since it boosts the structure's independence and improves the firm's profitability (Fahad et al., 2022). Therefore, gender diversity is relevant to the performance of the firms.

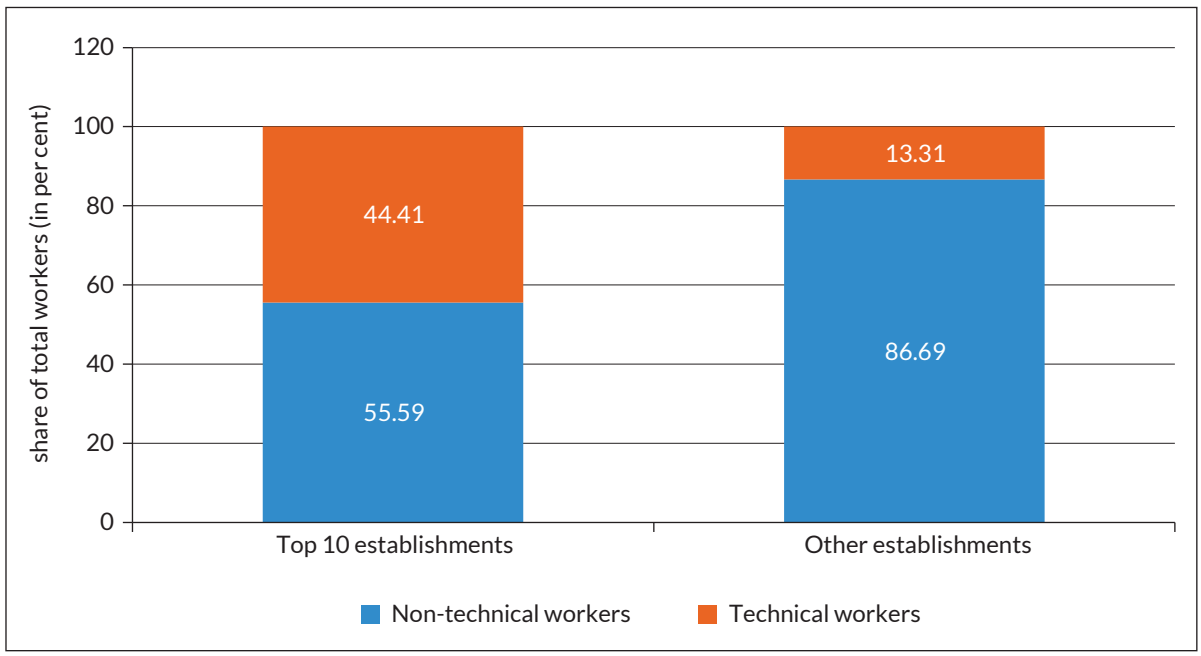
The survey incorporated more insightful questions to obtain precise information regarding Bangladesh's pharmaceutical establishments. As per the survey, the establishments began their operations from as early as 1958 to as recent as 2015. Being in the pharmaceutical industry for so long, 71 per cent of the establishments obtained internationally recognised quality certifications. The establishments were approved by the US FDA, Australia TGA, United Nations Children's Fund (UNICEF), Veterinary Medicines Directorate (VMD) UK, ANVISA Brazil, South African Health Products Regulatory Authority (SAHPRA) South Africa, National Pharmaceutical Regulatory Agency (NPRA) Malaysia, Pharmacy and Poisons Board (PPB) Kenya, Pharmacy and Drug Management (DPM) Ivory Coast, National Agency for Food and Drug Administration and Control (NAFDAC) Nigeria, and Directorate of Pharmacy and Medicine (DPM) Democratic Republic of Congo. International pharmaceutical clients have shown a great deal of interest in leading businesses' growing focus on highly regulated markets, including the USA, UK, Canada, Australia, and the EU (BAPI, 2024c).

Moreover, obtaining WHO pre-qualification is a crucial first step in entering the global pharmaceutical market (Rahman et al., 2021). The survey respondents stated that their establishments are also recognised by WHO pre-qualification, UK MHRA, European Union Germany, Turkey, Taiwan, Health Canada, Philippines, Kenya, Ethiopia, Uganda, United Arab Emirates, Sri Lanka, Democratic Republic of Congo, Colombia, Yemen GMP Certificates and many other regulatory authorities of different countries.

In Bangladesh, few manufacturing sectors are highly skilled, capital-intensive, and dependent on white-collar jobs like the pharmaceutical industry. On average, the country's leading top 10 pharmaceutical establishments, from the survey, have 10,350 full-time workers, including their managers, and other establishments have around 1,900 workers. The leading top 10 companies have 44.41 per cent of technical workers among these employees, and other pharmaceutical companies only have 13.31 per cent, as demonstrated by Figure 5. The difference in the share of technical workers between the top 10 pharmaceutical companies and other pharmaceutical companies is 31.1 per cent. Thus, as the leading companies of Bangladesh contain a significantly higher number of pharmaceutical technical workers than those not in the top 10, it aids them to be more productive and, hence, capture the highest share in Bangladesh's pharmaceutical market. This finding from the study aligns with the previous literature that local manufacturers in Bangladesh are the industry leaders, with a 90 per cent market share. In contrast, multinationals hold a 10 per cent share of the Bangladeshi pharmaceutical market (Pharmexcil, 2020).

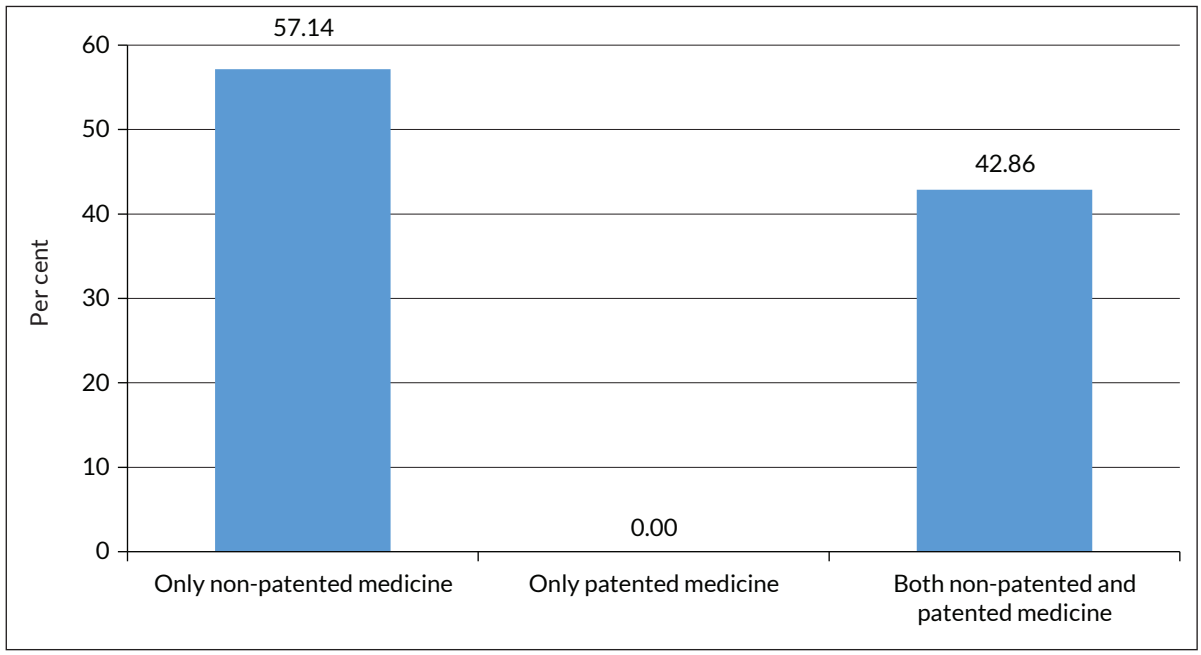
Based on the survey, 86 per cent of the pharmaceutical establishments export their products, of which 37.3 per cent are exported to other LDCs. Moreover, there is a significant amount of API

Figure 5: Technical workers as a share of the total number of workers in the top 10 and other pharmaceutical stablishments



Source: Authors' illustration based on the data from the survey conducted as part of this study.

Figure 6: The type of medicine manufacturing taking place in the firms



Source: Authors' illustration based on the data from the survey conducted as part of this study.

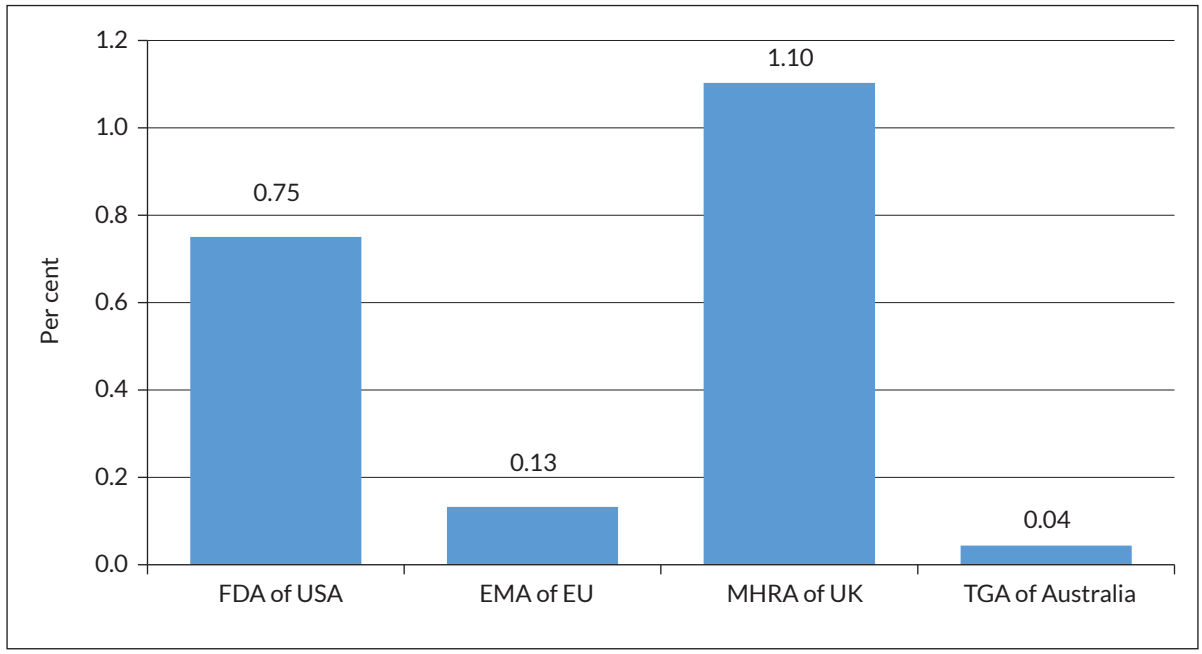
import because the local output of API is still below its demand (BIDA, 2020). The study reflects low local production of API and other inputs, where only 28.3 per cent of the establishments' purchases of material inputs or supplies were of domestic origin.

Figure 6 exhibits the type of medicines that the firms in the survey manufacture. The survey findings indicate that 57.14 per cent of the pharmaceutical firms produce only non-patented medication, and 42.9 per cent of them produce both patented and non-patented medicines. Initially, local firms in Bangladesh were known for producing simple generic drugs, while technologically intensive and patented products were primarily imported. As the industry grew, the abolition of product patent protection allowed local companies to diversify into more complex formulations (Chaudhuri, 2020). Now, on average, 12 per cent of patented medicines are manufactured by firms that produce patented and non-patented medicines. No surveyed firms produced pharmaceutical patented drugs exclusively.

The surveyed firms manufacture different types of products, ranging from 40 to a maximum of 879. On average, Bangladesh's top the top 10 medicine manufacturers produce 547 different medicines. None of these medicines are patented in Bangladesh.

Moreover, one of the primary goals of the NDP of 2005 (Ministry of Health and Family Welfare, 2005) is to manufacture high-quality pharmaceuticals domestically. To do so, the current good manufacturing practice (CGMP) rules established by WHO must be closely followed. Figure 7 represents the pharmaceutical products (per cent) that the USA, EU, UK, and Australia recognise. It shows that 1.1 per cent of the products are approved by MHRA of the UK, which is the highest number of approvals that Bangladeshi pharmaceutical firms received. The FDA

Figure 7: Pharmaceutical products (in per cent) recognised or approved by different countries

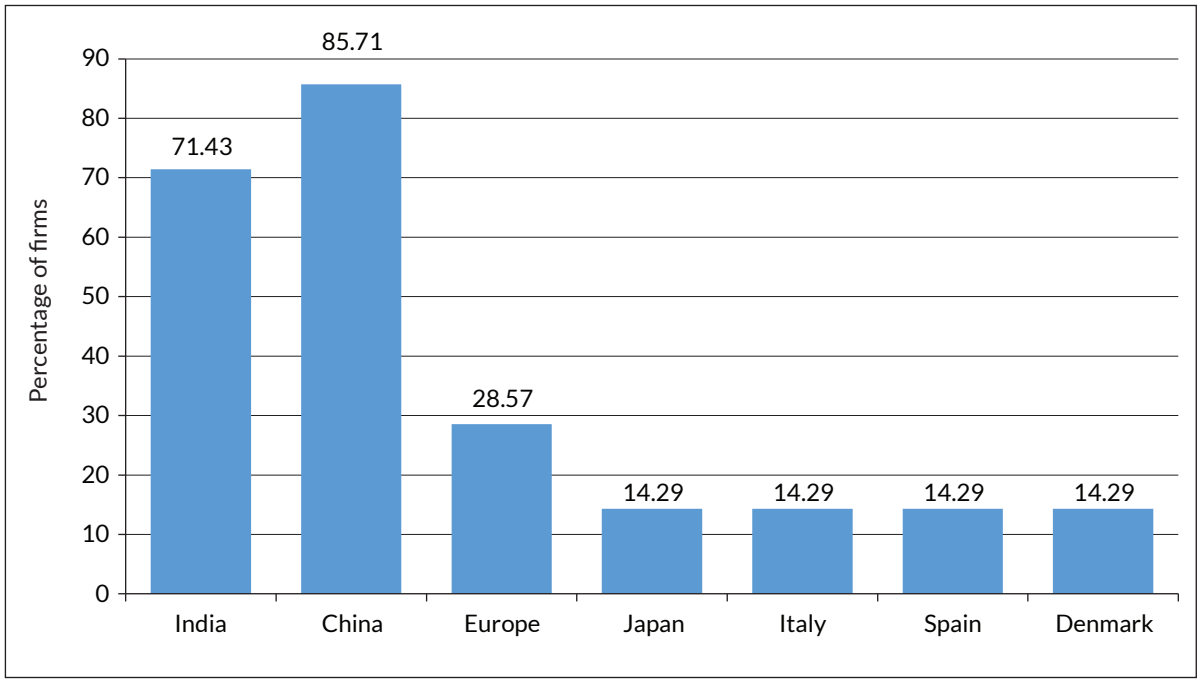


Source: Authors' illustration based on the data from the survey conducted as part of this study.

of the USA also recognises a total of 0.75 per cent, whereas 0.13 per cent and 0.04 per cent are approved by the European Medicines Agency (EMA) of the EU and TGA of Australia respectively. Bangladeshi pharmaceutical companies have acquired the technical competence to establish and manage GMP-compliant manufacturing facilities and create drugs that satisfy regulatory standards for international marketing authorisation (Chaudhuri, 2020).

Next, we designed the survey questions to learn more about the technical preparedness and R&D facilities of the pharmaceutical companies of Bangladesh. All the firms from our survey import the APIs used in their medicine manufacturing process. Our survey showed that 94.6 per cent of the APIs were imported in FY2024. Bangladesh discovered that importing APIs was less expensive than developing them in the country (Chaudhuri, 2020). Figure 8 shows that the surveyed pharmaceutical firms import most APIs from China and India, where 85.71 per cent of the firms imported APIs from China and 71.43 per cent from India. A study found that China and India have emerged as Bangladesh's primary suppliers of low-cost APIs with their fiercely competitive API markets (Chaudhuri, 2020). Fewer firms import APIs from Europe, Italy, Spain, Japan, and Denmark. Most APIs were imported from China and India in FY2021 (Rahman et al., 2021). Currently, 29 per cent of the firms take part in the production of APIs. On average, the surveyed firms produced 5 per cent of the APIs required for medicine production in the last fiscal year. These firms are also currently taking part in reverse engineering APIs. The remaining 67 per cent of the establishments that do not manufacture APIs plan to participate in API production and its reverse engineering in the future.

Figure 8: API import sources

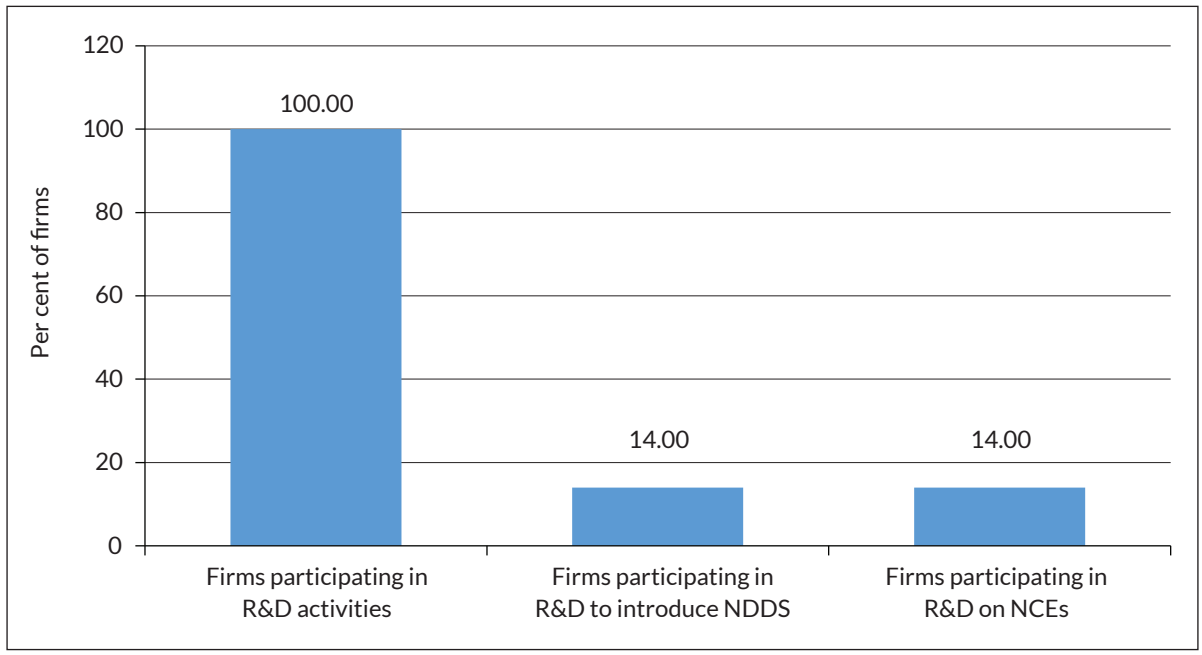


Source: Authors' illustration based on the data from the survey conducted as part of this study.

According to the survey answers, currently, all the establishments participate in R&D activities, having an average annual expenditure of 3.4 per cent on R&D as a percentage of their total expenditure, as shown in Figure 9. On the other hand, only 14 per cent of the firms participate in R&D activities to introduce NDDS. Among the rest who do not participate, only 50 per cent of them plan to participate in R&D activities to introduce NDDS or invent new molecules. Figure 9 also reveals that 14 per cent of the firms participate in research on NCEs, and based on the survey answers, half of the firms plan to participate in research on NCEs in the future. Additionally, none of the pharmaceutical companies in Bangladesh established production facilities in other LDCs. Most of the companies, 57 per cent, were against the idea of setting up production facilities in other LDCs in the future.

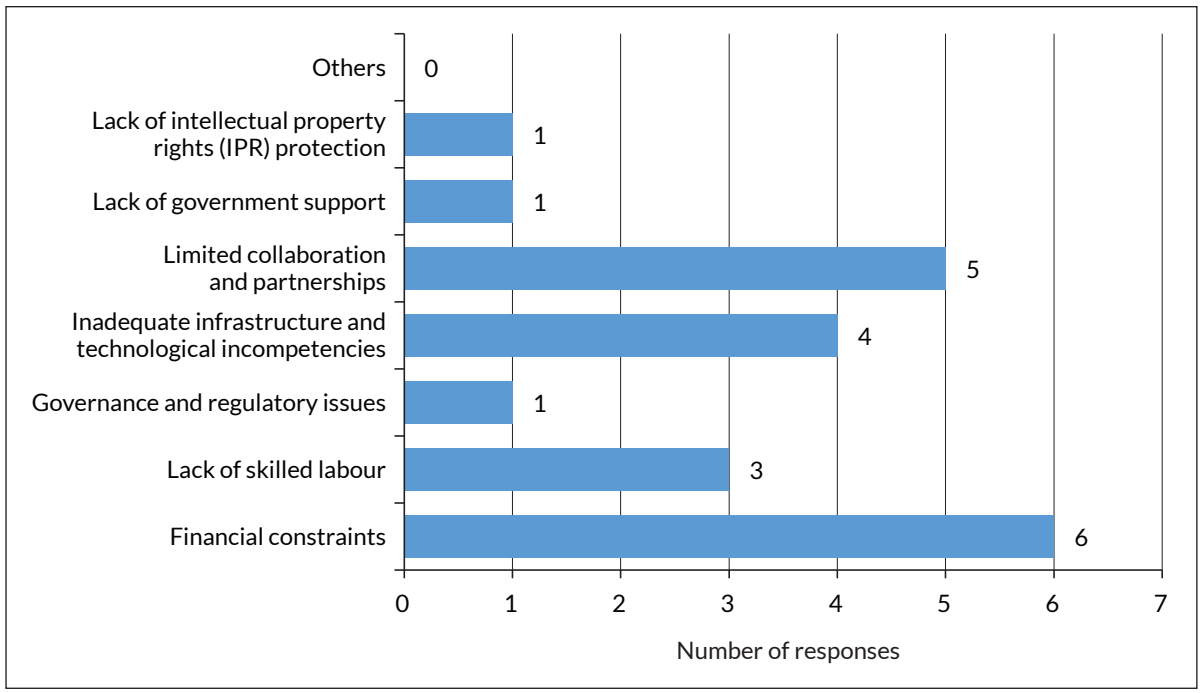
To understand the barriers to R&D in Bangladesh, we also inquired about the top 3 factors currently representing the firm's biggest obstacles to engaging in R&D activities. Figure 10 shows that five firms chose financial constraints as their biggest hurdle in participating in R&D activities. R&D financing came from philanthropic organisations (which included private businesses, non-governmental organisations, etc.) and the public sector (which included government corporations and organisations) (Karim et al., 2023). Other major challenges to carrying out R&D are inadequate infrastructure, technological incompetencies, and limited collaboration and partnerships between industries, research organisations, and academia. Based on our survey, workers in the pharmaceutical sector are not adequately skilled, which further hampers R&D activities.

Figure 9: Firms' participation in R&D



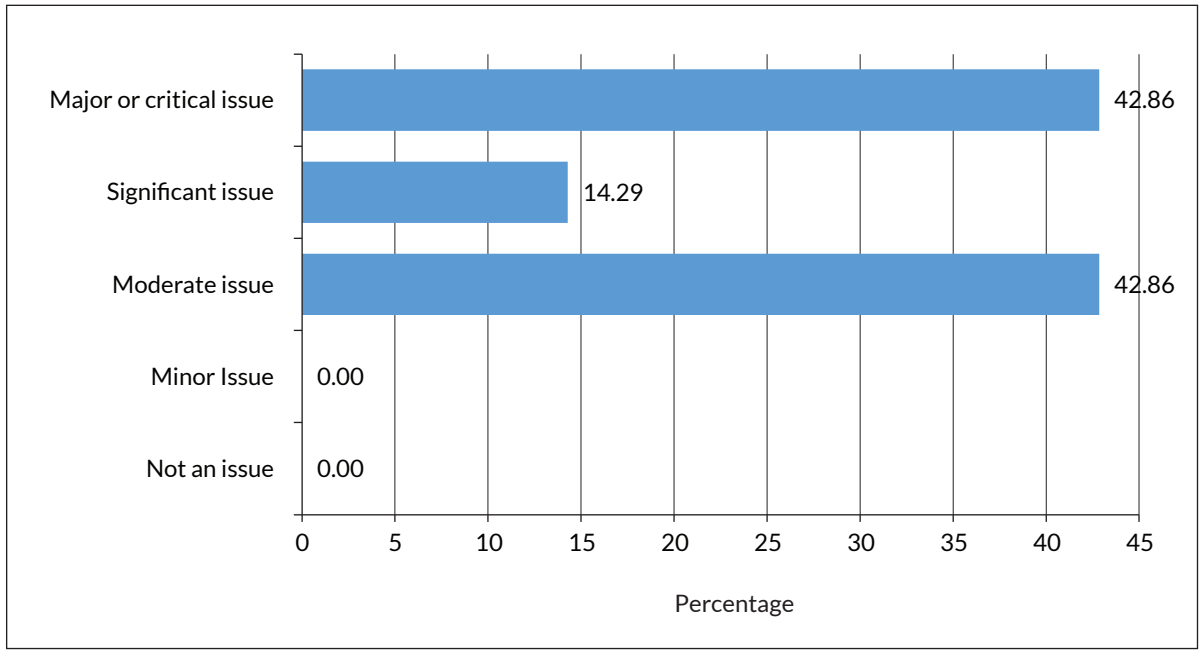
Source: Authors' illustration based on the data from the survey conducted as part of this study.

Figure 10: Biggest obstacles for establishments to engage in R&D activities



Source: Authors' illustration based on the data from the survey conducted as part of this study.

Figure 11: The extent to which workforce skill gaps hinder R&D activities



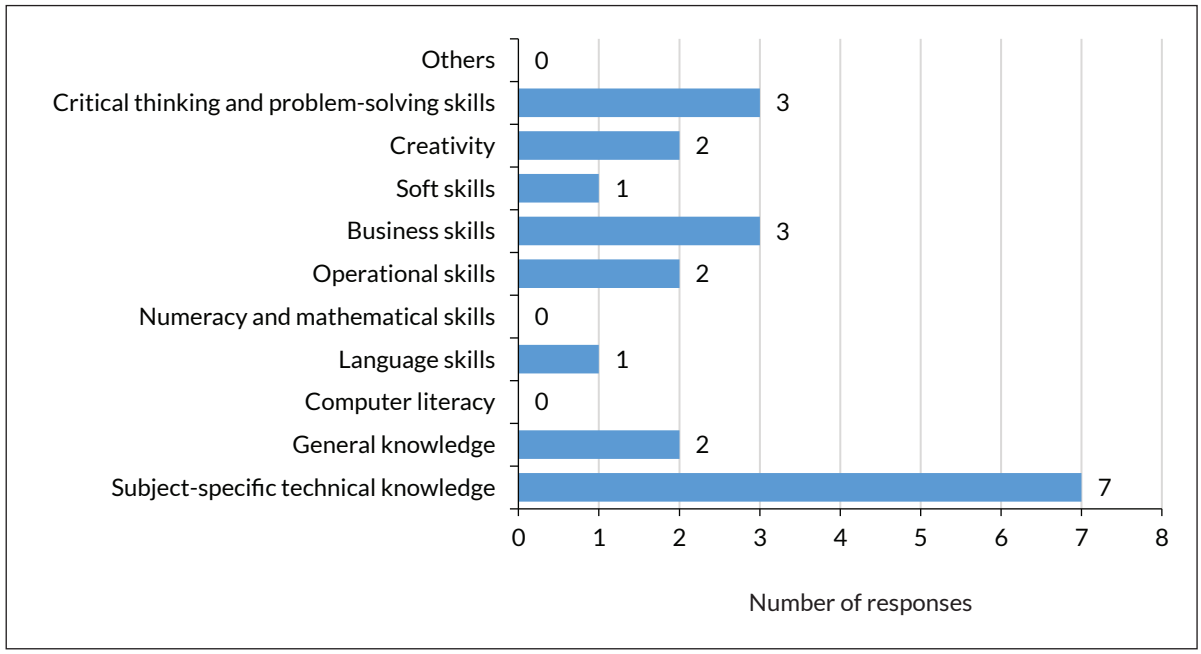
Source: Authors' illustration based on the data from the survey conducted as part of this study.

A crucial factor supporting innovation in the pharmaceutical industry is the availability of skilled labour and high-quality local infrastructure services (Sampath, 2007). From Figure 11, we can see that 42.86 per cent of the firms think that lack of relevant skills in the workforce is a major or critical issue when engaging in R&D activities. Similarly, to 42.86 per cent of the firms, workforce skill gaps are a moderate issue. Thus, the lack of skilled labour represents a constraint for R&D activities in the pharmaceutical sector.

The surveyed pharmaceutical firms mentioned that subject-specific technical knowledge is the most important skill they seek, which the current job seekers in the pharmaceutical sector lack (Figure 12). Critical thinking, creativity, operational skills such as the ability to operate specialised equipment, and business skills such as finance, accounting, management, and marketing are the competencies that employers also look for. Soft skills such as communication, teamwork, leadership, time management, professional networking skills, general knowledge and awareness about the current state of technology, and language skills are also skills that the pharmaceutical firms of Bangladesh are looking for.

Based on the CPD survey, only 14.3 per cent of the firms agree that the curriculum for pharmaceutical sciences in Bangladesh's universities is adequately designed to reflect the needs of the industry. In the pharmaceutical industry, learning and innovation are made possible by skill-building institutions like universities (Sampath, 2007). However, on the positive side, all the firms offer internships for university students seeking more hands-on industry-based training, of which 57 per cent offer paid internships for university students.

Figure 12: The skills that employers seek



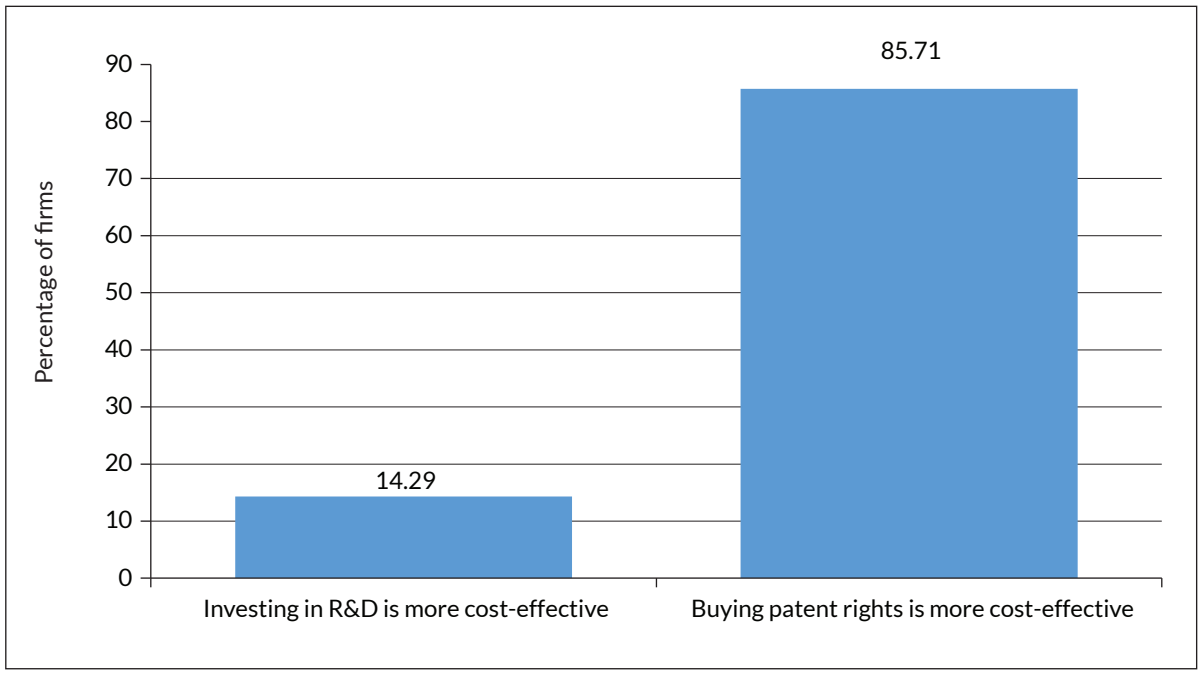
Source: Authors' illustration based on the data from the survey conducted as part of this study.

Despite the country having research institutes, Bangladesh has very low levels of collaboration between firms and public sector institutions involved in research and development, teaching, and health services. Similarly, we can see from our survey results that only 14.3 per cent of the establishments are collaborating with local universities or research organisations to conduct research, whereas 28.3 per cent of them are collaborating with foreign universities or research organisations to conduct their research. Moreover, 71.4 per cent of the establishments partner or collaborate with foreign pharmaceutical companies to produce their products at lower prices.

The API Park, built in Bangladesh with resources for bioequivalence testing, technical assistance, and medication replication, aims to minimise reliance on imports and maximise the benefits of the transitional phase of the TRIPS LDC pharma waiver. The survey findings show that 85.7 per cent of the firms invested in the API park built by the government. Forty-three per cent of the establishments invested time decoding formulation parameters of any patented pharmaceutical product to enhance their reverse engineering skills. Nevertheless, 14.3 per cent of the firms disagree that adequate government support schemes are in place to support the pharmaceutical industry as Bangladesh graduates from the LDC status. We also found that 43 per cent of the firms agree that lowering the costs of APIs by producing them locally could compensate for rising costs post-LDC graduation.

From Figure 13, it is observed that 85.71 per cent of the firms think that buying patent rights to produce the patented drugs post-LDC graduation is more cost-effective for the company to keep earning profits from patented medicines rather than investing in R&D to innovate new drug formulations to replace the patented ones. On the other hand, only 14.29 per cent of the

Figure 13: Cost-effectiveness of investing in R&D or buying patent rights



Source: Authors' illustration based on the data from the survey conducted as part of this study.

establishments believe that investing in R&D is more cost-effective for them to keep earning profits from patented medicines post-LDC graduation instead of buying patented rights.

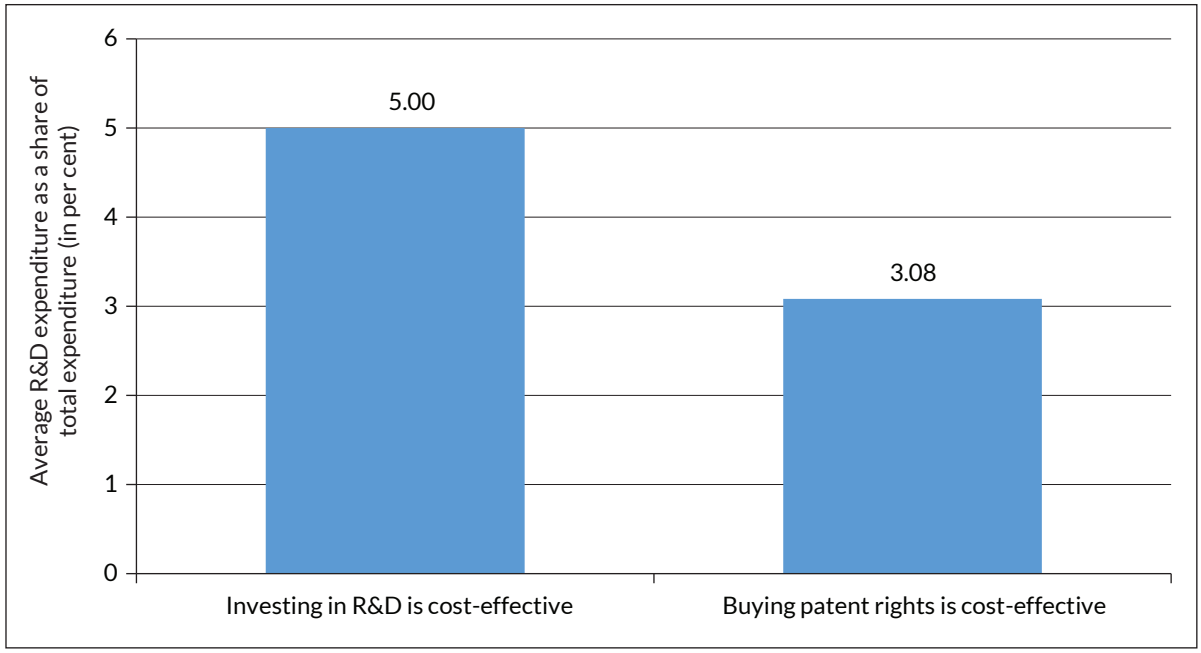
Figure 14 demonstrates the relationship between the average R&D expenditure of the firms and their response to whether it is more cost-effective to invest in R&D or purchase patent rights. Firms that spend 5 per cent of their total expenditure on R&D activities, on average, agree that investing in R&D is more cost-effective than buying patent rights. On average, the establishments that think buying patent rights is more cost-effective invest 3.08 per cent of their total expenditure on R&D. Therefore, we can see that the firms investing more in R&D tend to believe that investing in R&D is more cost-effective than buying patent rights.

Figure 15 shows that, on average, pharmaceutical establishments that export their products spend 3.83 per cent on R&D. Exporting establishments are exposed to global competition, which drives them to invest more in R&D to develop new products and augment their competitiveness. However, non-exporting firms spend only 0.5 per cent of their expenditure on R&D.

Figure 16 demonstrates that the sales of patented products as a share of the surveyed firm's total sales revenue was 1.53 per cent in Bangladesh. In contrast, 9.72 per cent of patented products were sold in foreign markets as a share of the firm's total sales revenue earned from foreign markets.

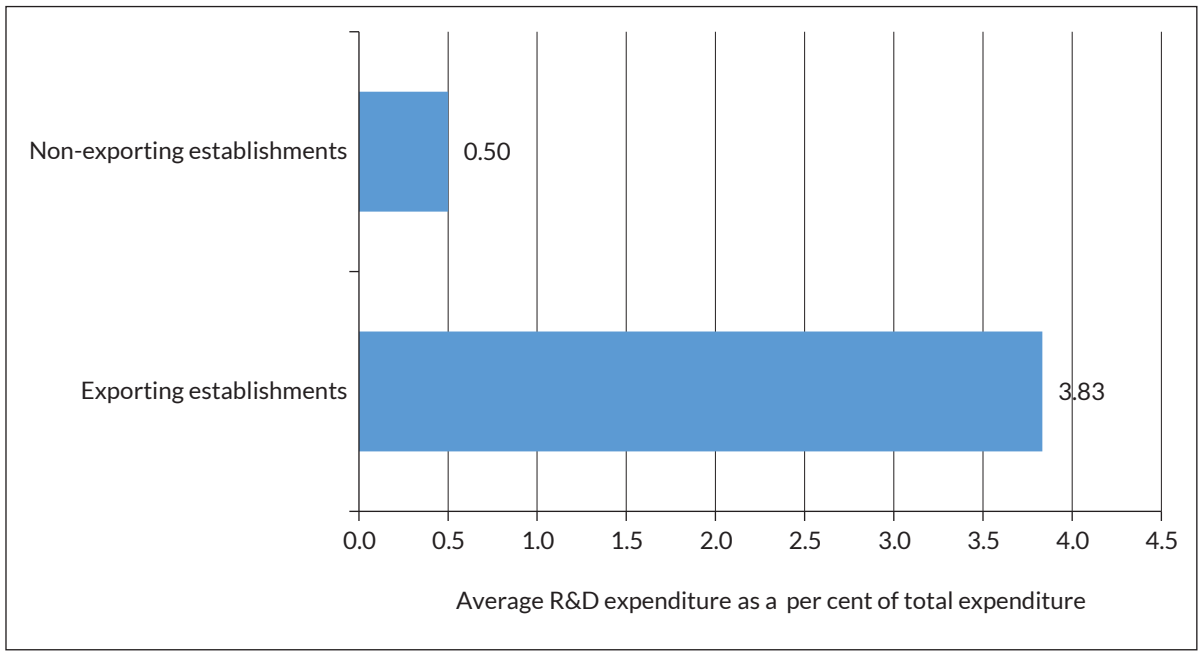
The pharmaceutical companies of Bangladesh had a common answer when asked about the extent to which they benefitted from the TRIPS pharmaceutical waiver. Most of them said

Figure 14: Relationship between average R&D expenditure and the cost-effectiveness of investing in R&D and buying patent rights



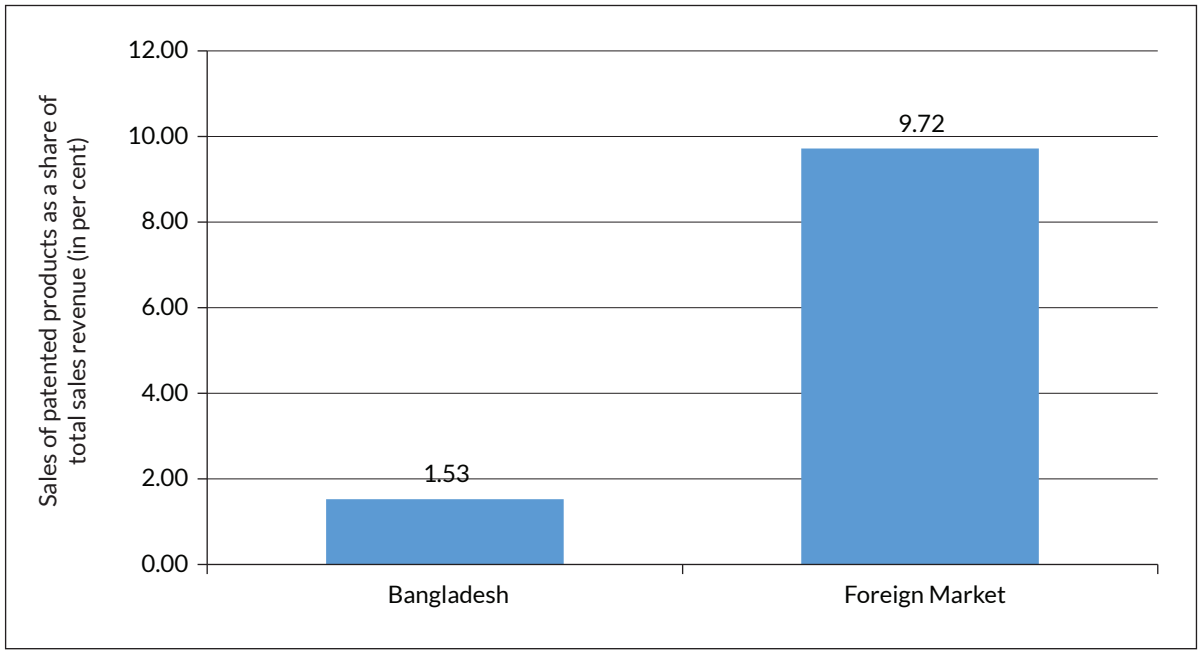
Source: Authors' illustration based on the data from the survey conducted as part of this study.

Figure 15: Relationship between firms who export and their average R&D expenditure



Source: Authors' illustration based on the data from the survey conducted as part of this study.

Figure 16: Sales of patented products as a share of total sales revenue (in per cent)



Source: Authors' illustration based on the data from the survey conducted as part of this study.

that they could produce lifesaving patented molecules at an affordable cost for the treatment of the people of Bangladesh. The low cost helped them launch different globally patented pharmaceutical products and export these products to other LDCs during the waiver period.

According to the CPD survey, the pharmaceutical industry in Bangladesh has greatly benefited from the TRIPS waiver, which allowed them to produce life-saving patented drugs at significantly lower costs than other countries. This enabled the industry to introduce essential, globally patented medications at affordable prices for the treatment and healthcare of the people of Bangladesh. The lower production costs also opened opportunities for exporting these medications to other LDCs during the waiver period. This advantage improved access to critical medicines and empowered the industry to respond swiftly to emerging healthcare needs by developing and launching new, time-sensitive products for patients.

The withdrawal of the TRIPs pharmaceutical waiver post-LDC graduation will increase the cost of APIs and other intermediate products for downstream biological synthesis, where the API cost is expected to be higher than India and China if Bangladesh's firms want to produce their API by reverse engineering. Thus, Bangladesh's pharmaceutical industry will face competition from cheaper imported APIs, making domestic production more costly and raising the price of patented medicines and new treatments. Treatment costs will rise, and accessibility will be problematic for patented medicines.

9. CONCLUSIONS

Bangladesh's pharmaceutical industry has evolved significantly, transitioning from the production of basic generic drugs to more complex and patented formulations. Initially, the industry focused on simple generics while relying on imports for technologically intensive and patented products. However, Bangladesh's pharmaceutical products started getting recognised, mainly through the FDA of the USA and MHRA of the UK. The abolition of product patent protection because of the TRIPS pharma waiver allowed Bangladeshi firms to diversify into more advanced products. Bangladeshi companies have since begun manufacturing and marketing patented medicines, including Sofosbuvir and Remdesivir, previously patented abroad. Currently, 12 per cent of the manufactured medicines are patented on average, according to the findings from this study.

The TRIPS waiver was pivotal in this transformation, allowing Bangladesh to produce life-saving patented drugs at lower costs than other countries. This not only made essential medicines more accessible to the local population but also created opportunities for exporting these drugs to other developed countries and LDCs. In the foreign market, Bangladeshi pharmaceutical industries have earned 9.72 per cent of total revenue by selling patented products. However, as Bangladesh approaches its graduation from LDC status, the impending end of the TRIPS waiver presents significant challenges. Almost all the firms in Bangladesh import the API required to produce medicines. Bangladesh imports APIs mainly from India and China, and in FY2024, 94.6 per cent of the APIs were imported into the country. The cost of APIs and other inputs for drug production is expected to rise, especially since Bangladesh remains dependent on imports for input materials. Competing with cheaper API imports from India and China could increase the cost of patented medicines and new treatments. On average, 5 per cent of the firms are currently taking part in the reverse engineering of APIs to produce APIs themselves. On the bright side, 83.3 per cent of the firms invested in the API park built by the government, which would support the pharmaceutical industries in preparing for the post-LDC withdrawal of the TRIPS waiver.

Apart from the post-LDC withdrawal of the TRIPs waiver, there are other barriers that the pharmaceutical manufacturers in Bangladesh face regarding technology adoption. Even though all the pharmaceutical establishments in Bangladesh participate in R&D activities, their average annual expenditure on R&D is only 3.4 per cent. Only 14.3 per cent of the firms think it is cost-effective to invest in R&D. Financial constraints and limited collaboration and partnerships between industries, research organisations, and academia are the biggest obstacles for the pharmaceutical companies of Bangladesh to engage in R&D activities. Moreover, workforce skill gaps are a significant issue that hinders R&D activities, and the workers in this industry mainly lack subject-specific technical knowledge and skills. On average, technical employees comprise only 26.6 per cent of all employees in Bangladesh's pharmaceutical industry.

To tackle these challenges, Bangladesh's pharmaceutical industry must strengthen its R&D efforts, enhance reverse engineering capabilities, and seek government support through updated patent laws and financial incentives. These steps will be critical for ensuring the long-term growth and competitiveness of the industry in a post-TRIPS environment.

10. POLICY RECOMMENDATIONS

Before Bangladesh graduates from the LDC group and loses the TRIPs pharmaceutical waiver, Bangladeshi pharmaceutical firms should strengthen R&D to establish the ability to create as many patented APIs and introduce as many patented goods locally as possible. This would help pharmaceutical companies reduce their reliance on API imports and address future challenges. Moreover, enriching backward integration to emphasise reverse engineering will also be important. Additionally, as many larger companies are already doing, investing in regulatory approvals for manufacturing facilities will boost exports of off-patent drugs and enable the production of patented drugs under licence agreements, helping mitigate potential losses once copy versions of patented drugs are restricted. The pharmaceutical industry in Bangladesh should focus on securing registration for new drugs within the next two years before the country transitions to a developing country status. After this, if multinational companies patent these drugs, local companies will be prevented from obtaining registration. Though marketing can be gradual, early registration is vital.

Leading businesses could invest in digital tools like artificial intelligence (AI), data analytics, and machine learning to augment the medication development process to enable companies to accelerate the drug development and approval process and further increase sales growth throughout the value chain. An adequate curriculum for pharmaceutical sciences in Bangladesh's universities, designed to reflect the needs of the industry requirements, should be developed to build the workforce's capacity. Moreover, firms should upscale their collaboration with the public and private institutions involved in research and development, teaching, and health services. Pharmaceutical firms should increase their collaboration with local and foreign universities or research organisations to conduct their research.

The government should take several key actions to strengthen Bangladesh's pharmaceutical industry before it loses the TRIPs pharmaceutical waiver. First, they should enhance technical and financial support in the API park to enhance local API production and medicine exports. Furthermore, infrastructural support and adherence to the TRIPS 'rollback clause', which allows countries like Bangladesh to retain certain intellectual property flexibilities and protections after graduating from LDC status to ease the transition to developing country requirements, will support local API manufacturing. They could also simplify the drug registration process until 2026 and extend patent waivers beyond the LDC graduation period through bilateral trade negotiations with the partner countries. Additionally, providing incentives for R&D and backward integration, boosting reverse-engineering skills, supporting the establishment of R&D labs with loans and scholarships, reducing import duties on raw materials, establishing common utilities in industrial zones, and offering tax holidays are also crucial in supporting the pharmaceutical industries of Bangladesh. Finally, strengthening the clinical trial infrastructure will be important, as a robust clinical trial system is vital for boosting pharmaceutical manufacturing in Bangladesh and supporting self-sufficiency.

References

American Pharmaceutical Review. (2024). *Pharmaceutical Manufacturing*. Retrieved July 31, 2024, from. https://www.americanpharmaceuticalreview.com/25310-Pharmaceutical-Manufacturing/#:~:text=In%20short%2C%20pharmaceutical%20manufacturing%20is,designed%20to%20improve%20the%20drug.

Amin, M., & Sonobe, T. (2013). *The success of the industrial development policy in the pharmaceutical industry in Bangladesh*. GRIPS Discussion Papers 13-07. National Graduate Institute for Policy Studies. Retrieved August 12, 2024, from https://econpapers.repec.org/paper/ngidpaper/13-07.htm

Asian Development Bank (ADB). (2024). *Strengthening the Clinical Trials Ecosystem in Bangladesh: Landscape and Policy Recommendations*. Retrieved October 29, 2024, from https://www.adb.org/sites/default/files/publication/985041/adb-brief-308-clinical-trials-ecosystem-bangladesh.pdf

Azam, M. (2016). Has the TRIPS Waiver Helped the Least Developed Countries Progress Towards Innovation and Compliance? In M. Azam, *Intellectual Property and Public Health in the Developing World* (pp. 239-277). Open Book Publishers. https://doi.org/10.11647/OBP.0093.05

Baimakova, K., & Trofimova, L. (2020). Import Dependence of Russian Pharmaceutical Market as the Country's Economic Security Threat. In I. Kovalev, A. Voroshilova, G. Herwig, U. Umbetov, A. Budagov, & Y. Bocharova (Eds.), *Economic and Social Trends for Sustainability of Modern Society* (Vol. 90, pp. 1350-1357). European Publisher. https://doi.org/10.15405/epsbs.2020.10.03.156

Banton, C. (2023, September 26). *Publicly Traded Company: Definition, How It Works, and Examples*. Retrieved September 18, 2024, from Investopedia. https://www.investopedia.com/terms/p/publiccompany.asp

Bangladesh Association of Pharmaceutical Industries (BAPI). (2024a). *API Park-Brief Outline*. Retrieved August 21, 2024, from http://www.bapi-bd.com/api-park/brief-outline.html

Bangladesh Association of Pharmaceutical Industries (BAPI). (2024b). *Bangladesh Pharma Industries-Advantages of TRIPS*. Retrieved November 13, 2023, from Bangladesh Association of Pharmaceutical Industries. http://www.bapi-bd.com/bangladesh-pharma-industry/advantages-of-trips.html#

Bangladesh Association of Pharmaceutical Industries (BAPI). (2024c). *Bangladesh Pharma Industry-Global Footprint*. Retrieved August 22, 2024, from Bangladesh Association of Pharmaceutical Industries. http://www.bapi-bd.com/bangladesh-pharma-industry/global-footprint.html

Bangladesh Association of Pharmaceutical Industries (BAPI). (2024d). *Bangladesh Pharma Industry-Overview*. Retrieved July 31, 2024, from Bangladesh Association of Pharmaceutical Industries. http://www.bapi-bd.com/bangladesh-pharma-industry/overview.html

Bangladesh Bureau of Statistics (BBS). (2023). *Labour Force Survey 2022 Bangladesh*. Retrieved July 31, 2024, from https://bbs.portal.gov.bd/sites/default/files/files/bbs.portal.gov.bd/page/b343a8b4_956b_45ca_872f_4cf9b2f1a6e0/2023-10-25-07-38-4304abd7a3f3d8799fbcb59ff91007b1.pdf

Bangladesh Bureau of Statistics (BBS). (2024a). *Research and Development (R&D) Survey 2022*. Retrieved September 25, 2024, from http://nsds.bbs.gov.bd/storage/files/1/R_&_D_Report_Full%20Book-26.05.2024.pdf

Bangladesh Bureau of Statistics (BBS). (2024b). *Statistical Yearbook Bangladesh 2023*. Retrieved August 25, 2024, from http://nsds.bbs.gov.bd/storage/files/1/Stat_Yearbook-23.pdf

Belousova, O., Groen, A., & Ouendag, A. (2020). *Opportunities and barriers for innovation and entrepreneurship in orphan drug development*. 161. https://doi.org/10.1016/j.techfore.2020.120333

Beximco Pharmaceuticals Limited. (2021). *Annual Report 2020-21*. Retrieved August 22, 2024, from https://beximco-pharma.com/investor/annual-report-2020-21.pdf

Bangladesh Investment Development Authority (BIDA). (2020). *Pharmaceuticals and API Industries*. Retrieved August 28, 2024, from https://bida.gov.bd/storage/app/uploads/public/616/6c2/000/6166c2000004a202755426.pdf

Bangladesh Investment Development Authority (BIDA). (2023). *Pharmaceuticals and API*. Retrieved November 13, 2023, from Bangladesh Investment Development Authority. https://bida.gov.bd/pharma-api#section3

Botha, F. (2020, April 29). *The Importance Of Separating Ownership And Management; 3 Steps To Get Families Started*. Retrieved September 18, 2024, from Forbes. https://www.forbes.com/sites/francoisbotha/2020/04/29/the-importance-of-separating-ownership-and-management-3-steps-to-get-families-started/#:~:text=The%20advantages%20of%20separating%20ownership%20and%20management&text=This%20ensures%20continuity%20withi

Bottazzi, G., Dosi, G., Lippi, M., Pammolli, F., & Riccaboni, M. (2001, July). Innovation and corporate growth in the evolution of the drug industry. *International Journal of Industrial Organization*, *19*(7), 161-1187. Retrieved November 13, 2023, from https://doi.org/10.1016/S0167-7187(01)00068-6

Burke, H. (2024a, February 2). *Top 10 drugs with patents due to expire in the next five years*. Retrieved September 9, 2024, from Proclinical. https://www.proclinical.com/blogs/2024-2/top-10-drugs-with-patents-due-to-expire-in-the-next-5-years

Burke, H. (2024b). *Who are the top 10 pharmaceutical companies in the world?* Retrieved September 8, 2024, from Proclinical. https://www.proclinical.com/blogs/2024-7/who-are-the-top-10-pharma-companies-in-the-world-2024

Chaudhuri, S. (2020). *Evolution of the Pharmaceutical Industry in Bangladesh, 1982 to 2020*. Centre for Development Studies, Working Paper 495. https://doi.org/10.2139/ssrn.3767822

Compton, K. (2024). *Big Pharma and Medical Device Manufacturers*. Retrieved September 8, 2024, from Drugwatch. https://www.drugwatch.com/manufacturers/#who-owns-big-pharma

Doha, A., Pagell, M., Swink, M., & Johnston, D. (2018, July). The Imitator's Dilemma: Why Imitators Should Break Out of Imitation. *Journal of Product Innovation Management*, *35*(4), 489-672. https://doi.org/10.1111/jpim.12427

Drug Patent Watch. (2023, July 24). *Which pharmaceutical companies have the largest patent portfolios?* Retrieved August 19, 2024, from Drug Patent Watch. https://www.drugpatentwatch.com/blog/which-pharmaceutical-companies-have-the-largest-patent-portfolios-6/

Fahad, H., Mahmud, I., & Rahman, A. (2022). Gender diversity on board and its relevance to firm performance: A study on the pharmaceutical industry of Bangladesh. *Asian Finance & Banking Review, 6*(1). https://doi.org/10.46281/asfbr.v6i1.1520

Gautam, A., & Pan, X. (2016). The changing model of big pharma: impact of key trends. *Drug Discovery Today, 21*(3), 379-384. https://doi.org/10.1016/j.drudis.2015.10.002

Gay, D. (2018). *Pharmaceutical Dreams: TRIPS and drugs policy in Bangladesh*. https://doi.org/10.13140/RG.2.2.27964.13446

Gay, D., & Gallagher, K. (2020). *CDP Policy Review Series: The need to extend the WTO TRIPS pharmaceuticals transition period for LDCs in the COVID-19 era: Evidence from Bangladesh*. UN. Retrieved November 14, 2023, from https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/CDP-review-2020-1.pdf

Golova, I., & Sukhovey, A. (2015). Innovation And Technological Development Of Industrial Regions In The Conditions Of Socio-Economic Insecurity. *Scholarly Journal(1)*, 131-144. Retrieved October 15, 2024, from https://www.proquest.com/openview/a6e43130caa548a0af29c3b838c4f84a/1?pq-origsite=gscholar&cbl=5002427

Hossain, M., & Shila, M. (2024). Exploring the Adoption and Challenges of Industry 4.0 in Pharmaceutical Industries of Bangladesh. *Bauet Journal*, *4*(2), 1-8. https://doi.org/10.59321/BAUETJ.V411.1

Incepta. (2024). *Incepta Pharmaceuticals Ltd*. Retrieved August 22, 2024, from Research & Development Facility. https://inceptavaccine.com/research-dev.php

Islam, D., Kaplan, W., Wirtz, V., & Gallagher, K. (2020, May). *The Social Costs of Graduating from Least Developed Country Status: Analyzing the impact of increased protection on insulin prices in Bangladesh*. Global Development Policy Centre. Retrieved November 14, 2023, from https://www.bu.edu/gdp/files/2020/05/GEGI-GDP_WorkingPaper_038_REV.pdf

Islam, M., & Apurbo, S. (2023). Revisiting the patent regime of Bangladesh: compatibility with TRIPS and international best practices. *Journal of Intellectual Property Law & Practice*, *18*(7), 512-527. https://doi.org/10.1093/jiplp/jpad051

Islam, S., Rahman, A., & Al-Mahmood, A. (2018). Bangladesh Pharmaceutical Industry: Perspective and the Prospects. *Bangladesh Journal of Medical Science, 17*(4), 519-525. https://doi.org/10.3329/bjms.v17i4.38306

ITC. (2024). *List of importing markets for the product exports by Bangladesh in 2023*. Retrieved August 28, 2024, from ITC Trade Map. https://www.trademap.org/Country_SelProductCountry.aspx?nvpm=1%7c050%7c%7c%7c%7c30%7c%7c%7c2%7c1%7c2%7c2%7c1%7c1%7c2%7c1%7c1%7c1

Kale, D. (2017). Re-developing Knowledge Creation Capability: Innovating in Indian Pharmaceutical Industry under the TRIPS-Compliant Patent Regime. In S. Little, F. Go, & T.-C. Poon, *Global Innovation and Entrepreneurship- Challenges and Experiences from East and West* (pp. 229-247). Palgrave Macmillan. https://doi.org/10.1007/978-3-319-43859-7_13

Kale, D., & Wield, D. (2008). *Exploitative and Explorative Learning as a Response to the TRIPS Agreement in Indian Pharmaceutical Firms. 15*(1), 93-114. https://doi.org/10.1080/13662710701850725

Kapczynski, A., & Kesselheim, A. (2016). 'Government Patent Use': A Legal Approach To Reducing Drug Spending. *Health Affairs*, *35*(5), 791–797. https://doi.org/10.1377/hlthaff.2015.1120

Karim, O., Srishti, S., Naher, N., & Ahmed, S. (2023). *Pharmaceuticals Research and Development (R&D) in Bangladesh: ground realities and prospects*. BRAC James P Grant School of Public Health, BRAC University. Retrieved August 22, 2024, from https://repository.graduateinstitute.ch/record/301830?v=pdf

Koul, A. (2018). WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement). In A. Koul, *Guide to the WTO and GATT: Economics, Law and Politics* (6th ed., pp. 505-534). New Delhi, India: Springer and Satyam Law International. https://doi.org/10.1007/978-981-13-2089-7

Macrotrends. (2024). *Bangladesh Manufacturing Output 1960-2024*. Retrieved August 27, 2024, from Macrotrends. https://www.macrotrends.net/global-metrics/countries/BGD/bangladesh/manufacturing-output#:~:text=Bangladesh%20manufacturing%20output%20for%202020,a%2011.42%25%20increase%20from%202018.

Manik, M. (2023). Emerging Generics and Manufacturers of the Pharmaceutical Industry in Bangladesh. *Journal of Community Pharmacy Practice*, *3*(3). https://doi.org/10.55529/jcpp.33.1.8

Ministry of Foreign Affairs, Bangladesh. (2022). *Bangladesh Rising-The Success Stories of Bangladesh*. Public Diplomacy Wing, Ministry of Foreign Affairs, Dhaka, Bangladesh. Retrieved August 18, 2024, from https://mofa.portal.gov.bd/sites/default/files/files/mofa.portal.gov.bd/page/37199c6d_96b8_4715_bf54_d999c9b02ff9/Bangladesh%20Rising%20May%202022%20%28Final%29.pdf

Ministry of Health & Population Control. (1986). *The National Drug Policy 1982*. Retrieved August 2, 2024, from https://dgda.portal.gov.bd/sites/default/files/files/dgda.portal.gov.bd/law/d7161df8_ee32_4d19_bf16_a663382ae7b5/drug-policy-1982.pdf

Ministry of Health and Family Welfare. (2005). *National Drug Policy 2005*. Retrieved August 16, 2024, from https://cdn.who.int/media/docs/default-source/searo/hsd/edm/nmp-ban-2005-goweb-ok.pdf?sfvrsn=101bc39d_2

Ministry of Law, Justice and Parliamentary Affairs. (1982). *The Drugs (Control) Ordinance, 1982*. Retrieved August 20, 2024, from Laws of Bangladesh. http://bdlaws.minlaw.gov.bd/act-details-623.html

Ministry of Law, Justice and Parliamentary Affairs. (2022, April 11). *Bangladesh Patents Act 2022*, *5*(q). Retrieved October 3, 2024, from Laws of Bangladesh. http://bdlaws.minlaw.gov.bd/act-1401/section-50909.html?lang=en

Mitsumori, Y. (2018). *An Analysis of the Impact of TRIPS' Special. Portland International Conference on Management of Engineering and Technology PICMET '18 Conference: Technology Management for Interconnected World*. Waikiki. Retrieved November 13, 2023, from https://ieeexplore.ieee.org/document/8481873

Mitsumori, Y., & Kubo, H. (2022, September). An Analysis of the Bangladeshi Pharmaceutical Industry after LDC Graduation: Prospects and Challenges. *IIAI Letters on Business and Decision Science*. https://doi.org/https://doi.org/10.52731/lbds.003.153

Mohiuddin, A. (2019). An A-Z Pharmaceutical Industry: Bangladesh Perspective. *Asian Journal of Research in Pharmaceutical Sciences*, *9*(1). https://doi.org/10.5958/2231-5659.2019.00004.3

Narayan, P. (2011). *Current Protocols*. https://doi.org/10.1002/0471141755.ph0703s55

Natioanl Board of Revenue (NBR). (2024, October 31). *Duty Calculator*. Retrieved October 27, 2024, from https://bangladeshcustoms.gov.bd/users/search_operative_tariff?description=87012200

Petrova, E. (2014). Innovation in the Pharmaceutical Industry: The Process of Drug Discovery and Development. In M. Ding, J. Eliashberg, & S. Stremersch, Innovation and Marketing in the *Pharmaceutical Industry Emerging Practices*, *Research*, *and Policies* (Vol. 20, pp. 19-81). New York: Springer. https://doi.org/10.1007/978-1-4614-7801-0_2

Pharma Specialists. (2023, March 9). *Top 30 Pharmaceutical Companies in Bangladesh*. Retrieved September 2, 2024, from https://www.pharmaspecialists.com/2023/03/top-30-pharmaceutical-companies-in-bd.html

Pharmexcil. (2020). *Bangladesh Pharma Market & Regulatory Report*. Retrieved July 31, 2024, from https://pharmexcil.com/uploads/countryreports/Bangladesh_Market_Regulatory_report2020.pdf

Rabbani, G., & Chowdhury, S. (2014). Quality of Higher Education in Bangladesh: Governance Framework and Quality Issues. *Beykent University Journal of Social Sciences*, *7*(1), 78-91. Retrieved November 11, 2024, from https://dergipark.org.tr/en/download/article-file/482120

Rahman, M., & Farin, S. (2018). *WTO Decision on TRIPS and Public Health A Window of Opportunity for Bangladesh's Pharmaceutical Industry* (Research Report 2). Centre for Policy Dialogue (CPD). Retrieved November 13, 2023, from https://cpd.org.bd/wp-content/uploads/2018/08/Research-Report-2-Rahman-and-Farin-2018_WTO-Decision-on-TRIPS-and-Public-Health.pdf

Rahman, M., Wirtz, V., Kaplan, W., Thrasher, R., & Gallagher, K. (2021). Policy Space for Building Production Capabilities in the Pharmaceuticals Sector in Low- and Middle-Income Countries: Evidence from Bangladesh. *De Gruyter*, *12*(2), 221–261. https://doi.org/10.1515/jgd-2021-0009

Raihan, S., Khondker, B., & Chowdhury, O. (2022). *Skill Gap in the Pharmaceutical Industry of Bangladesh*. SEIP, Finance Division, Ministry of Finance. Retrieved August 14, 2024, from https://seip-fd.gov.bd/wp-content/uploads/2023/03/Skill-Gap-in-the-Pharmaceutical-Industry-of-Bangladesh-1.pdf

Razzaque, M., Rabi, M., & Dad, H. (2020, March). *Bangladesh's Pharmaceutical Exports: Trends*, *Market Prospects*, *and Policies*. 363–408. Retrieved November 13, 2023, from https://www.researchgate.net/publication/346274418_Bangladesh's_Pharmaceutical_Exports_Trends_Market_Prospects_and_Policies

Rizwan, N., & Kathuria, S. (2016). The Pharmaceutical Sector in Bangladesh. In *Attracting Investment in Bangladesh—Sectoral Analyses* (pp. 193-206). World Bank. https://doi.org/10.1596/978-1-4648-0924-8

Sampath, P. (2007, September). *Innovation and Competitive Capacity in Bangladesh's Pharmaceutical Sector* (Working Paper Series). Retrieved November 13, 2023, from https://collections.unu.edu/eserv/UNU:513/wp2007-031.pdf

Sarkar, M., & Plahe, J. (2021). Accessing Affordable Medicines in a Post-TRIPS Environment: The Case of Bangladesh. *South Asia: Journal of South Asian Studies*, *44*(6), 1186-1205. https://doi.org/10.1080/00856401.2021.1981532

Staropoli, C. (1998). Cooperation in R&D in the pharmaceutical industry—The network as an organisational innovation governing technological innovation. *Technovation*, *18*(1), 13-23. https://doi.org/10.1016/S0166-4972(97)00107-7

Statista. (2024, June). *Pharmaceuticals - Bangladesh*. Retrieved July 31, 2024, from Statista. https://www.statista.com/outlook/hmo/pharmaceuticals/bangladesh

Takebe, T., Imai, R., & Ono, S. (2018). The Current Status of Drug Discovery and Development as Originated in United States Academia: The Influence of Industrial and Academic Collaboration on Drug Discovery and Development. *Clinical and Translational Science*, *11*, 597–606. https://doi.org/10.1111/cts.12577

United Nations. (2017). *What LDC graduation will mean for Bangladesh's drugs industry*. Retrieved November 14, 2023, from United Nations- LDC Portal. https://www.un.org/ldcportal/content/what-ldc-graduation-will-mean-bangladesh%E2%80%99s-drugs-industry

Vora, L., Gholap, A., Jetha, K., Thakur, R., Solanki, H., & Chavda, V. (2023). Artificial Intelligence in Pharmaceutical Technology and Drug Delivery Design. *Pharmaceutics*, *15*(7), 1-46. https://doi.org/10.3390/pharmaceutics15071916

World Health Organization (WHO). (2024). *SDG Target 3.8 | Achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and safe, effective, quality and affordable essential medicines and vaccines for all*. Retrieved August 18, 2024, from https://www.who.int/data/gho/data/themes/topics/indicator-groups/indicator-group-details/GHO/sdg-target-3.8-achieve-universal-health-coverage-(uhc)-including-financial-risk-protection#:~:text=Indicator%20Groups-,SDG%20Target%203.8%20%7C%20Achieve%20univer

World Health Organization (WHO). (2024). *WHO Analytical Index - TRIPs Agreemnet Article 66 (Practice)*. Retrieved September 30, 2024, from https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art66_oth.pdf

World Intellectual Property Organization (WIPO). (2019). *Global Innovation Index 2019*. Cornell University, INSEAD, & WIPO. Retrieved September 3, 2024, from https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2019.pdf

World Trade Organization (WTO). (2023). *TRIPS and public health*. Retrieved November 13, 2023, from https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

World Trade Organization (WTO). (2024). *WTO members agree to extend drug patent exemption for poorest members*. Retrieved August 18, 2024, from https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm

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