

Policy Brief

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Accelerating the Growth of Bangladesh's Pharmaceutical Industry: Policies for LDC Graduation and Beyond

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Highlights

- Importing Active Pharmaceutical Ingredients (APIs) is still less expensive than developing them in the country, and 94.6 per cent of APIs were imported in 2024.
- On average, pharmaceutical manufacturers in Bangladesh spend 3.4 per cent of their total annual expenditure on research and development (R&D).
- After graduating from the least developed country (LDC) status, 83.3 per cent of firms think buying patent rights to produce patented drugs will be cheaper than investing in R&D.
- Bangladesh must enhance technical and financial support in the API Park to increase local API production and medicine exports and focus on developing R&D.

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 an essential 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 the LDCs signed by WTO members in 2001, has allowed the industry to thrive by producing affordable generic versions of patented medicines for domestic use without prior authorisation from the developer. Under Article 66.1, TRIPS grants LDCs a unique exemption from pharmaceutical patents until

2033 (WTO, 2023). When Bangladesh graduates from the LDC status, this waiver will be withdrawn.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.

After Bangladesh's LDC graduation, the pharmaceutical industry will be subject to more robust intellectual property regulations and increased costs associated with patent compliance. This 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 substantial loss of the export revenue earned from this sector. When Bangladesh must ensure compliance with the TRIPS agreement, the government may have limited ability to protect the domestic industry against its global competitors.

This factor, in particular, underlines the urgent need for strategic planning and policy adjustments to mitigate these potential threats.

Considering this fact, it is crucial to evaluate the technological preparedness and innovation necessary for Bangladesh's pharmaceutical industry to sustain its growth and global competitiveness and ensure a smooth transition as Bangladesh graduates from LDC status so that the industry continues to thrive and support public health efforts in Bangladesh and other LDCs. This policy brief is based on a study on the technological preparedness of the pharmaceutical industry of Bangladesh conducted by the Centre for Policy Dialogue (CPD).

Justification and Policy Relevance

The WTO Doha Declaration on the TRIPS Agreement and Public Health aided in framing the intellectual property system's health policy framework (WTO, 2023). The patent waiver benefits allow the Bangladeshi pharmaceutical industry to produce generic versions of patented medicines. This has enabled Bangladeshi firms to expand their technological capabilities through technology imitation and reverse engineering (UN, 2017).

Bangladesh's pharmaceutical industry can export to other LDCs and non-WTO member countries without patent protection. It can also export to countries where patents have not been filed or where compulsory licences allow production (BAPI, 2024b). Bangladesh's pharmaceutical industry exports to 120 countries, including 31 LDCs (Gay & Gallagher, 2020). The sector has exported products worth USD 169 million in Fiscal Year (FY) 2021 (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 waiver and extended transition period enable Bangladeshi pharmaceutical manufacturers to produce patented drugs, facilitating imitation and follow-on innovation, which helps them accumulate experience in producing these medicines, which require significant technological understanding (Rahman & Farin, 2018).

Under the Drug Control Ordinance 1982 regulations, Bangladesh's pharmaceutical industry is protected from import penetration (Rahman & Farin, 2018).

Besides, the growth rate of Bangladesh's pharmaceutical industries was 17 per cent from 2014 to 2020 (BIDA, 2023). Bangladesh's export-oriented pharmaceutical industry, benefiting from TRIPS flexibility and strong supply capacity, is well-positioned to meet rising demand in LDC markets by producing generic versions of patented and non-patented drugs (Rahman & Farin, 2018). Bangladeshi pharmaceutical firms have the potential to become global players (Mitsumori & Kubo, 2022).

LDC graduation risks slowing down the technological learning process that has fuelled development in Bangladesh's pharmaceutical industry by driving up costs, preventing imitation, hindering innovation, and limiting access to essential research and development (R&D) resources (UN, 2017). The impoverished population of Bangladesh and other LDCs and developing nations may no longer have access to life-saving medicines at affordable prices after the TRIPS waiver withdrawal (UN, 2017). While most medicines produced in Bangladesh are off-patent, the demand for patented drugs is expected to rise with changing disease patterns, increasing costs post-LDC graduation due to royalty payments. Bangladesh's pharmaceutical industry relies heavily on imported raw materials, especially active pharmaceutical ingredients (APIs), emphasising the need to build local production capacity to reduce vulnerabilities in times of global insecurity. Patent protection could hinder efforts to reduce import dependency and impact API manufacturing (Razzaque et al., 2020).

Furthermore, the country's limited R&D and chemical synthesis skills challenge its ability to innovate and manufacture essential medicines independently. For instance, introducing new chemical entities (NCEs) heavily relies on extensive R&D and involves creating new drug molecules. New drug delivery systems (NDDS) require advanced pharmaceutical capabilities, progressing from basic formulation skills to innovative drug delivery methods. Moreover, clinical trials are essential to discovering new pharmaceutical products as regulatory authorities require them to maintain the effectiveness and safety of new drugs or vaccines. However, due to a shortage of skilled researchers and financial viability, Bangladesh is underrepresented in clinical research (ADB, 2024).

The withdrawal of the TRIPS waiver amid the rise of non-communicable diseases will significantly challenge the achievement of Sustainable Development Goal (SDG) 3.8, which aims to provide universal access to safe, effective, high-quality, and affordable essential medicines and vaccines for all (WHO, 2024). As LDCs seek low-cost drugs, Bangladesh can capitalise on its growing manufacturing expertise under the TRIPS waiver, especially as China and India lose their cost advantage (Gay & Gallagher, 2020).

Overview of the Pharmaceutical Industry in Bangladesh

The pharmaceutical sector in Bangladesh employs 0.34 per cent of all workers in the country (BBS, 2023). The country exported USD 134 million worth of pharmaceutical products to the rest of the world in 2023, where the highest share of exports, 19.6 per cent, went to Sri Lanka (ITC Trade Map, 2024). The pharmaceutical industry exports a wide range of pharmaceutical products including all main therapeutic classes, dosages formats, and APIs. 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, 2024c). Under paragraph 5 of Article 66.1 of the TRIPS Council's 2005 decision, the LDCs must ensure that any changes to their laws during the transition period do not reduce TRIPS compliance. Due to their existing intellectual property regimes, this 'no-rollback' clause restricts LDCs from utilising TRIPS flexibilities like reverse engineering beyond graduation from the LDC group. Financial constraints and a significant lack of skills and training among the pharmaceutical industry workforce are the major barriers to technology adoption, apart from intellectual property rights.

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). Moreover, the government is constructing an API Industrial Park in Munshiganj, where 42 plots will establish API manufacturing industrial units, providing about 25,000 jobs (BAPI, 2024a).

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. Some Bangladeshi companies have cutting-edge R&D facilities, making developing novel and challenging products easy.

Key Findings

This section provides insights into Bangladesh's pharmaceutical industry's present scenario and technological preparedness, including its R&D situation.

As per the survey, 71.43 per cent of the pharmaceutical industries of Bangladesh are private limited companies, and the establishments began their operations as early as 1958 and as recently as 2015. Being in the pharmaceutical industry for so long, 71 per cent of the establishments obtained internationally recognised Good Manufacturing Practices (GMP) certifications. The survey respondents stated that their establishments are recognised by World Health Organization (WHO) pre-qualification, the Food and Drug Administration (FDA) of the USA, the Therapeutic Goods Administration (TGA) of Australia, the Medicines and Healthcare Products Regulatory Agency (MHRA) of the UK, the European Medicines Agency (EMA) of the EU, and many other regulatory authorities of different countries.

In Bangladesh, few manufacturing sectors are as highly skilled, capital-intensive, and dependent on white-collar jobs as the pharmaceutical industry. On average, the top 10 pharmaceutical establishments in the country, from our survey, have 10,350 full-time employees, including their managers, and other establishments have around 1,900 employees. 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. Thus, as the top 10 companies of Bangladesh contain a significantly higher number of pharmaceutical technical workers, it aids them to be more productive and, hence, capture the highest share of the pharmaceutical market in the country.

Based on the CPD survey, 86 per cent of pharmaceutical companies exported their products, of which 37.3 per cent were exported to other LDCs. Moreover, there was a significant amount of API 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 purchases of material inputs or supplies were of domestic origin.

The CPD 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 focused on simple generics, Bangladeshi pharmaceutical firms have expanded into more complex formulations as the industry grew and product patent protection was abolished (Chaudhuri, 2020). Now, on average, 12 per cent of patented medicines are manufactured by firms that produce patented and non-patented medicines.

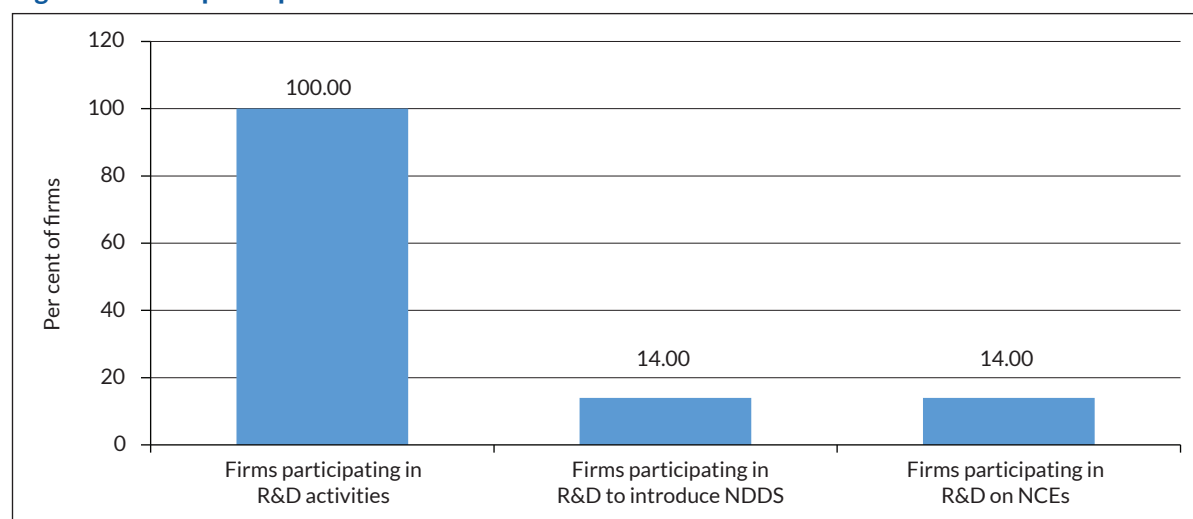
The surveyed firms manufacture different types of products, ranging from 40 to a maximum of 879 products. The UK MHRA has approved 1.1 per cent of the total number of products, the highest number of approvals Bangladeshi pharmaceutical firms have received. The FDA of the USA also recognises 0.75 per cent, whereas 0.13 per cent and 0.04 per cent are approved by the EMA of the EU and TGA of Australia, respectively.

All the firms from the CPD survey import the APIs used in their medicine manufacturing process. The survey showed 94.6 per cent of the APIs were imported in FY2024. Bangladeshi pharmaceutical firms discovered that importing APIs was less expensive than developing them in the country (Chaudhuri, 2020). 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 Italy, Spain, Japan, and Denmark. 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 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.

According to the CPD survey, 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 1. Contemporarily, only 14 per cent of the firms participate in R&D activities to introduce new drug delivery systems (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 1 also reveals that 14 per cent of the firms participate in research on new chemical entities (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.

Figure 1: Firms' participation in R&D



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

Data from the CPD survey shows that financial constraints are the biggest obstacle for pharmaceutical firms in engaging in R&D activities. Other major barriers to R&D in Bangladesh are inadequate infrastructure, technological incompetencies, and limited collaboration and partnerships between industries, research organisations, and academia. Based on the survey, workers in the pharmaceutical sector are not adequately skilled, which further hampers R&D activities. Moreover, 42.86 per cent of the firms think the lack of relevant skills in the workforce is a major or critical issue when engaging in R&D activities.

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. 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 the pharmaceutical firms of Bangladesh are looking for while recruiting employees.

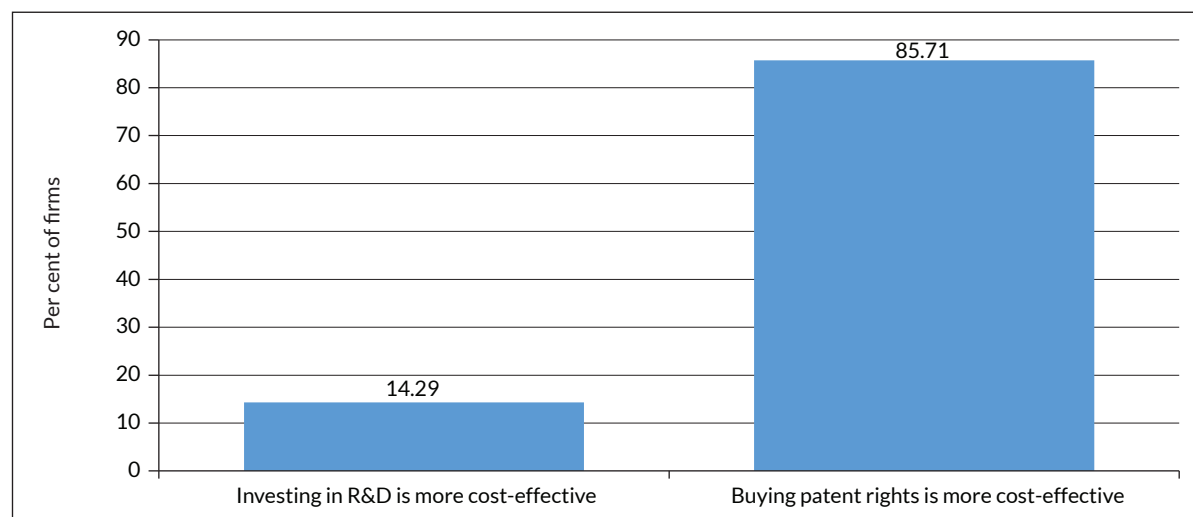
Based on our survey, 85.7 per cent of the firms disagree that the curriculum for pharmaceutical

sciences in Bangladesh's universities is adequately designed to reflect the needs of the industry. 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. Unfortunately, only 14.3 per cent of companies collaborate with local universities or research organisations, whereas 28.3 per cent collaborate with foreign universities or research organisations to conduct their research. Also, 71.4 per cent of the companies partner or collaborate with foreign pharmaceutical companies to produce their products at lower prices.

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 in decoding formulation parameters of any patented pharmaceutical product(s) 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.

Figure 2 shows that 85.71 per cent of the firms think buying patent rights to produce the patented drugs post-LDC graduation is more cost-effective 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 establishments believe that

Figure 2: 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.

investing in R&D is more cost-effective for them to keep earning profits from patented medicines post-LDC graduation by innovating instead of buying 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, 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. 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, sales of patented products as a share of the firm's total sales revenue in foreign markets was 9.72 per cent.

According to the 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 advantage improved access to critical medicines and empowered the industry to respond swiftly to emerging health needs by developing and launching new, time-sensitive products for patients. Post-LDC graduation, the withdrawal of the TRIPS waiver will raise API costs for Bangladesh's pharmaceutical industry, leading to higher production expenses, increased competition from cheaper imports, and elevated prices for patented medicines, making treatments less accessible.

Recommendations

Based on the study findings, the following recommendations are put forth for the policymakers:

- Developing R&D to establish the ability to create as many patented APIs as possible before Bangladesh graduates from the LDC status and loses the TRIPs pharmaceutical waiver.
- Introducing as many patented goods locally as possible before the TRIPs waiver expiration to help pharmaceutical companies reduce their reliance on API imports and address future challenges.
- Enriching backward integration to emphasise and boost reverse engineering skills.
- Investing in regulatory approvals for manufacturing facilities to 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.
- Securing registration for new drugs within the next two years before the country transitions to a developing country status so that multinational competitors cannot prevent local companies from obtaining registration.
- Investing in digital tools like artificial intelligence (AI), data analytics, and machine learning to augment the medication development process to enable companies to accelerate drug development.
- Enhancing technical and financial support to the API park built by the Bangladesh government to increase local API production and medicine exports, offer incentives and improve infrastructure.
- Adhering to the TRIPS 'rollback clause' to allow Bangladesh to retain certain intellectual property flexibilities and protections after graduating from the LDC status, easing the transition to developing country status and supporting local API manufacturing.
- Simplifying the drug registration process until 2026 and extending patent waivers beyond the LDC graduation period through bilateral trade negotiation with the partner countries.
- Providing incentives for R&D and supporting the establishment of R&D labs with loans and scholarships.
- Strengthening clinical trial infrastructure for boosting pharmaceutical manufacturing in Bangladesh and supporting self-sufficiency.
- Reducing import duties on raw materials, establishing common utilities in industrial zones, and offering tax holidays to support Bangladesh's pharmaceutical industries.
- Building the workforce's capacity by providing an adequate curriculum for pharmaceutical sciences in Bangladeshi universities, designed to reflect the needs of the industry.
- Upscaling collaboration between firms and public sector institutions involved in research and development, teaching, and health services.
- Increasing establishments' collaboration with local and foreign universities or research organisations to conduct valuable research.

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