Final Report

LDC Graduation and Bangladesh's Pharmaceutical Industry: Implications for Medicine Prices, Accessibility, and Affordability

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List of Abbreviations

API	active pharmaceutical ingredients
BAPI	Bangladesh Association of Pharmaceutical Industries
BIDA	Bangladesh Investment Development Authority
BPA	Bangladesh Patent Act
CES	constant elasticity of substitution
CGE	computable general equilibrium
CL	compulsory licensing
DGDA	Directorate General of Drug Administration

EPB	Export Promotion Bureau
FAO	Food and Agriculture Organization
FDC	fixed dose combination
FDI	foreign direct investment
FGD	focused group discussion
FY	fiscal year
GDP	gross domestic product
GTAP	Global Trade Analysis Project
HIES	Household Income and Expenditure Survey
HS	harmonised system
IEA	International Energy Agency
IMF	International Monetary Fund
IP	intellectual property
IPR	intellectual property rights
IQVIA	I (IMS Health), Q (Quintiles), and VIA (by way of)
ITC	International Trade Centre
KII	key informant interview
LDC	least developed countries
MNCs	multinational companies
OECD	Organisation of Economic Co-operation and Development
QUAIDS	quadratic almost ideal demand system
R&D	research & development
SCM	Subsidy and Countervailing Measures
SME	small and medium-sized enterprises
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNDESA	United Nations Department of Economic and Social Affairs
WHO	World Health Organisation
WTO	World Trade Organization

Glossary

Bolar Provision- A provision in IP laws that allows generic manufacturers to carry out preapproval tests and clinical trials using patented drugs before the expiration of the drug to the timely release of generic drugs upon expiration of the patent of the brand name.

Compulsory Licensing- A legal mechanism that allows a government to permit a third party to produce patented drugs without the consent of the patent holders. The primary purpose of this mechanism is to improve the availability of vital medicines and be invoked for causes such as public health needs or national emergencies.

Evergreening- Evergreening refers to the practice of extending the patent term of exclusivity of an already patented drug by introducing minor modifications to the existing drug that does not significantly improve the efficacy of the drug.

Market Exclusivity- To reward the drug developers and encourage further innovation, a period of time is often allowed during which the brand names are protected from competition from generic drugs; this duration is called market exclusivity.

Neglected Disease- A group of infectious diseases that are prevalent in developing countries. The development of treatment of such diseases often receives inadequate attention as their market is mostly in poor countries with low incomes.

Parallel Importation- The practice of importing and selling original goods without the producer's authorization. Manufacturers often charge different prices in different countries for the same drugs, and parallel importing of such drugs can enable the availability of drugs at potentially lower prices.

TRIPS Plus- Refers to additional intellectual property provisions beyond the requirements of the TRIPS Agreement. These provisions are often stricter than those of TRIPS as they are designed to provide a greater degree of protection to the patents of developed countries and are often included in bilateral or regional agreements. Examples may include extended patent terms and restriction of generic competition, among others.

Executive Summary

LDC Graduation and Bangladesh's Pharmaceutical Industry: Implications for Medicine Prices, Accessibility, and Affordability

I. Introduction

Bangladesh's imminent graduation from least developed country (LDC) status in November 2026 marks a critical juncture for its pharmaceutical sector. Over the years, the country has leveraged the policy space afforded to LDCs under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO) to strengthen domestic pharmaceutical production, ensuring affordable access to essential medicines while reducing reliance on multinational corporations. However, graduation from LDC status means some of these policy privileges will be lost, requiring new regulatory and market challenges to be confronted.

This policy brief examines the implications of LDC graduation on Bangladesh's pharmaceutical industry, focusing on medicine prices, accessibility, export dynamics, and the sector's overall resilience. Through qualitative and quantitative analyses, including econometric modelling and stakeholder consultations, the brief identifies critical findings and provides actionable recommendations to navigate the transition. It underscores the importance of targeted policies to strengthen domestic capacities, safeguard public health priorities, and maintain competitiveness in a stricter global regulatory environment.

II. Key Findings

Household Medicine Expenditures:

- Out-of-pocket expenditure on medicines accounts for 73 per cent of total health spending in Bangladesh, significantly higher than the global average of 17 per cent.
- An Analysis of the Household Income and Expenditure Survey 2022, by the Bangladesh Bureau of Statistics, shows 16.2 per cent of households having at least one member suffering from a chronic illness.
- On average, poor households, defined as the bottom 40 per cent of the population by income, spend up to 20 per cent of their income on medicine-related costs. High health expenditures exacerbate poverty risks, particularly for families managing costly chronic conditions like cancer or kidney diseases.

Medicine Prices and Accessibility in Bangladesh's New Patent Regime

- Bangladesh has introduced the Bangladesh Patent Act (BPA) 2023 to align with the rules under TRIPS Agreement. The Act excludes pharmaceutical products from patent protection until the country's graduation from LDC status. Additionally, this exemption can be extended for three more years after graduation, based on a decision made at the WTO's 13th Ministerial Conference to support a smooth transition.
- Bangladesh's current capacity to produce patented medicines remains limited, reducing the likelihood of immediate disruptions post-graduation.
- Only about 5 to 10 per cent of currently produced drugs are patented, and LDC graduation is unlikely to increase their prices, as these drugs do not meet the novelty criteria for patents post-LDC graduation even if they remain within their patent protection timeframe.
- Medicine prices are expected to remain stable post-LDC graduation partly due to the BPA 2023, which integrates critical TRIPS flexibilities such as choice of patentability, compulsory licensing, and parallel importation. These measures aim to protect public health and prevent monopoly pricing.
- BPA 2023 limits royalties for producing patented drugs to a maximum of 4 per cent of local sales revenue, ensuring that the prices of new patented medicines remain affordable. If negotiations with the patent holder fail at this royalty rate, the government can issue a compulsory license to produce the drugs without the patent holder's permission, provided that there would be domestic production capacity.

Poverty and Welfare Impacts:

- Bangladesh's graduation from LDC status is unlikely to have a substantial impact on household poverty as significant price increases for medications due to LDC graduation *per se* are not anticipated.
- On the other hand, structural reforms addressing healthcare financing are critical to alleviating the broader economic burden on households.

Export and Industry Dynamics:

- The discontinuation of export subsidies, a WTO requirement post-graduation, may lead to an estimated 6.9 per cent decline in export earnings for pharmaceuticals. However, pharmaceutical exports comprise a relatively small portion of the sector’s revenue and Bangladesh’s overall exports, mitigating broader economic impacts.
- Reliance on imported Active Pharmaceutical Ingredients (APIs), which make up 95 per cent of domestic API use, leaves the sector vulnerable to supply chain disruptions. Enhancing local API production is crucial to reducing costs and increasing resilience.

Regulatory Framework and Industry Preparedness:

- The transition to a stricter intellectual property regime post-LDC graduation will necessitate enhanced institutional and legal capacities to manage patent filings, resolve disputes, and ensure compliance with global standards.

III. Policy Recommendations

Leveraging Transitional Policy Space:

- Fully utilise the three-year post-graduation period provided under the WTO's decision to continue with the current patent-free regime for pharmaceuticals and export incentives. This can maintain access to affordable medicines while allowing time for capacity building and adjustment to stricter intellectual property rules.

Strengthening Domestic Capacities:

- Accelerate the operationalisation of the API Industrial Park and promote investment in synthetic chemistry and petrochemical industries to reduce reliance on imported APIs. These efforts will enhance production efficiency and support local pharmaceutical manufacturing.
- Establish bioequivalence testing facilities to meet international standards and boost the credibility of Bangladeshi pharmaceuticals in global markets.

Enhancing Healthcare Accessibility:

- Address structural challenges in healthcare financing by increased public spending on health, expanding health insurance coverage, introducing targeted subsidies for vulnerable populations, and implementing bulk purchasing strategies for essential medicines to lower costs.
- Strengthen public procurement systems to reduce supply shortages and improve medicine availability in healthcare facilities.
- Use import policy strategically to promote competition and improve quality standards, ensuring consumer benefits while safeguarding the domestic industry's competitiveness.

Building Institutional and Legal Capacities:

- Enhance the capabilities of the Department of Patents, Designs, and Trademarks (DPDT) and judicial systems to handle patent-related disputes and prevent abuse of intellectual property provisions, such as evergreening.
- Explore alternative mechanisms to access advisory support post-LDC graduation, given the loss of discounted services from the Advisory Centre on WTO Law.

IV. Conclusion

Bangladesh's upcoming graduation from LDC status presents both challenges and opportunities for its pharmaceutical sector. The proactive enactment of the BPA 2023 has laid a strong foundation to navigate the transition, incorporating critical TRIPS flexibilities to safeguard access to affordable medicines. Medicine prices are expected to remain stable, and export impacts are likely to be moderate, given the sector's limited dependence on subsidies.

Nonetheless, systemic healthcare challenges, such as high out-of-pocket expenditures and limited domestic API production, remain significant hurdles. Addressing these issues through strategic policy interventions—enhancing local production, strengthening institutional frameworks, and improving healthcare financing—will be essential to sustaining the sector's growth and ensuring equitable access to medicines. By leveraging the transitional policy space and aligning efforts with global standards, Bangladesh can secure a robust pharmaceutical future while supporting broader public health objectives.

LDC Graduation and Bangladesh's Pharmaceutical Industry: Implications for Medicine Prices, Accessibility, and Affordability

I. Background of the Study

Since the late 1980s, Bangladesh has experienced significant expansion in its pharmaceutical manufacturing capabilities, contributing to the achievement of numerous public health objectives, particularly ensuring access to affordable medications. Once reliant on multinational pharmaceutical corporations for essential medicine supplies, Bangladesh has transitioned to sourcing medicines predominantly from domestic production. This shift towards self-sufficiency has been greatly facilitated by policy interventions that bolster the country's pharmaceutical sector, enabling it to emerge as a dynamic sector predominantly targeting the domestic market, with some capacity to export medicines as well.

Central to the development of this domestic pharmaceutical capacity is Bangladesh's status as a Least Developed Country (LDC). Operating within this framework, Bangladesh has been able to regulate domestic pharmaceutical production effectively. This has been achieved by refraining from granting patents for medicines and exercising control over the importation of medications that could be domestically produced. However, the impending graduation from LDC status, set to take place in November 2026, would mean Bangladesh no longer has the liberty to leverage these policy mechanisms.

The ramifications of this transition could be significant, potentially encompassing both the accessibility of essential medicines within the country and the broader outlook for the local pharmaceutical industry (Babyar, 2023; Islam et al., 2019; Tenni et al., 2022). The cessation of policy space afforded by LDC status is widely anticipated to impede access to vital medications for the population, with the pharmaceutical sector facing challenges in adapting to the new regulatory landscape. This necessitates measures to navigate this transition effectively (Islam et al., 2022; Rahman & Farin, 2018; Tenni et al., 2024).

Following Bangladesh's graduation from LDC status, local pharmaceutical companies will encounter a new set of challenges in producing newly patented medicines when such domestic capacity would exist. Negotiations with patent holders, often multinational pharmaceutical giants, will become imperative to secure production licenses, along with the obligation to pay royalties, thereby raising the costs associated with manufacturing these medicines. Consequently, the

retail prices of these medications are expected to rise, potentially undermining their affordability and accessibility for the general population (Azam, 2017; Chaudhuri, 2019; Islam et al., 2022).

The post-LDC landscape will also be subject to the alteration of preferential market access in certain countries. Additionally, because of the rules of the World Trade Organization (WTO), export subsidies currently provided to the exporters of medicines and APIs will have to be discontinued. The combination of these two factors will have an impact on the external competitiveness of the local industry on the global stage (Razzaque et al., 2020).

The changes in the policy landscape could also result in the import liberalisation of medicines, presenting a dichotomy of potential outcomes. While it may enhance the accessibility and efficacy of medicines by facilitating the influx of diverse pharmaceutical products from abroad, it also exposes the domestic industry to heightened foreign competition. This double-edged effect necessitates a delicate balance between reaping the benefits of increased access to superior medications and safeguarding the interests of local pharmaceutical firms from external market pressures. Achieving this equilibrium will be crucial in navigating the complexities of import liberalisation post-LDC graduation and ensuring the sustained growth and competitiveness of the local pharmaceutical industry.

Given the above backdrop, this study investigates the economic impact of graduating from LDC status on Bangladesh's pharmaceutical industry, particularly in terms of medicine prices, local market accessibility, and implications for households, especially lower-income ones. More specifically, it analyses the potential effects on medicine prices and the accessibility of essential medicines and assesses the prospects of the pharmaceutical industry post-graduation, focusing on the industry's export performance.

To explore the potential impacts on prices and accessibility, this study utilises household survey data from the latest Household Income and Expenditure Survey (HIES) 2022 of Bangladesh. This data is employed to calculate the market demand elasticities of medicines used in treating various chronic diseases. The estimated elasticities indicate that demand for these medicines remains relatively stable, with values generally below one in absolute terms. This suggests that changes in medicine prices do not significantly alter consumer demand.

These elasticities serve as the foundation for computing the disease-specific markup of medicines and estimating the implied marginal costs of their production. The calculated markups vary considerably, ranging from approximately 20 per cent to around 150 per cent over the marginal costs. Notably, the median markup for chronic disease medications is approximately 44 per cent, indicating that firms have the flexibility to raise prices significantly

above marginal costs. This analysis underscores the pricing dynamics within the pharmaceutical industry, highlighting the potential profit margins and pricing latitude enjoyed by firms producing medicines for chronic diseases. Such insights are crucial for understanding the various scenarios and evaluating the potential repercussions of policy changes triggered by LDC graduation. As such, five different scenarios of potential impacts are considered.

Scenario 1 considers the accessibility of patented medicines that cannot be produced domestically. These medicines will continue to be imported with the consequent effects being unchanged by LDC graduation.

Scenario 2 highlights the importance of maintaining the ability to produce generic versions of medicines currently under patent protection in foreign jurisdictions. It considers a counterfactual setting where monopoly marketing rights will be awarded to patent holders for these medicines. Simulation results indicate that monopolies could inflate prices by several folds, underscoring the critical role of policy in safeguarding access to essential medicines. However, Bangladesh has ceased the mailbox option of the patent application and will not grant patents for medicines for which generic versions are currently produced by a domestic pharmaceutical firm. Hence, despite LDC graduation, Bangladesh can continue producing these generics, averting potential monopolistic pricing structures and ensuring accessibility and affordability.

Scenario 3 focuses on the potential increase in production costs for generic versions of currently patented medicines post-LDC graduation, primarily due to higher import prices of active pharmaceutical ingredients (APIs). This rise in costs may lead to elevated medicine prices, posing challenges for economically disadvantaged households in accessing essential treatments.

Scenario 4 addresses the implications of patent laws on medicines invented after 2029, requiring permission and royalties for producing generic versions. Negotiating royalty payments could impact medicine accessibility and affordability, with higher fees leading to price hikes. This underscores the importance of balancing patent protection with ensuring access to vital medicines for all segments of society.

Scenario 5 explores the potential impact of allowing the tariff-free importation of off-patent generic medicines after Bangladesh's LDC graduation.[1] By permitting unrestricted importation, market concentration among domestic firms may decrease, potentially reducing medicine prices.

[1] Currently, Bangladesh prohibits the importation of medicines that can be domestically manufactured to shield local pharmaceutical firms from foreign competition. This restriction needs to be lifted after LDC graduation. However, Bangladesh can retain the ability to impose sufficiently high tariffs to restrict imports in the post-LDC period.

Simulations suggest that such a scenario could lead to price reductions ranging from 2 per cent to 18 per cent across various chronic disease medications. These lower prices could arguably enhance medicine accessibility and affordability.

This study also estimates the impact of LDC graduation on household poverty under these various scenarios. Overall, the impact of LDC graduation on household poverty is expected to be insignificant; it will marginally increase the poverty rates for households with members suffering from some chronic diseases. In the most likely scenarios, the monthly medicine expenditure will increase between 2 to 3 per cent, and poverty for households with members suffering from chronic diseases will increase by less than a percentage point due to the rise in medicine prices resulting from LDC graduation.

Using administrative customs data, this study also examines the impact of LDC graduation on medicine and API exports from Bangladesh. Regression analyses indicate that a complete cessation of export incentives (i.e., subsidies) might result in a substantial decline of 5.8 to 6.9 per cent in pharmaceutical exports, amounting to a loss of approximately $10 to $12 million in medicine exports. These results are also supported by the simulations performed using a global computable general equilibrium model. The overall domestic production of pharmaceuticals shows a potential decline of 1.2 to 2.3 per cent if Bangladesh loses access to the TRIPS waiver post-graduation. This decline is attributed to increased capital costs and API import prices resulting from patent protection. However, amidst these challenges, API production might expand by 2.6 per cent to 5.1 per cent due to the rise in API import prices, showcasing dynamic changes in the pharmaceutical landscape triggered by LDC graduation.

The study concludes that LDC graduation per se is not Bangladesh's main concern, as the prices of medicine will not increase significantly. This is due to the removal of the mailbox system and the incorporation of TRIPS flexibilities. However, the more pressing issue lies in the long-standing structural weaknesses of Bangladesh’s healthcare system. The low public health expenditures and high out-of-pocket expenditures borne by households represent significant barriers to equitable healthcare access. These systematic challenges overshadow the implications of LDC graduation on access to medicine.

The rest of the paper is organised as follows: Section 2 provides an overview of the state of Bangladesh’s pharmaceutical sector and public health. A comprehensive literature review on both legal and economic aspects of LDC graduation and access to essential medicines is placed in section 3. Section 4 outlines various methods of quantitative and qualitative analysis. Section 5 discusses the findings on elasticities, markups, and prices of medicines and access to essential medicines for households with members suffering some chronic diseases. Also,

simulation results of the industry-wide impact of LDC graduation utilising a global computable general equilibrium model are discussed in this section. The policy implications and recommendations based on the findings are discussed in section 6. Finally, section 7 concludes the study.

II. Overview of Bangladesh's Pharmaceuticals Sector and Public Health

2.1. Bangladesh's pharmaceutical sector

Domestic market: Bangladesh's pharmaceutical sector has emerged as one of the fastest-growing, technology-driven industries. The pharmaceutical industry stands as one of Bangladesh's largest white-collar intensive employment sectors; however, recent literature does not provide an estimate of the latest employment figures (Gay, 2017). According to the Bangladesh Bureau of Statistics, the gross output of the pharmaceutical industry was valued at around BDT 268.6 billion in 2019, which is around $3.2 billion (BBS, 2020). Based on growth rates from the National Account Statistics, this figure is projected to have reached around BDT 425 billion ($3.5 billion) in FY24.[2] Until the early 1980s, multinational companies (MNCs) dominated Bangladesh, manufacturing three-quarters of all drugs (Ahmed & Islam, 2012). Currently, domestic pharmaceutical firms possess the capability to meet around 98 per cent of the domestic demand (UNCTAD, 2024). To achieve this self-sufficiency, the Drugs (Control) Ordinance (1982) and the National Drug Policy (1986) have played a crucial role. Initiating drug price controls, reducing the market dominance of the MNCs, and prohibiting pharmaceutical patents to achieve various public health goals are some of the key policies that have helped this sector to grow. Subsequently, two more drug policies adopted in 2005 and 2016 shaped the industry's future by establishing an API park and improving quality.

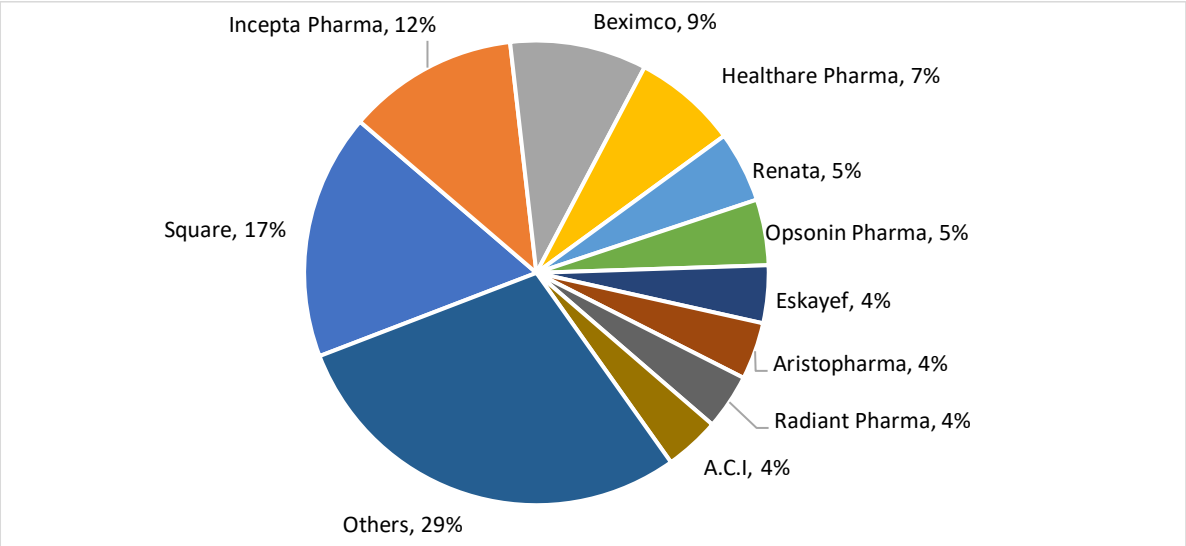
Furthermore, due to Bangladesh's status LDC, pharmaceutical firms have been privileged with several waivers and concessions. These include exemptions related to intellectual property rights, such as reduced obligations concerning patents and other proprietary rights. As an LDC, Bangladesh has often received preferential treatment and relaxed regulations in international trade agreements, facilitating easier market access for its pharmaceutical products. Additionally, the LDC status has entailed advantages in terms of tariff reductions, enabling cost-effective import of essential raw materials and active pharmaceutical ingredients (APIs) crucial for pharmaceutical manufacturing. The LDC status has, therefore, played a pivotal role

[2] The depreciation of the taka between 2019 and 2024 has been accounted for in the estimation of the sector's gross output in US dollar terms.

in fostering a conducive environment for the growth and competitiveness of the pharmaceutical industry in Bangladesh.

As of 2024, Bangladesh is home to 284 registered pharmaceutical companies (Bangladesh Association of Pharmaceutical Industries, 2024). The industry is notably concentrated, with the top ten firms commanding approximately 71 per cent of the total market share (Figure II.**1**). Regarding production, around 80 per cent of the drugs manufactured are off-patent, while the remaining 20 per cent fall under patent protection (LightCastle Analytics Wing, 2020). However, according to industry sources, firms produce around 5 to 10 per cent on-patented drugs, and the rest are off-patented. The low market concentration and the TRIPS flexibilities give Bangladesh an edge in producing drugs at a very low cost compared to other countries (UNCTAD, 2024).

Figure II.1: Market share of top pharmaceutical manufacturers in Bangladesh



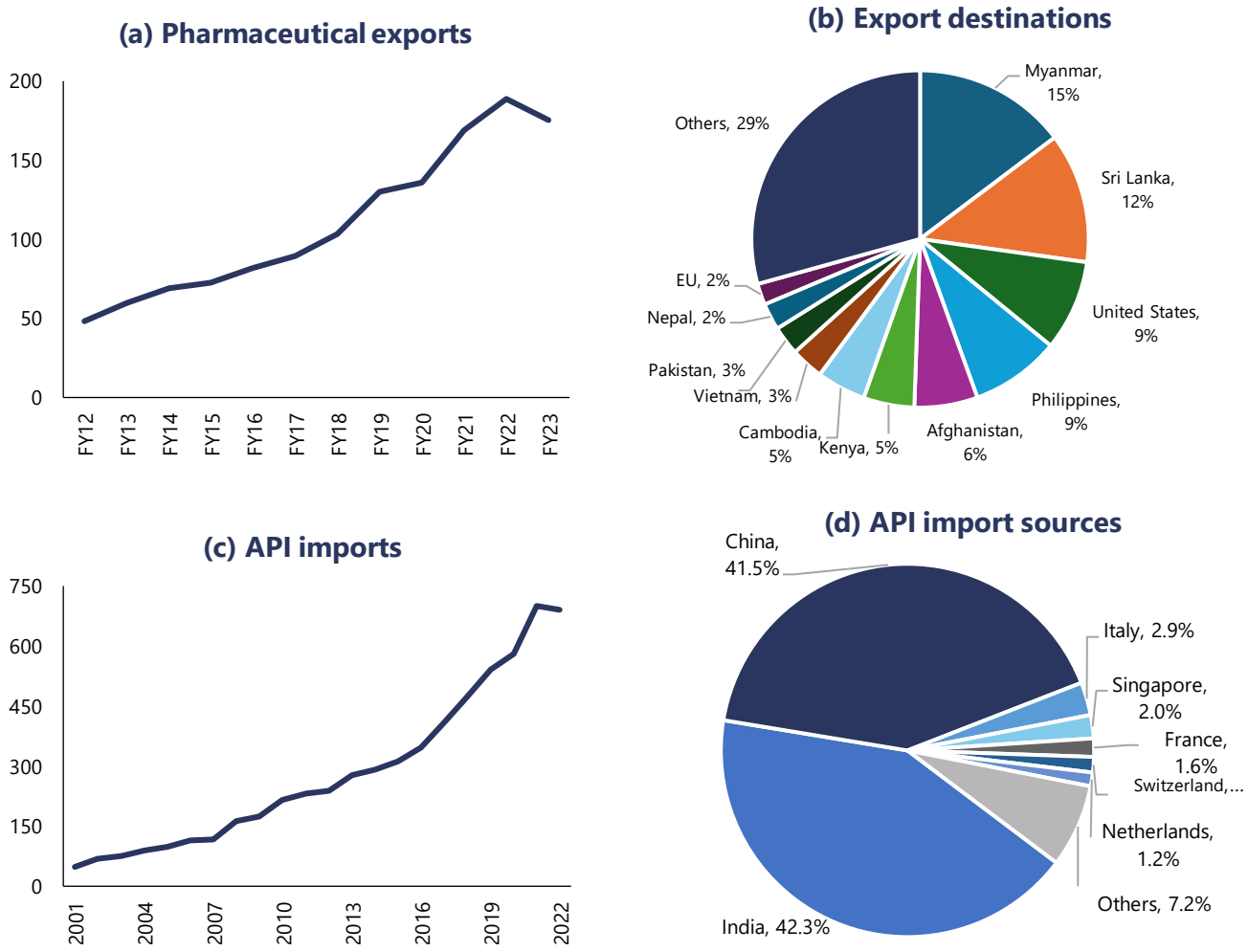
Source: Authors' estimation using IQVIA data.

Export-import performance: According to Export Promotion Bureau (EPB) data, Bangladesh has successfully exported pharmaceutical products to approximately 156 countries in the last three years. In FY23, the export revenue from pharmaceutical products reached around $175 million, reflecting a slight decline of approximately 7 per cent from the preceding year (**Error! Reference source not found.**). Nonetheless, the sector has exhibited commendable progress, with exports escalating more than threefold from less than $50 million in FY12, maintaining an average export growth of 13 per cent. **Error! Reference source not found.** represents the top ten destinations of Bangladesh's pharmaceutical export market. Approximately 70 per cent of export earnings stem from these countries, with Myanmar standing out as the top destination, contributing around 15 per cent to the export earnings, followed by Sri Lanka

(12.5 per cent) and the United States of America (8.7 per cent). Analysing Bangladesh's pharmaceutical export data from the last five years reveals positive growth in exports across all major destinations (See Annex A1).

While Bangladesh is nearly self-sufficient in producing finished drugs, the sector heavily relies on external sources for Active Pharmaceutical Ingredients (API). According to Bangladesh Economic Review (2023), the country imports around 95 per cent of API from various countries. In 2022, the country has imported around $691 million worth of API (**Error! Reference source not found.**). China and India are the two main sources of API, accounting for more than 80 per cent of total API imports (**Error! Reference source not found.**).

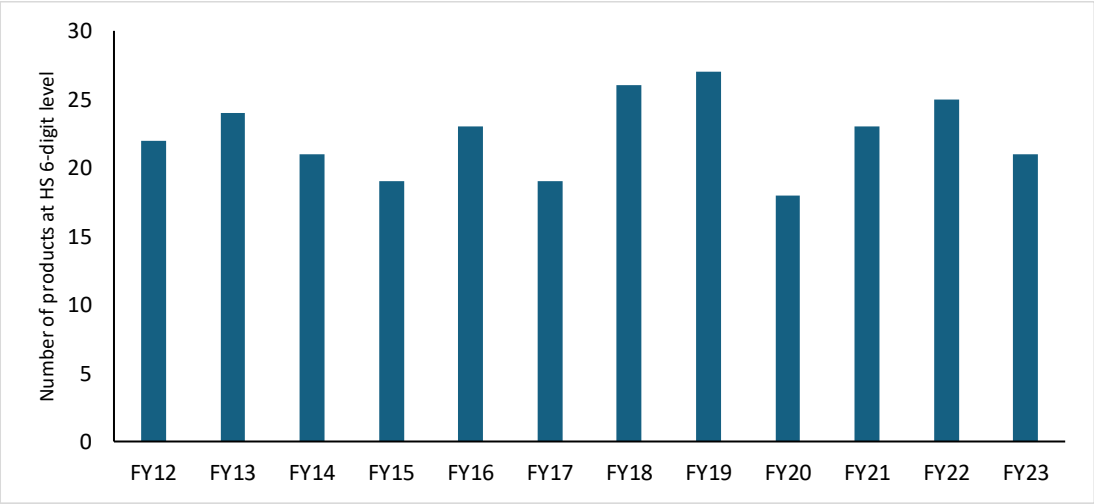
Figure II.2: Bangladesh's pharmaceutical exports and APIs import trends (Million US$)



Source: EPB (2024) and ITC Trade Map (2024)

The number of pharmaceutical products exported (at the HS 6-digit level) has fluctuated, reaching 27 in FY19 before declining to 21 in FY23 (Figure II.**3**). Of these 21 products, the top five items together constitute approximately 95 per cent of all pharmaceutical export receipts, with HS 300490 alone capturing over 70 per cent of the same (Table II.**1**).

Figure II.3: Number of medicines products exported from Bangladesh at HS 6-digit level



Source: Authors' estimation using EPB data.

Table II.1: Top pharmaceutical products exported from Bangladesh in FY 2023

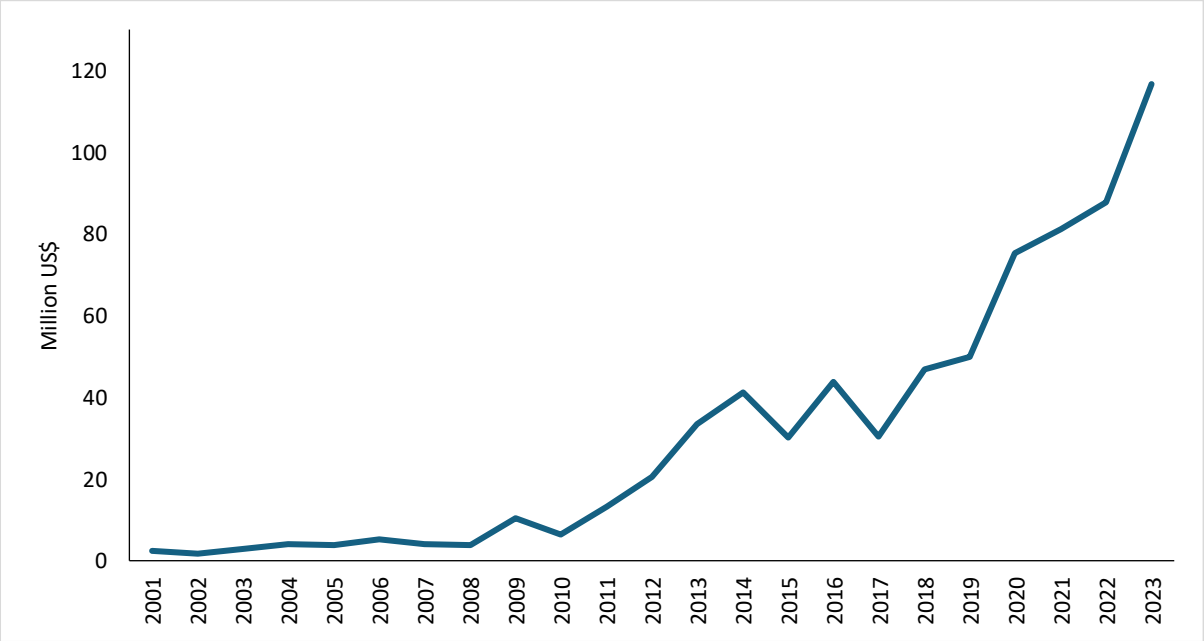
Products (HS 6 digit)	Description	Trade Value (USD)	Share (%)
300490	Other medicaments of mixed or unmixed products	124.0	70.7
300320	Medicaments of other antibiotics	14.6	8.3
300439	Medicaments of other hormones	12.2	6.9
300410	Medicaments of penicillin or streptomycin	7.9	4.5
300390	Other medicaments with & gt;=2 constituents	6.9	3.9
	Others	9.8	5.6

Source: Authors' estimation using EPB data.

Foreign direct investment in pharmaceutical sector: In 2023, the chemical and pharmaceutical sectors attracted a net foreign direct investment (FDI) of about $117 million (Figure II.**4**), reaching an all-time high and accounting for around 4 per cent of the total net FDI inflow (Bangladesh Bank, 2023). Over time, FDI inflows have shown steady growth, particularly with an annual increase of about 27 per cent since 2018. Such impressive growth is attributed to government initiatives to encourage investment in this sector, including offering a percentage-based tax holiday depending on the production capability of API, providing cost-effective import

facilities for API producers, and other supportive measures. To meet its own demand for raw materials and enter the global API market as an exporter, the Bangladesh government has undertaken a project to establish an API Industrial Park 37 km away from the national capital. The project, which is implemented on 200 acres of land, will have 42 Pharmaceutical Ingredients Manufacturing Industrial units with employment potential for 25,000 individuals. To attract foreign investment into the park, necessary infrastructural facilities such as the common effluent treatment plant (CETP) and waste Dumping Yard are also to be made available in the park. The scheme is still in the preliminary developmental stage, and once completed, it is expected to lower Bangladesh's vulnerability to external shock and dependency on foreign suppliers and give the country a competitive edge in the global market for pharmaceutical exports.

Figure II.4: Net FDI inflow in chemical and pharmaceutical sector (million US$)



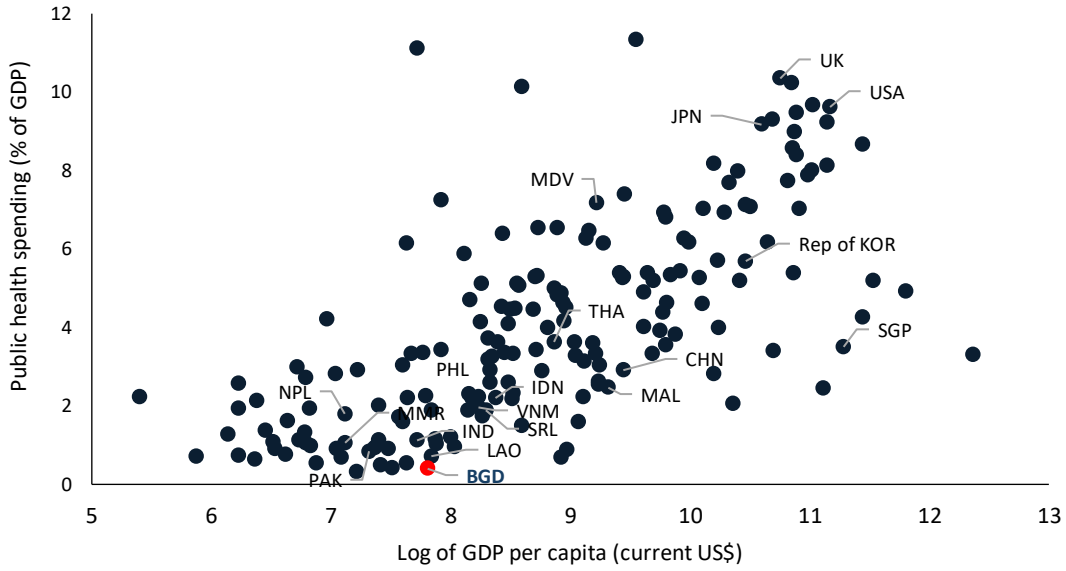
Source: Bangladesh Bank (2023)

2.2. Public Health Expenditure in Bangladesh

Bangladesh's public health expenditure ranks among the lowest in the world. As per the latest data from World Health Organization, in 2021, public health expenditure in Bangladesh was only 0.4 per cent of its GDP–ten times lower than the global average (Figure II.**5**). The consequences of such a low level of public expenditure are reflected in the high out-of-pocket health expenditure. In 2021, out-of-pocket health expenses in Bangladesh accounted for a staggering 73 per cent of total health spending, compared to the global average of just 17

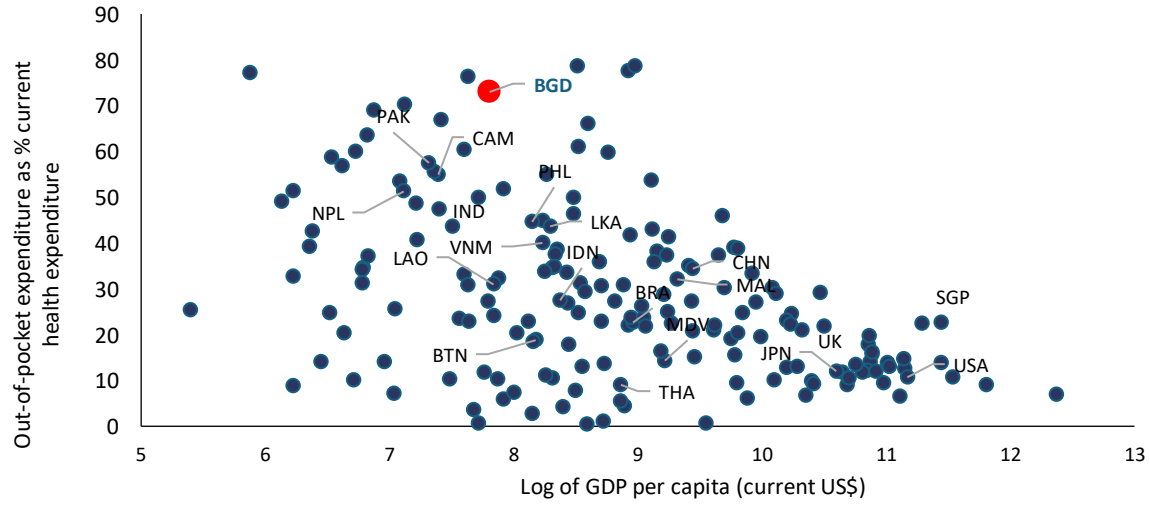
per cent (Figure II.**6**). This excessive financial burden on individuals places immense strain on households, particularly among low-income groups.

Figure II.5: Public Health Expenditure and GDP per capita



Source: World Bank Group (2023a); World Health Organization (2023). Note: Countries are indicated as BGD = Bangladesh, CHN = China, IND = India, IDN = Indonesia, JPN = Japan, LAO = Lao PDR, MAL = Malaysia, MDV = Maldives, MMR = Myanmar, NPL = Nepal, PAK = Pakistan, PHL = Philippines, Rep of KOR = Republic of Korea, SGP = Singapore, SRL = Sri Lanka, VNM = Viet Nam, UK = United Kingdom, USA = United States

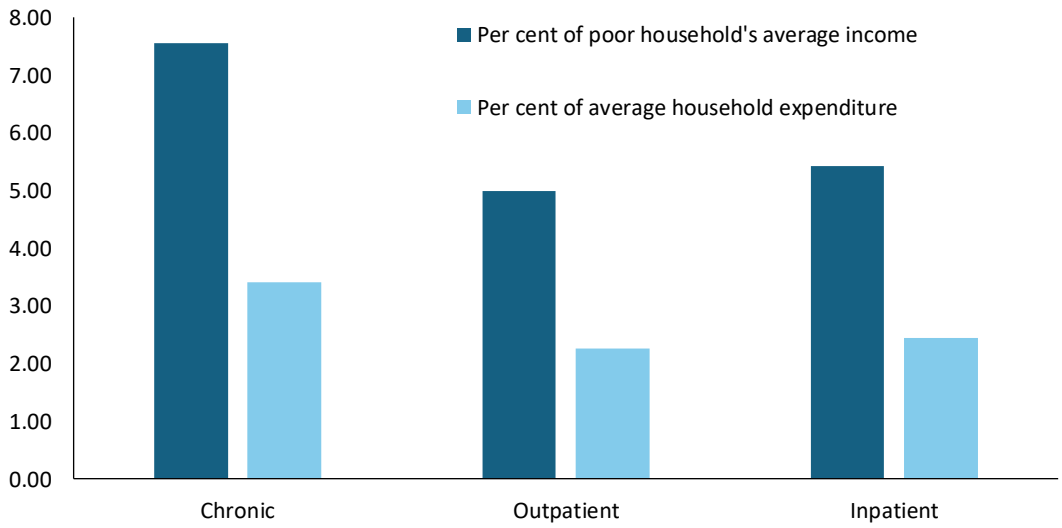
Figure II.6: Out-of-pocket expenditure as percentage of current health expenditure and GDP per capita



Source: World Bank Group (2023b, 2023a). Note: Countries are indicated as BGD = Bangladesh, BTN = Bhutan, CAM = Cambodia CHN = China, IND = India, IDN = Indonesia, JPN = Japan, LAO = Lao PDR, MAL = Malaysia, MDV = Maldives, MMR = Myanmar, NPL = Nepal, PAK = Pakistan, PHL = Philippines, Rep of KOR = Republic of Korea, SGP = Singapore, SRL = Sri Lanka, THA = Thailand VNM = Viet Nam, UK = United Kingdom, USA = United States

Data from the latest Household Income and Expenditure Survey (HIES) highlights the breakdown of annual per-person out-of-pocket spending on medicines across three main categories: chronic, outpatient, and inpatient medicine expenses. The data shows that 16.2 per cent of households have at least one member suffering from chronic illness. Overall, the total annual out-of-pocket expenditure on medicines for a household with one member suffering from a chronic disease accounted for about 3.4 per cent of the total annual expenditure (Figure II.7). For a poor household, defined as the bottom 40 per cent of the population by income, with a member suffering from chronic disease, approximately 7.6 per cent of its total income was spent on medicines. Moreover, if an average household incurred outpatient and inpatient medicine expenditure in addition to the expenditure on medicines for chronic illness, the proportion of medicine expenditure would exceed 8 per cent of the total annual household consumption expenditure. For a poor household, the corresponding proportion would be close to 20 per cent.

Figure II.7: Per person out-of-pocket expenditure on medicines (% of poverty line income, and average household expenditure)



Source: Estimated from using HIES 2022 data.

III. Pharmaceutical Policies and LDC Graduation Implications

The World Trade Organization's (WTO) TRIPS Agreement provides the global framework governing pharmaceutical policies, setting out minimum standards for regulating various forms of intellectual property as they apply to medicines (TRIPS Agreement, 1994). It specifies how drugs are patented worldwide, ensuring that patent holders typically enjoy an exclusive period of 20 years to manufacture and market their innovations. However, TRIPS also includes provisions for differential treatment of LDCs, allowing them extensions and exemptions to help them meet their public health needs without stringent IP constraints. For instance, LDCs have been granted extensions until at least 2033 to enforce patents and data protection for pharmaceutical products, enabling them to produce or import generic medications affordably. This special consideration under TRIPS is designed to balance the need to stimulate innovation through patent protection with the imperative of ensuring access to affordable medicines in the world's poorest nations.

3.1. Implications of TRIPS Agreement and legislative landscape in Bangladesh in the context of LDC graduation

The TRIPS Agreement, as part of the World Trade Organization (WTO) agreements, encompasses several key provisions relevant to the pharmaceutical sector. It mandates WTO member countries to grant patent protection for pharmaceutical inventions, facilitating the exclusive rights of patent holders. TRIPS also addresses issues such as compulsory licensing and parallel importation, defines patentability and exceptions to patent rights, and provides a framework for balancing intellectual property rights with public health considerations (South Centre, 2011). However, while implementing such flexibilities, some developing countries like Thailand, Brazil, and South Africa faced challenges from pharmaceutical companies. Also, their actions were alleged to be non-compliance with WTO by developed countries (Verma, 2019).

In 2001, the TRIPS council arranged a special session to explain the connection between the TRIPS Agreement and Public Health, prompted by a proposal from its members. Subsequent negotiations between developing and developed nations led to the adoption of the Doha Declaration, which strengthens member countries' flexibility in adopting measures safeguarding public health and facilitating access to essential medicines. While the TRIPS Agreement sets international standards, the specific implementation of these provisions may differ among countries, enabling adaptation to various national contexts. The Doha Declaration (2001) exempted LDCs from the obligation to protect pharmaceutical patents until 2016, and the exemption was further extended until 2033 or the member country's graduation year, whichever eventuality comes first (WTO, 2015). As an LDC, companies in Bangladesh have the liberty

to manufacture any drug, regardless of its patent status. However, after LDC graduation, this privilege will no longer be applicable.

Bangladesh's patent regime has undergone significant evolution. Initially governed by the Patents and Design Act 1911 (PDA 1911), which allowed both product and process patents, policy shifts began with the National Drug Policy (NDP) 1982. The NDP recommended excluding pharmaceutical products from patent protection, but no legal amendment was followed, leaving the recommendation as policy rather than law. In 2008, the Department of Patents, Designs, and Trademarks (DPDT) ceased granting patents for pharmaceutical products and established a mailbox system to store patent applications. Following LDC graduation, Bangladesh would have been obligated to honour these applications retroactively. However, in 2022, the DPDT abolished the mailbox system, along with the applications stored within it, and enacted the Bangladesh Patent Act 2022 to comply with TRIPS requirements. A year later, the BPA 2023 replaced this legislation, further refining the country's patent framework.

Apart from adopting BPA 2023, Bangaldesh also adopted a new law namely Bangladesh Drug and Cosmetics Act 2023. According to this law, foreign firms without a factory in Bangladesh can manufacture authorised drugs by entering contract manufacturing or loan license only for export, and such drugs cannot be marketed locally (Drugs and Cosmetics Act, 2023). This implies foreign firms must have a factory in order to sell the drug domestically. Such regulations violate the national treatment principle. Hence, after LDC graduation, Bangladesh will have to amend this act and accommodate foreign suppliers to sell their medicines without requiring domestic productive capacity.

LDCs are allowed to export patented drugs where patents do not cover medicine or where compulsory licensing is permitted without the patent holder's consent (Gay, 2017). After graduation, Bangladesh may export patented drugs by using compulsory licensing for export, given that the importing country also issued such licensing (Urias & Ramani, 2020). In addition, Bangladesh provides export incentives for pharmaceutical exports. Exporters get a 10 per cent incentive on API exports and 8 per cent for pharmaceutical products (Bangladesh Bank, 2024). Such incentives do not comply with the WTO Agreement on Subsidy and Countervailing Measures (SCM) (SCM Agreement, 1994). Article 39.3 of the TRIPS Agreement mandates member countries to safeguard undisclosed test data from unfair commercial practices. However, as per Section 66 of the Drug and Cosmetic Act 2023, stakeholders are obligated to submit test data to licensing authorities without clear guidelines on how the data will be protected, which is non-compliant with the TRIPS Agreement (Azam, 2012; Rahman & Farin, 2018). To align with TRIPS requirements, specific provisions pertaining to data protection must be incorporated (Islam, 2013).

Table III.1: Compliance of Bangladesh's patent and drug law with WTO

Issues	Current Practice	WTO compliant
Patent protection	Bangladesh's current Patent Act 2023 does not cover pharmaceutical products.	No. After graduation, pharmaceutical patents must be required.
Patent Duration	Bangladesh currently provides a patent duration of 20 years.	Yes
Manufacturing on-patented drug	Bangladesh can manufacture without the right holder's consent.	Possible, through compulsory licensing.
Export of patented drug	Bangladesh can export patented drugs to LDC or any country where patents do not cover them.	Possible, through compulsory licensing for export
Export subsidy	Producers receive incentives based on export performance.	No. This is a violation of the WTO's SCM Agreement.
Test data protection	Currently, there is no provision in IP or drug laws on how regulators will safeguard test data.	No. Under the TRIPS Agreement, test data must be protected.
Export performance requirement for MNC	MNCs with no production facility in Bangladesh can only produce medicine for export purposes.	No. This is a violation of TRIPS Agreement Article 3 national treatment.

Initially, under the TRIPS agreement, various measures are in place to mitigate negative consequences. The Doha Declaration in 2001 reaffirmed the existence of several flexibilities. (WTO, 2001). These provisions are intended to allow member states to protect public health interests even after TRIPS is fully implemented. Member countries capitalise on these flexibilities by incorporating them into their patent laws. Table III.**2** lists the public health-related flexibilities available in the TRIPS Agreement:

Table III.2: Flexibilities under the TRIPS Agreement

Measure	Define
Choice of patentability criteria	WTO members have considerable policy space to define what an invention is and to apply rigorous standards of patentability to avoid the grant of patents that, without making a genuine technical contribution, may distort market competition.
LDC waiver	LDCs are exempted from providing patent protection for pharmaceuticals until 2033 or the date of LDC graduation, whichever comes first.
Compulsory licensing (CL)	Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself.
Government use authorisation	In many cases, governments have the right to use patented inventions for non-commercial purposes, such as ensuring the supply of essential medicines.

CL for the supply of medicines to countries with a lack of or insufficient manufacturing capacity	Compulsory licenses exclusively for the export of medicine can be granted under the amendments introduced to TRIPS Agreement in 2017 and the waiver adopted by the WTO in 2003. Previously, CL could be issued for supplying medicine to domestic market only.
Test data protection	The TRIPS Agreement (Article 39.3) requires WTO members to protect test data against unfair competition, which does not create exclusive rights.
Parallel importation	Importing protected medicines from any country where they can be purchased cheaper than locally is consistent with the TRIPS Agreement.
Pre and post-patent grant opposition	Procedures before patent office provide for the possibility for third parties to contribute to the examination process through "observation" or "opposition", whether before or after the grant of a patent or both.
Use of competition law to address the misuse of IPRs	Competition law may be applied to correct market distortions created through the abuse of IPRs.
Bolar exception	WTO members can use a patented medicine for the purpose of conducting research and tests for regulatory approval for generic medicines so that they can enter the market as soon as possible after the expiry of the patent.
Experimentation exception	The experimentation exception is permissible under TRIPS, but it may be formulated with different scope and conditions. The allowed acts would vary depending on the formulation of the exception. It will be important to implement exceptions that, as a minimum permit research on an invention for commercial and non-commercial purposes.
Disclosure requirement, particularly for biologics	The full and precise disclosure of an invention is crucial for the patent system to perform its informational function. Deficient disclosure may unjustifiably extend the coverage of a patent and prevent legitimate acts by third parties. This is particularly relevant for biologicals, which cannot be described in the same way as medicines produced by chemical synthesis.
Flexibilities in enforcement of IP	Measures to enforce IP -such as reversal of the burden of proof, determination of damages, border measures- if overly broad, may distort competition by discouraging or preventing market entry and the availability of generic medicines. However, there is room to design such measures in a manner that is fair and equitable to all parties engaged in administrative or judicial procedures regarding IP.
Security exception	Compliance with obligations under the TRIPS Agreement can be suspended, among other things, in cases of emergency in international relations, such as in the case of pandemic (Articles 73 (b) of the Agreement).

Source: Adopted from South Centre (2018) Correa & Hilty (2022)

Among these flexibilities, compulsory licensing is the most used flexibility among developing and developed countries in order to ensure affordable medicine. Between 2001 and 2016, there were 176 occurrences where 89 countries implemented TRIPS flexibilities and non-patent related measures ('T Hoen et al., 2018). Out of these instances, 100 involved the

adoption of compulsory licensing and public non-commercial use licenses. The grounds upon which compulsory licenses can be granted are not limited by TRIPS. Article 5 of the Doha Declaration clearly states that the members have the right to determine what constitutes a national emergency. Many studies in the literature have reported the impact of implementing compulsory licensing on reducing drug prices. Research conducted in various developing countries, including Brazil, Ecuador, India, Indonesia, Malaysia, Thailand, and Zimbabwe, has indicated that prices could decrease by 6.7 to 98 per cent for different medicines due to the issuance of compulsory licensing (Urias & Ramani, 2020). Even the study highlighted that compulsory licensing is more effective in achieving price reduction than domestic production.

Parallel importation is another important flexibility a country could use that gives importing countries negotiation power over the patent holder. Manufacturers often discriminate prices among countries based on income, market share, and other relevant factors. A country with limited resources can afford more branded medicine by allowing parallel importation. However, the parallel importation only applies to countries that follow international or regional exhaustion regimes (Bonadio, 2011). A study examining the German market revealed that prices of patented drugs decreased through parallel importation, though no significant impact was observed on generic drug prices (Duso et al., 2014). Similarly, in Sweden, on-patent drug prices fall by 15 to 17 per cent due to parallel import (Granlund & Koksal-Ayhan, 2015).

Bangladesh's new Patent Act incorporates several TRIPS flexibilities that were inadequately addressed in the previous two laws. Additionally, the earlier laws contained provisions that were inconsistent with WTO standards, which the new Act seeks to rectify. For instance, the Patent and Design Act 1911 lacked a clear definition of inventions, which could lead to issues like evergreening.[3] Also, the grounds for issuing compulsory licensing were limited. Thus, a new patent act was required to address these issues and exploit the TRIPS flexibilities without violating WTO principles. The new patent law incorporates provisions enabling Bangladesh to benefit from TRIPS flexibilities post-LDC graduation. Table III.**3** below summarises the flexibilities Bangladesh could take benefits from after LDC graduation to tackle any adverse situation.

Table III.3: Scope of utilising TRIPS flexibilities under Bangladesh's patent law

TRIPS Flexibilities	Have Bangladesh incorporated in IP law?	Define

[3] According to the Patent and Design Act 1911 invention is defined as any manner of new manufacture and includes an improvement (Patents And Designs Act, 1911).

Choice of patentability criteria	Yes.	Section 2(6) of BPA 2023 defines an invention as a new product or process which involves inventive steps and industrial application. This definition reflects article 27 of the TRIPS, which provides novelty, inventive steps and industrial application as preconditions for patentable products or processes.
LDC waiver	Yes.	Section 6(2) of BPA 2023 provides that Bangladesh will not provide any patent protection to pharmaceuticals and agrochemical products as long as it receives waiver under the decisions of the TRIPS Council.
Compulsory license	Yes.	The BPA 2023 provides in section 36, a detailed list of cases in which compulsory license can be issued against any product, including public interest, national security, nutrition, development of any essential sector of the national economy, anti-competitive practice, abuse of exclusive right, the patentable invention is not available to an adequate extent or at a predetermined reasonable price, and a patent cannot be exploited without infringing another patent. Compulsory license can also be granted in case of non-working of the patent and essential services, which include the production and marketing of fixed-dose combination (FDC) drugs. Before obtaining the compulsory license, it is mandatory to attempt to secure license from the patent owner at a just commercial condition. Moreover, the compulsory license will be non-exclusive and non-assignable.
Government use authorisation	Yes	Section 38 of BPA 2023 states that the government can also declare compulsory license in cases of national emergency, other cases of extreme urgency and non-commercial use. The Act further elaborated the phrase 'urgency' as to include international health emergencies, HIV, pandemics, cancer, diabetics, tuberculosis and other related drugs.
CL for the supply of medicines to countries with a lack of or insufficient manufacturing capacity	Yes	Section 39 of the BPA 2023 specifies that a compulsory license can be granted for export purposes to provide medicine to countries lacking manufacturing capacity.
Parallel importation	Yes	Section 60 of the BPA 2023 allows parallel importation of patented foreign products. It also states that Bangladesh follows an international exhaustion regime. This is a prerequisite of parallel importation. TRIPS includes this flexibility in Article 6.
Pre and post-patent grant opposition	Yes	The BPA 2023 permits any concerned individual to lodge an opposition against a patent application on specified grounds.

		Sections 19 and 20 outline the grounds and procedures for pre- and post-patent opposition.
Use of competition law to address the misuse of IPRs	Yes	Section 36(2) states that compulsory licensing could be employed to rectify patent misuse resulting from a lack of competition.
Experimentation exception and Bolar exception	Yes	Article 62 of the BPA 2023 covers research exception flexibilities.

Source: Author analysis based on Bangladesh Patent Act, 2023.

3.2. TRIPS and medicine affordability

In the previous subsection, we discussed some of the facilities that will be unavailable after the LDC graduation. These changes will affect producers and consumers in several ways. Numerous studies have been undertaken to assess the impact of the TRIPS Agreement on drug prices and accessibility. This subsection examines both quantitative and qualitative literature published after 2005 to comprehensively understand the impact. Developing countries were mandated to reform their IP laws by 2005; hence, only studies published after the patent reform were considered. Quantitative studies aid in estimating precise price changes, while qualitative studies provide insights into how these changes may impact consumers. Current literature predominantly focuses on the impact of TRIPS-compliant intellectual property rights (IPR) on price, affordability, and accessibility for selected developing countries, including India, Brazil, Thailand, and South Africa. The emphasis on these particular nations stems from the limited number of developing countries with a substantial pharmaceutical industry that significantly contributes to the domestic economy.

Various quantitative studies have confirmed that a more robust IPR regime leads to an escalation in the prices of essential drugs, however, at different magnitudes. In a study by Islam et al. (2022), the estimation using a micro-founded model indicates an eightfold increase in insulin prices, taking into account behaviour and expenditure patterns. The study suggests that such price hikes may result in reduced welfare and increased poverty in households with diabetic patients. Another study by Chaudhuri (2019) compares drug prices before and after patent expiration in India. The results indicate a significant decrease, ranging from 74 to 94 per cent, in the prices of specific drugs following the expiration of patents. However, the study highlights certain drugs, despite the expiration of their patents, continue to be sold at high prices due to the absence of generic producers. In contrast, Duggan et al. (2016) discovered that drug prices in the Indian market increased after the reform of patent laws, although not to the extent estimated by the two aforementioned studies. Analysing drug prices spanning from 2003 to 2012, this study revealed that the prices did not rise as significantly as

anticipated. Dutta (2011) computes the effect of patent enforcement on prices, consumer surplus, profits, and social welfare for 43 medicines in the Indian market. The results indicate a trade-off between intellectual property protection and consumer welfare. While foreign companies benefit financially from patent protection, a major section of the population's access to medications and consumer welfare is severely compromised.

A systematic review paper found that despite price Increases due to patenting, future accessibility will increase as patent protection will incentivise producers to introduce new drugs in the market (Yamabhai & Smith, 2012). A study found that after reforming their patent law to be compliant with the TRIPS Agreement, drug prices increased in India and Brazil (Strand, 2014). This is primarily due to the extended patent term, causing delays in generic manufacturing. While allowed under the agreement, compulsory licensing had consequences, as observed in Thailand, as the pharmaceutical company had withdrawn the pending patent application for the Thai market as a punishment. However, availability did not improve in any of the case studies, suggesting that it remained restricted by both high prices and other factors.

While the TRIPS Agreement requires providing member countries with a minimum level of protection, the TRIPS Plus provision requires more stringent requirements for the partner countries. The provision under TRIPS Plus typically involves additional intellectual property protections that go beyond what TRIPS mandates. These provisions may include stricter patent laws, longer patent terms, data exclusivity/market exclusivity, and enhanced enforcement measures. These provisions result in significant monopolisation within the pharmaceutical sector, hindering the accessibility and affordability of medicine (Tenni et al., 2022). An examination concentrating on the consequences of price and accessibility in Thailand's local market, attributed to TRIPS-Plus, reveals that the presence of generic drugs resulted in a cost-saving of approximately 104.5 per cent and an accessibility increase of 53.6 per cent in 2003 (Akaleephan et al., 2009). This study further contends that the extended period of exclusivity under TRIPS-Plus will diminish both savings and accessibility.

Kesselheim & Solomon (2010) carried out a retrospective study to assess the impact of market exclusivity of Colchicine on medicine access. The Colchicine manufacturers were found to have increased their price by more than fifty times after receiving the market exclusivity, negatively affecting medicine access to the patients. It was also expected to affect accessibility negatively as it was found that the new price can add up to $50 million per year to insurance budgets, where insurance providers are actively trying to cut down costs. Another study employed retrospective econometric modelling to estimate the increase in cost resulting from extending the market exclusivity period for six months for three classes of medicine over an

18-month period after the patent's expiration (Nelson et al., 2011). The result was found to increase Medicaid[4] costs by $2.2 million for the state of Utah and $430 million (in 2007 prices) for the whole of the United States' Medicaid population. This increase in cost was expected to lower accessibility to the general population. The anticipated price decline due to the non-extension of market exclusivity was estimated to range from 3.8 to 24.4 per cent for various classes of medicines. A similar study by Kesselheim et al. (2006) explored the impact of patient extension on medical expenditure due to the slow introduction of generics ”nd s'bstitutions in the USA. The study found $1.5 billion, which is the equivalent of an increase in Medicaid expenditure in 2000-2004 due to the price hike, shortage of available generics, and delay in adopting substitutes resulting from an extension of IP protection.

For Canada, a modelling exercise to assess the impact of patent extension on the country's national expenditure reveals a cost increase of 392 million Canadian dollars had the two-year patent extension been implemented in 2015, making medication hard to access by the general population (Bagnol & Busby, 2018). A prospective modelling approach involves creating a hypothetical scenario to predict future outcomes using various parameters, assumptions, mathematical models, and simulations. Following a different method, Harris et al. (2013) employed retrospective econometric modelling, where historical data is analysed to understand the economic impact of certain interventions or treatments to assess the effect of increasing patient duration on the accessibility of pricey drugs in Australia. The study has found the cost of extending patients to be around 240 million Australian dollars in the medium term for 2012-'13 in 2012 dollars. These studies suggest that patient extensions increase costs to the consumers as such extensions reduce generic competition, and these higher levels of price and lower levels of availability of substitutes negatively affect access to medicines for the general population.

Amin & Kesselheim (2012) assess the impact of secondary patenting on market exclusivity and generic competition on two different antiretroviral medicines. The analysis showed that secondary patenting could delay the introduction of generics after patent expiration, negatively affecting the introduction and availability of generics and hampering competition in the market. Moir's (2016) empirical case study discovered that evergreening resulted in the transfer of AUD 150 million from Australian taxpayers to the pharmaceutical company and incurred a cost of approximately AUD1.1 billion over eight years due to the delayed availability of generic

[4] A medical joint federal and state program of the United States that provides insurance facilities for children and adults belonging to households with limited income. This program is different from the federal Medicare program that mostly provides health insurance for elderly people aged 65 and above (Sommers & Grabowski, 2017)

medicines, particularly because of the secondary 'evergreening' of a specific medicine named Omeprazole. Such increases in medicine prices and inadequate availability and cheap alternatives are usually associated with lower levels of accessibility.

Table III.4: Impact of TRIPS compliance on the price and affordability of medicines

Study	Objective	Method and data source	Result
Islam et al. (2022)	Estimate the effect of Bangladesh's LDC graduation on the price of insulin in terms of price, welfare, and poverty rate	Quadratic Almost Ideal Demand System (QUAIDS) and used Household Income and Expenditure data.	The price of insulin could rise by 8 times, causing a 5 to 50 per cent welfare loss and increasing the poverty rate from 20 to 36 per cent for households with diabetic patients.
Chaudhuri (2019)	Assess the impact on drug prices in the Indian market after TRIPS compliance	Drug price comparison before and after the patent expired	-Substantial reduction in drug prices after the drug goes out of patent. -Due to a lack of competition, the originator sold the medicine at a high price, despite the drugs being off-patent.
Duggan et al., (2014)	Examine the effects of the 2005 implementation patent of products in India on pharmaceutical prices and quantity sold.	OLS regression analysis using pharmaceutical sales data from 2003 to 2012	Implementation of patent protection led to slight increases in the price of medicine, following a slight decrease in quantity sold.
Akaleephan et al., (2009)	Quantify the impact of the extension of exclusivity in Thailand on medicine expense and medical accessibility.	Estimating costs and accessibility using data from the Thai FDA and the Drug & Medical Supply Information Centre	The TRIPs-Plus proposal would result in a significant increase in medicine expenses and a delay in the increase in drug accessibility via generics.
Yamabhai & Smith, (2012)	Review the implication of patent protection on health and economy globally, with a particular focus given to Thailand.	Systematic literature review of 43 papers	Patenting -increase the price, but the magnitude of change differs based on the methodology and country -increases the future accessibility of medicine as manufacturers have an incentive to introduce new drugs in the market.
Strand (2014)	Analyse the effects of TRIPS on selected	Mixed method	-Drug price increase in India and Brazil

	countries by examining the extension of patent terms, delaying generic manufacturing in Brazil, India, South Africa, and Thailand.		-Brazil experienced a supply shortage of patented drugs and subsequent price hikes after being TRIPS-compliant.
Dutta (2011)	Examine the welfare implication of a weak patent system to a strict patent regime in the Indian pharmaceutical industry.	Structural demand and supply model using drug sales data	-There is significant heterogeneity among firms within and across different therapeutic segments, predicting small gains in profits for the global patent holders while large losses for consumers.
Kesselheim & Solomon (2010)	Examine the impact of market exclusivity on drug accessibility in the USA.	Retrospective study	-Higher prices can lead up to $50 million of additional expenses in the insurance budget per year.
Nelson et al. (2011)	Estimate the increase in cost resulting from data exclusivity extension in the USA.	Retrospective economic modelling	-Increased medical costs by $2.2 million for the state of Utah. - Increase of $430 million for the whole of USA (in 2007 prices). -Market could have enjoyed a decrease in price by 3.8 to 24.4 per cent for different medicine classes had the exclusivity not been extended.
Kesselheim et al. (2006)	Estimate the increase in medical expenditure due to patient extension in the USA.	Retrospective economic modelling	-$1.5 billion is the equivalent of an increase in the government's medical expenditure resulting from price hikes and lower availability of generics.
Bagnol & Busby (2018)	Assess the impact of patient extension on national expenditure in Canada.	Prospective modelling	-National expenditure for medical care would have increased by CAD 392 million, making medication hard for the population to access.
Harris et al. (2013)	Estimate the effect of patient extension on cost of expensive medicines in Australia	Retrospective econometric modelling	-Extending the patient would have increased expenses by AUD 240 million in the medium term of 2012-13 (in 2012 dollars).
Amin & Kesselheim (2012)	Examine the impact of secondary patenting on accessibility and competition in the USA.	Retrospective study	-Secondary patenting can delay the introduction of generics by a period of 12 years -Slower entry of generic variation negatively affects market competition and accessibility for patients.

Moir (2016)	Estimate the cost of 'evergreening' through secondary patenting in Australia.	Retrospective empirical case study	-Evergreening transferred around AUD 150 million from taxpayers to pharmaceutical industries. -Cost around AUD 1.1 billion in 8 years due to delayed availability of cheaper alternatives.

3.3. Impact of intellectual property rights (IPR) policy changes on the pharmaceutical industry

A prospective evaluation specifically centred on Bangladesh's graduation from the LDC status emphasised that the pharmaceutical industry would encounter heightened competition from MNCs following the reform (UNDESA, 2020). Various policy measures have shielded Bangladesh's pharmaceutical industry from foreign competition; however, post-LDC graduation, these measures will be deemed inconsistent with the principles of the WTO. Additionally, the analysis underscored that pharmaceutical exports from Bangladesh are likely to decrease post-graduation due to the cessation of flexibilities for LDCs under various agreements of WTO.

One notable change addressed in many studies is that more funds have been invested in research and development (R&D) after a country reforms its IPR regime. Bedi et al. (2013) examined the effect of revised IPR in India's pharmaceutical industry and found that investments in both R&D and innovation increased in the post-TRIPS era. However, the increase was mostly concentrated in larger firms with technologically rich capacity, and the SME firms were found struggling to adapt to the new developments of the policy. Horner (2014) conducted a firm-based study and found that after 2005, firms were more focused on innovation by domestic firms collaborating with the MNCs. However, the study found that R&D investment for neglected diseases remained low after 2005. These findings echo the findings of Kyle & McGahan (2009). They also found that the R&D investment in the pharmaceutical industry improved after the TRIPS Agreement in wealthy countries. However, in developing countries, R&D for neglected diseases has not improved after the patent's introduction. Another study on the Indian market came up with similar findings (Joseph, 2012). Despite various initiatives, such as public-private partnerships, soft loans, grants, and incentives, the development of new drugs remains low in India.

Nauriyal (2006) found that the new TRIPS-compliant laws have increased expenditure on R&D in India, with larger firms choosing the strategy of cooperation and competition to smoothly shift from reverse engineering to new drug development. The paper also suggests that demand for contract work, such as developing drug delivery processes and clinical trials, from foreign

firms to India will increase due to its new patient regime. The findings match those of Kamiike (2020), who assessed the impact of TRIPS compliance on India's pharmaceutical industry's growth within a Global Value Chain framework and found India's R&D expenditure to Increase along with collaboration with foreign firms. Additionally, it indicates a shift in India's R&D focus, now emphasising lifestyle diseases rather than local tropical diseases.

Gamba (2017) found that the number of innovations rises following the introduction of IPR protection. By analysing data from 74 developed and developing countries, Gamba found that both groups of countries profit from their innovation but at different levels. Developing countries benefit less compared to developed countries due to their low capabilities to maintain a strong IPR regime. However, Pandey & Paul (2019) found that after strengthening the IPR regime, patent filing in low- and middle-income countries saw a decline.

Chaudhuri et al. (2006) employed detailed product-level data to calculate price elasticities and supply-side parameters. These calculations were then utilised in counterfactual simulations to estimate prices, firms' profits, and welfare losses. The estimated welfare loss ranged from a lower limit of $144 million to $450 million, with a small portion attributable to domestic firms. Interestingly, in some cases, domestic firms experienced increased profits as consumers shifted to other domestically produced molecules due to product withdrawals resulting from patent protection. For consumers, the primary source of welfare loss was the reduction in variety, and switching among sub-segments only had limited efficacy in mitigating this loss.

In terms of trade, Smith et al. (2009) found that developed countries benefited from exporting patented drugs as developing countries could not produce them. Also, it has been highlighted that developing countries often do not use available flexibilities under the TRIPS Agreement due to a lack of domestic resources and capacity and often rely on foreign donors. A similar finding was also observed in the Indian market. India saw a negative export growth of pharmaceutical goods after the patent regime changed (Jafar & Sajna, 2018). Also, foreign firms operating in India focused more on selling imported drugs to domestic markets than focusing on exports. The existing literature on this matter primarily concentrates on the Indian scenario, indicating that stronger Intellectual Property Rights (IPR) tend to undermine domestic firms within the industry. Jafar and Sajna (2018) assert that since India complied with TRIPS in 2005, multinational corporations (MNCs) have displayed heightened interest in the Indian market, leading to numerous acquisitions of domestic firms by these MNCs. This increased MNC presence has correlated with a decline in competition. Given that MNCs hold a substantial number of patents, it has granted them monopolistic power and comparative advantage, thereby weakening domestic firms. Strand (2014) corroborates these findings in their India-focused case study, revealing that enhanced collaboration and takeovers by MNCs in the

Indian pharmaceutical market, coupled with the expiration of some common patents, have diminished competition and resulted in increased prices of essential medicines since 2005.

Table III.5: Impact of IPR regime change on the pharmaceuticals industry

Author	Objective	Method and Data	Result
UNDESA (2020)	To assess the possible impacts of the graduation of Bangladesh from the category of LDC	Based on various empirical studies	-An increase in healthcare costs is anticipated due to a lack of competition with the reinstatement of the patent regime for pharmaceuticals. -Potential impact on domestic API production as the domestic market opens to MNCs after the reform. -Possibility of increased competition for local manufacturers if MNCs enter the domestic market, potentially leading to their weakening. -Anticipated decrease in pharmaceutical exports attributed to the absence of preferential market access and the discontinuation of patented drug production.
Horner (2014)	Assessing how the Indian pharmaceutical industry responded to extensive patent protection in 2005	Firm-based assessment, including stakeholders' interview	After 2005, -firms were more concentrated on innovation, mostly to capture the global North market. -FDI increased -Collaboration with MNCs -Price increased for small number of medicines -R&D for neglected diseases remained low.
Joseph (2012)	Assessing the effect of TRIPS-compliant policies on the Indian pharmaceutical industry	Discussion paper	-R&D for neglected diseases declined after the reform. -FDI increased for conducting trials, and technological transfer improved marginally.
Kyle & McGahan (2009)	Assess the effect of increased level of IP protection on the R&D effort for neglected diseases across all countries	Negative binomial regression model	-Patent protection in developing countries and LDCs does not increase investment for neglected diseases.

Gamba (2017)	Analysing the impact of IPR protection on pharmaceutical domestic innovation in developed and developing countries	Used negative binomial model	-The introduction of IPR protection, particularly TRIPS-compliant protection, leads to a significant increase in domestic innovations, with a more than 58 per cent rise in weighted applications in developed countries.
Pandey & Paul (2019)	The study aims to assess the impact of pharmaceutical product patent laws in the TRIPS agreement on number of patent filings in 65 high-, middle- and low-income countries	Negative binomial model	-The number of pharmaceutical patents filed has decreased after TRIPS compliance, with a larger decline in upper-middle and lower-middle-income countries than in low-income countries. There is an increasingly declining trend of low patent activity across low- and middle-income countries.
Chaudhuri et al. (2006)	-Investigate the welfare effect in the Indian pharmaceutical industry to enforce TRIPS requirement	Counterfactual simulations using product-level data	- The enforcement of product patents under the TRIPS agreement is associated with substantial welfare losses to the Indian economy, primarily driven by the loss of consumer welfare. -Domestic firms often make small profits as consumer substitutes for domestically manufactured drugs due to the unavailability of some patented drugs.
Smith et al., (2009)	Examine whether the TRIPS agreement has an impact on developing country's pharmaceutical export.	Exploratory data analysis of the pharmaceutical industry from developed and developing countries	The unequal trade between developed and developing countries in the pharmaceutical market raises concerns about access to medicines, exacerbated by TRIPS-plus provisions.
Jafar & Sajna (2018)	Examining the impact of strengthening India's IPR regime on their pharmaceutical trade.	Exploratory data analysis and literature review	-India's pharmaceutical exports decreased, whereas branded drug imports increased. -Access to medicine declined due to higher prices.
Bedi et al. (2013)	Examine the effect of TRIPS-compliant laws on the R&D behaviour of firms in India	Retrospective study	-Large pharmaceutical firms with high technological capacities are increasing R&D expenditure and innovations -SME firms are struggling to cope with the new laws.
Nauriyal (2006)	Examine how pharmaceutical firms	Retrospective study	-Firms are moving to cooperation and competition to smoothly shift from

	are adopting to TRIPS compliant laws in India		reverse engineering to original inventions. -There has been an increase in demand for contractual work in India from foreign big pharmaceutical.
Kamiike (2020)	Examine the impact of TRIPS-compliant IPR laws on the R&D approach of the pharmaceutical industry in India	Discussion paper using the global value chain (GVC) framework	-Share of revenue spent on R&D by large firms has increased, -R&D has been focused on medicines with markets in high-income countries.

IV. Methodologies and Estimation Frameworks

The study employs a combination of qualitative and quantitative methods to accomplish the objectives outlined in the terms of reference. Qualitative methods encompass an extensive desk review, Key Informant Interviews (KIIs), and consultations with relevant stakeholders through focus group discussions (FGDs). Quantitative approaches involve the application of the Quadratic Almost Ideal Demand System (QUAIDS) to estimate the price elasticity of medicine demands in Bangladesh. Additionally, panel regression analysis is utilised to explore the impact of Bangladesh's LDC graduation on medicine exports in the post-graduation period.

A descriptive trend analysis has been conducted to comprehend the current state of the pharmaceutical industry in Bangladesh. The study also employs Computable General Equilibrium (CGE) to simulate the effects of LDC graduation on the pharmaceutical industry. This section provides a detailed discussion of these methodologies.

4.1 Qualitative methodology

This study conducted an extensive review of literature pertinent to the issues linked with the WTO's TRIPs Agreement, legal provisions in Bangladesh, and concerns regarding medicine accessibility and affordability resulting from adherence to the global patent protection regime. Efforts were made to understand how Bangladesh's IPR laws have been adapted to comply with WTO regulations. Secondary data from published articles and other sources, such as the International Trade Centre, were utilised in the review process.

As part of the study, consultation meetings and key informant interviews (KIIs) were held with pharmaceutical and legal experts in the country. Key informants were questioned using a checklist that covered both the legal and economic impacts of LDC graduation on the costs, prices, and accessibility of medicines, as well as the broader implications for the industry itself.

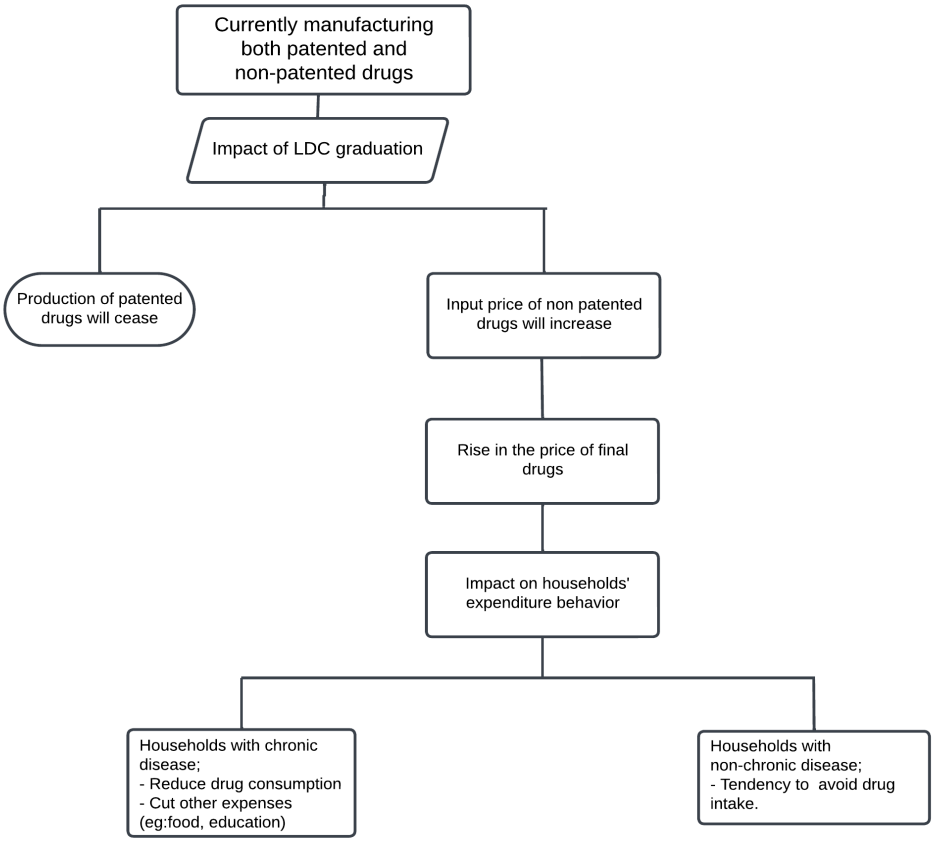
4.2 Quantitative methodology

Different quantitative methods have been applied to investigate various impacts of LDC graduation on access to medicine and the pharmaceutical sector in Bangladesh. To estimate the impact on access to essential medicine, it is necessary to compute the own- and cross-price elasticities of medicine demands in Bangladesh. Households can purchase less than the required number of medicines or reduce consumption of food or their essential expenditure items like education when faced with the higher prices of medicine. It is also important to capture these substitution patterns (see Figure) to assess the effect of LDC graduation on access to medicine.

4.2.1 Effect on access to medicine

Evaluating the impact on the local market involves analysing the patterns of household demand and expenditure behaviour. We hypothesise that with Bangladesh's graduation from the LDC status, the cost of producing medicines domestically will increase, subsequently leading to an increase in the prices of the medicines. We anticipate that this alteration may instigate a shift in household consumption behaviour. Specifically, households grappling with chronic diseases might either cease their medication intake or reduce other expenditures, such as food and education (Figure). Conversely, households not afflicted by chronic diseases might exhibit a propensity to forgo the prescribed drugs. This situation is particularly relevant to households subsisting at the poverty level.

Figure IV.1: Channels of the impact of LDC Graduation on access to medicine in Bangladesh



To capture these various types of substitutions, we use the latest Household Income and Expenditure Survey (HIES) data and a Quadratic Almost Ideal Demand System (QUAIDS) framework to estimate the price and income elasticities of major expenditure items, such as food, education, and medicine costs for households with members suffering from chronic and non-chronic diseases. We use the QUAIDS framework as in Islam et al. (2022), which is based on the indirect utility function as presented in the study by Banks et al. (1997). The detailed methodology is given in Annex A2.

To measure the impact of the increase in medicine prices because of LDC graduation on the accessibility and affordability of medicines, we estimate the current and post-LDC graduation monthly health expenditure at the household level. Thus, by comparing monthly health expenditures before and after LDC graduation, we can estimate the proportion of households that fall below the poverty line due to Bangladesh's LDC graduation.[5]

[5] Catastrophic health expenditure refers to a situation where an individual or household incurs healthcare costs so high relative to their income or economic capacity that it results in severe financial hardship. This concept is often

4.2.2 Effects on the export of medicines

Bangladesh exports generic versions of off-patent medicines worldwide, including to some developed countries like the USA, Canada, etc. Generic versions of on-patent medicines are also exported from Bangladesh to other LDC countries. In the post-LDC period, Bangladesh could no longer export generic versions of on-patent medicines. For off-patent medicines, Bangladeshi pharmaceutical firms can export them but will face stricter competition, as the costs of producing these medicines could increase following LDC graduation, as explained in the previous section. Using data from Bangladesh Customs and the International Trade Centre (ITC), we identify the current exports of on-patent medicines from Bangladesh to other LDCs. The export income from this trade will be lost in the post-LDC period. To measure the impact on the exports of off-patent medicines, we estimated the demand function for Bangladeshi medicines in the rest of the world using data from Bangladesh Customs and ITC. Specifically, we estimated the following fixed-effect panel regression:

$$lnExport_{it} = \alpha_i + \delta_t + \beta_1 lnPrice_{it} + \beta_2 lnPGDP_{it} + u_{it} \quad (1)$$

Where $lnExport_{it}$ is the log of the amount of exports to country *i* in year *t*, $lnPrice_{it}$ is the corresponding log of the price of medicine, and $lnPGDP_t$ is the world GDP in year t in log. β_1 in (8) is the price elasticity of Bangladesh's exports of medicines. To estimate the potential loss in the export of medicines following the LDC graduation, we use the post-LDC estimates of medicine prices from the previous section, the cessation of export incentives, and the results of (1). This allows us to predict the loss in the intensive margin of medicine exports.

4.2.3 Effects on the prospects of the pharmaceutical industry

Upon graduating from the LDC status, Bangladesh will be required to adhere to TRIPS regulations, necessitating the reinstatement of pharmaceutical patents and a review of pertinent laws. This adjustment may potentially result in an increase in drug prices and healthcare expenditures. The post-graduation landscape may present challenges such as a rise in Active Pharmaceutical Ingredients (API) prices, potential industry consolidation, increased import

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defined by out-of-pocket health-related expenses that exceed a certain percentage of a household's income. Such expenditures can lead to economic distress, impoverishment, or create barriers to accessing necessary healthcare services. According to the World Health Organization (WHO), "Catastrophic health expenditure occurs when a household's financial contribution to the health system is large relative to its ability to pay, often defined as exceeding a certain percentage of a household's income or capacity to pay" (WHO, 2010). This definition was further discussed in the WHO report, "Making Fair Choices on the Path to Universal Health Coverage: Final Report of the WHO Consultative Group on Equity and Universal Health Coverage"(WHO, 2014).

competition, and impacts on exports due to higher production costs and the need to comply with TRIPS. Post-graduation, Bangladesh will lose preferential market access in numerous destination countries, resulting in a hike in tariff rates. It will no longer be able to provide export subsidies, which are presently set at 10 per cent for API exports and 8 per cent for other medicinal exports (Bangladesh Bank, 2024). The loss of preferential market access and export subsidy could affect the industry's export competitiveness and reduce incentives for exporting. This will also affect domestic production, employment, exports, and investment in the pharmaceutical sector.

To analyse the economic impact of LDC graduation on Bangladesh's pharmaceutical industry and its implications for the local drugs market, we employed a Computable General Equilibrium model, more specifically, a standard version of the Global Trade Analysis Project (GTAP) model. GTAP is a multiregional, multisector model and accounts for linkages between economic agents–including households, governments, and the rest of the world. This widely used modelling approach was designed and developed by the Centre for Global Trade Analysis, Purdue University (Hertel, 1997). The GTAP model is widely employed to analyse the impact of global and regional trade policy changes.

The GTAP model is impactful in performing a comprehensive evaluation of a policy or regulatory shock. On the production side, the model assumes perfect competition and constant returns to scale. The production for every sector and every region in the model is identified and represented by a Constant Elasticity of Substitution (CES) function. It also works based on the Armington assumption and so, each firm employs a CES composite of domestic and imported intermediate goods in fixed proportions with endowment factors or value-added commodities like land, labour, capital, natural resources, etc.

On the demand side of the model, total income is distributed following a fixed share across households, government, and savings expenditure. The model captures supply-demand linkages and equates them by accounting for changes in production, consumption, exports, and imports. The behavioural equations in the model dictate production, private consumption, exports, imports, and market-clearing conditions that equate supply with demand. Elasticities determine the substitution between various input and output parameters in the production and consumption behavioural equation. Elasticities used by the GTAP model are determined from data and literature.

V. Explanation of Results

5.1 Stakeholder's perspective on LDC graduation and its implication on pharmaceutical sector

The pharmaceutical industry in Bangladesh has undergone significant transformations over the years, driven by both domestic policy interventions and external factors. However, the impending graduation from LDC status brings forth a new set of challenges and constraints for the industry. The international trade regime for the pharmaceutical sector, governed by the WTO Agreement on TRIPS, establishes a minimum global standard of IPR protection. LDCs, including Bangladesh, have benefited from transition periods and waivers under the TRIPS Agreement, enabling them to nurture their pharmaceutical industries without implementing patent protection for pharmaceutical products. Nonetheless, LDC graduation will terminate these transition periods and waivers, presenting challenges for Bangladesh's pharmaceutical sector.

Post-LDC graduation, pricing dynamics and competition within the pharmaceutical industry are expected to undergo significant changes. The enforcement of patent protection is likely to escalate the production costs of patented drugs, resulting in higher prices and reduced accessibility for consumers, especially for essential medicines. The heightened involvement of MNCs and the removal of import restrictions may intensify market competition, posing challenges for local manufacturers. Additionally, the limited capacity in R&D and technology transfer could impede innovation and hinder the sector's competitiveness.

Moreover, the discontinuation of export incentives and the tightening of export regulations may dampen export performance, particularly for SMEs. Without adequate support measures, SMEs may struggle to compete in global markets, leading to a decline in pharmaceutical exports from Bangladesh. The loss of preferential treatment and trade concessions enjoyed by LDCs may affect Bangladesh's pharmaceutical exports and market access. Graduating from LDC status may result in the loss of preferential access to certain markets, leading to increased tariffs and trade barriers for Bangladeshi pharmaceutical products. This could hinder export growth and limit the industry's access to international markets, particularly in regions where tariff barriers are high. Furthermore, stricter regulatory requirements and quality standards in target export markets may pose challenges for local manufacturers in meeting compliance and certification requirements.

The pharmaceutical industry's capacity for innovation and technological advancement may be constrained by limited R&D capabilities and inadequate investment in technology transfer. Despite advancements in generic drug manufacturing and reverse engineering, Bangladesh's pharmaceutical sector still lags in developing novel drugs and advanced therapeutic treatments. The transition to a post-LDC landscape may exacerbate these challenges by reducing access

to international collaborations, funding opportunities, and technology transfer agreements. Without adequate investment in R&D infrastructure and technology acquisition, local manufacturers may struggle to keep pace with global advancements in pharmaceutical research and development.

Maintaining competitiveness in the global pharmaceutical market post-LDC graduation will necessitate Bangladesh to address several key issues, including pricing pressures, market saturation, and supply chain vulnerabilities. The industry's dependence on imported raw materials and APIs could expose it to supply chain disruptions and price fluctuations, particularly in the aftermath of geopolitical tensions or trade conflicts. Moreover, heightened competition from established pharmaceutical markets such as India and China may pose challenges for Bangladesh's domestic manufacturers, particularly in niche therapeutic areas or high-value drug segments.

Increased competition from MNCs and limited government support are likely to impact the industry's profitability and growth. If the industry's growth is hampered or if there is a reduction in the productive capacity of domestic pharmaceutical firms in the post-LDC period, it will also affect the accessibility of essential medicines. Though increased international competition will potentially lower the prices of most common off-patent generic medicines, it will erode the overall profit margins of the local pharmaceutical firms. Hence, the country could become increasingly dependent on imported medicines, which could endanger overall medicine accessibility.

Imported medicines are generally expensive, and most middle-income and lower-income households cannot afford these essential medicines. According to the latest Household Income and Expenditure Survey (HIES) data, approximately 43 per cent of individuals who sought treatment for their illness could finance the treatment and medicine costs from their regular income, while the remainder had to borrow money or sell their assets. Moreover, many individuals did not seek any treatment for their illness because they could not afford the costs. Thus, in the post-LDC period, access to healthcare and essential medicines will likely worsen if pharmaceutical firms lose the capacity to meet local demand.

Furthermore, there are several longstanding constraints that are hindering the pharmaceutical sector from reaching its full potential. One such crucial constraint is the lack of a dedicated area or specialised economic zone (SEZ) specifically tailored for the pharmaceutical industry. Within such an SEZ, pharmaceutical firms could invest in research and development, as well as develop cost-effective production technologies and reverse engineering capabilities. The establishment of a dedicated SEZ would facilitate the creation of essential infrastructure, including a central effluent treatment plant (CETP), dedicated testing facilities, and uninterrupted power supply.

The absence of an SEZ severely limits the industry's capacity to attract foreign direct investment (FDI) and engage in collaborations with foreign pharmaceutical firms for joint or contractual production of more effective and innovative medicines. Although an API park was established in 2008 to address some of these constraints, it has yet to be fully operationalised.

To understand the industry stakeholders' perspectives, long-standing constraints, and emerging challenges because of LDC graduation for the pharmaceutical sector, we conducted several key informant interviews (KIIs). A thorough review of the transcripts of these interviews reveals the sector's collaborative efforts to strengthen research and development (R&D) capabilities, address impending cost increases, and navigate the complexities of IPR in a post-LDC landscape. To capture the essence of these discussions, a word cloud was created based on the transcripts, providing a visual representation of the key themes and emphases that emerged from the KIIs (Figure 0.1). Important developments influencing Bangladesh's pharmaceutical industry are predicted, and subtle insights are sought through this analysis.

Figure 0.1: Visualising key insights through word cloud based on KII with pharmaceutical industry representatives

Source: Based on interviews with stakeholders.

Bangladesh's firms have developed the capacity to produce generic versions of most drugs by reverse engineering. Stakeholders highlighted during interviews that Bangladeshi firms swiftly manufactured generic copies of three drugs–Remdesivir, Molnupiravir, and Paxlovid–

within 2 to 3 months of their launch in the USA. Bangladesh was the first country to produce generic versions of these drugs. Significant quantities of these drugs were provided to government hospitals free of charge, and some were donated to other countries for humanitarian reasons. Importantly, the prices of these products were significantly lower compared to those in the USA (Table).

Table 0.1: Price comparison of COVID-19 drugs

Drugs Name	Price in Bangladesh	Price in the USA
Remdesivir	$20	$520
Molnupiravir	$5	$700
Paxlovid	$32	$530

Source: Information gathered from industry representatives

Access and affordability could be impacted following LDC graduation as certain flexibilities would be revoked. While talking with the pharmaceutical industry representatives, they unanimously agreed that the absence of the current flexibility of producing patented drugs without the consent of patent holders will limit the availability of such drugs. This problem will be acute for biological drugs. Biologic drugs, which are protein-based and rely on living systems like bacteria, yeast, or cell lines for production, represent a new generation of targeted treatments primarily for cancer and autoimmune disorders such as arthritis and psoriasis. They enjoy robust patent protection and command high prices. For instance, Humira (adalimumab), the world's top-selling drug and seven of the top 10 drugs globally, are biologics, reflecting their significant market presence. Developing and manufacturing biologics requires substantial investment and technical expertise. Manufacturing companies strictly protect these kinds of drugs through patents and often extend the life of such patents through evergreening. Overall, they have mentioned that the price of patented drugs could rise by 30 to 50 per cent, limiting affordability and accessibility.

During one of the KIIs, the resource person mentioned some of the biological drugs Bangladesh currently produces. The prices of these drugs are compared with the Indian price of these drugs to see the difference (Table). Apart from the four drugs, the market price of these drugs is lower in Bangladesh compared to the Indian market price.

Table 0.2: Biologic drugs price comparison between Bangladesh and India

Drugs	Description	Patent status	Bangladesh's price in BDT	India's price in BDT	Difference
Pembrolizumab	100 mg/4ml	Till 2028	1,40,000	2,61,672	87%

Rituximab	100 mg/10ml	Expired	11,000	10,095	-8%
Denosumab	120 mg/1.7ml	Till 2033	35,000	38,189	9%
Nivolumab	40 mg/4ml	Till 2037	47,000	52,799	12%
Adalimumab	40 mg/0.8ml	Till 2035	15,000	40,119	167%
Bevacizumab	100 mg/4ml	Expired	23,511	24,206	3%
Trastuzumab	440 mg/20ml	Till 2030	60,000	72,516	21%
Bortezomib	2gm/vial	Till 2032	12,000	6,833	-43%
Erythropoietin	10000 IU	Expired	3,800	2,608	-31%
Filgrastim	300 mcg/0.5 ml	Till 2028	2,500	2,012	-20%
Pegfilgrastim	6 mg/0.6 ml	Till 2028	4,000	5,154	29%
Peg-interferon alfa 2a	180mcg/0.5 ml	Till 2027	9,800	12,172	24%
Etanercept	50 mg/ 1ml	Expired	13,635	22,778	67%
Darbepoetin alfa	40mcg/0.4 ml	Expired	4,500	3,642	-19%

Source: Drug names were gathered during interviews. Note: A positive percentage indicates that the drug price for a particular disease is higher in India compared to Bangladesh, while a negative percentage indicates that the drug price for the disease is lower in India compared to Bangladesh. The Maximum Retail Price (MRP) per unit was used to estimate the price difference. The exchange rate used was 1 INR = 1.3266 BDT. Medicine prices in Bangladesh were collected from Medex, while prices in India were sourced from Netmeds and Pharmeasy. Accessed on 02 March 2024.

Industry experts have indicated that the prices of registered drugs will remain unaffected by the impending LDC graduation. Stakeholders have noted that any drugs registered in the Bangladesh market before November 2026 can continue production, even if they were patented elsewhere. This applies similarly to patented drugs currently produced in Bangladesh. As a result, the country will encounter challenges in accessing medicines introduced after LDC graduation. One stakeholder suggested taking advantage of the existing benefit by licensing the most important 446 novel drugs approved by the US FDA from 2012 to 2022. Such action will allow firms to produce those drugs without paying royalties.

Bangladesh can be extend the existing patent-free regime till 2029 leveraging the MC13 decision: The recent decision adopted by the WTO during MC13 concerning "Smooth Transition Support Measures in Favour of Countries Graduated from the LDC Category" allows graduating LDCs to benefit from the Special and Differential Treatment (S&DT) provision outlined in Article 24 of the Dispute Settlement Understanding for a duration of three years after graduation (DSU, 1994). Article 24.1 calls members to exercise due restraint in initiating cases involving LDC members and in requesting compensation or authorisation to suspend

concessions or other obligations against an LDC member.[6] This suggests that even in the absence of patent protection offered by Bangladesh till November 2029, members should not take any legal action. Thus, Bangladesh can postpone the provision of patent protection for pharmaceuticals for an additional three years.

Experts suggest that strengthening the domestic capacity to produce API will be crucial to remaining competitive after LDC graduation. Industry insiders emphasise the importance of reducing reliance on foreign API suppliers. Firms need to prioritise domestic API production in order to maintain competitiveness in the face of ongoing geopolitical crises, forex crises, and post-LDC crises. According to experts, a mere 50 per cent decrease in reliance on imported APIs could considerably boost a company's competitiveness on a national and international level. Interviews do, however, highlight divergent opinions among participants. Some contend that the higher cost of producing APIs domestically as opposed to imports discourages businesses from producing them locally. The high costs are caused by high utility costs and the fact that the API industry is still in its early stages and has not yet reached economies of scale that would make domestic production more cost-effective.

Industry insiders raise concern that the cessation of cash incentives, which will likely reduce exports and also demotivate small and medium-sized firms from engaging in export activities. The representatives stated that reducing export incentives would reduce firms' competitiveness in global markets. This reduction will have a greater impact on small and medium-sized businesses than on large businesses. Small and medium-sized businesses are often encouraged to export in order to take advantage of cash incentives. With cash incentives becoming unavailable in the future, representatives are actively advocating for alternative forms

[6] Article 24, Special Procedures Involving Least-Developed Country Members, of Dispute Settlement states:

1. At all stages of the determination of the causes of a dispute and of dispute settlement procedures involving a least-developed country Member, particular consideration shall be given to the special situation of least-developed country Members. In this regard, Members shall exercise due restraint in raising matters under these procedures involving a least-developed country member. If nullification or impairment is found to result from a measure taken by a least-developed country Member, complaining parties shall exercise due restraint in asking for compensation or seeking authorization to suspend the application of concessions or other obligations pursuant to these procedures.

2. In dispute settlement cases involving a least-developed country Member, where a satisfactory solution has not been found in the course of consultations the Director-General or the Chairman of the DSB shall, upon request by a least-developed country Member offer their good offices, conciliation and mediation with a view to assisting the parties to settle the dispute, before a request for a panel is made. The Director-General or the Chairman of the DSB, in providing the above assistance, may consult any source which deems appropriate.

of support. They have stated that the industry receives support for competitive formulation imports. Extending similar support to API has the potential to accelerate industry growth. This strategic approach recognises the sector's evolving needs and emphasises the importance of adapting support mechanisms to foster long-term development and competitiveness.

Industry experts urge investing in capacity building in IPR-related issues and research and development (R&D) as this initiative will be crucial after LDC graduation. Following graduation, Bangladesh will be required to offer patent protection, leading to a surge in patent filing applications. To assess drug novelty, regulatory authorities must possess the capability to conduct comprehensive tests. Additionally, an increase in patent infringement cases is anticipated, necessitating a bolstering of institutional capacity to address such challenges effectively. Moreover, enhancing the capacity to navigate regulatory affairs is imperative for exports, particularly for firms with a presence in the US and EU markets, where regulatory comprehension is paramount. However, industry experts note that existing capacity falls short of requirements. Some companies have initiated efforts to strengthen capacity in IPR issues. Stakeholders also highlight the limited scope of research in Bangladesh despite the nation's proficiency in reverse engineering. Thus, concerted efforts are needed to expand research opportunities and bolster capabilities in both basic research and IPR-related issues.

The impact of foreign competition on domestic drug prices post-LDC graduation remains ambiguous. In investigating the potential implications of foreign competition in domestic drug markets, industry experts noted that foreign firms may be inclined to manufacture complex patented drugs to leverage monopoly pricing. Conversely, for off-patented drugs, the risk of substantial competition appears minimal, partly due to the already lower prices of these drugs in domestic markets. Additionally, the relatively lower profitability associated with such drugs may deter foreign firms from entering these markets.

A comparative price analysis has been conducted for both patented and off-patented drugs. In Table , the unit prices of patented drugs in Bangladesh and India are presented by drug types. Among the various drugs, with the exception of antiviral, skin, and urinary medications, the prices are lower in Bangladesh compared to India. When comparing the prices of off-patented drugs, many drugs are significantly cheaper in Bangladesh compared to India (Table). For example, the price of anaesthetic drugs is 164 per cent higher in India than in Bangladesh, while osteoarthritis drugs are approximately 215 per cent higher in India compared to Bangladesh. However, the prices of antifungal, gastrointestinal, hematologic disorders, and skin disease medications are lower in India than in Bangladesh. Overall, among 176 off-patented drugs, 130 drugs have lower prices in Bangladesh compared to India's market prices.

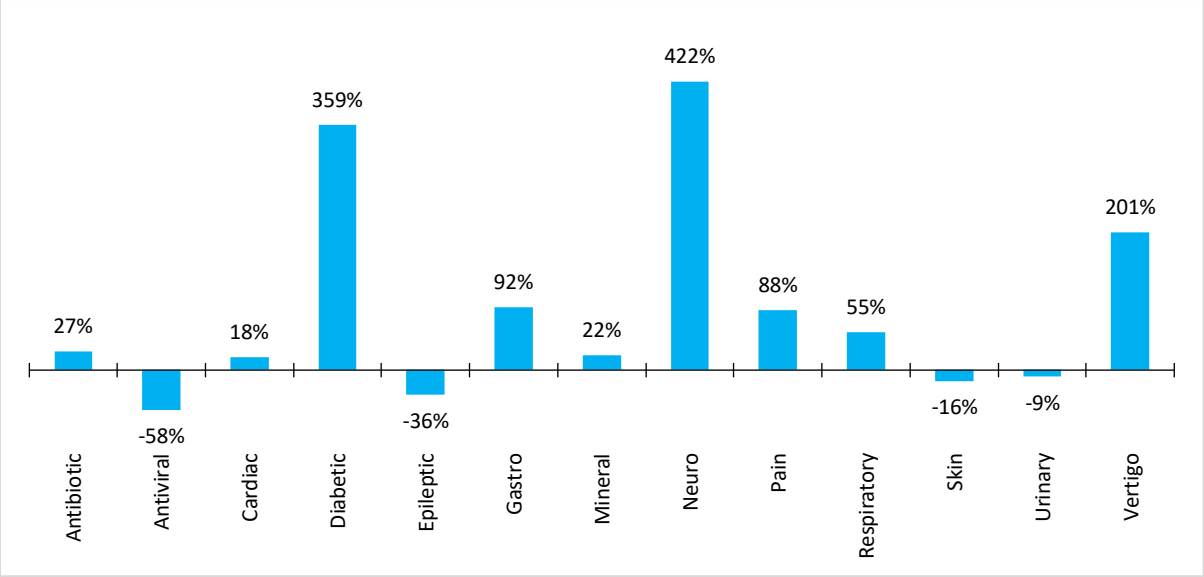
The detailed list of medicine prices is given in Annex A3.

Table 0.3: Patented drug price comparison between Bangladesh and India

Generic	Disease	Description	Bangladesh's price (BDT)	India's price (BDT)	Difference (%)
Acetylcysteine	Respiratory	600 mg tab	20	26.7	33%
Acitretin	Skin	25mg tab	85.2	104.1	22%
Betahistine	Vertigo	8mg tab	3	9.0	201%
Bosentan	Respiratory	62.5 mg tab	50	137.4	175%
Cefdinir	Antibiotic	300 mg tab	57	72.3	27%
Dexpanthenol	Gastro	5% ointment/50 gram	125	240.0	92%
Favipiravir	Antiviral	200 mg	200	83.5	-58%
Flupentixol	Neuro	1 mg	6	31.3	422%
Glycopyrronium	Respiratory	20 mg inhalation table	20	22.4	12%
Icosapent	Cardiac	Icosapent Ethyl 1gm	50	57.5	15%
Indacaterol	Respiratory	Indacaterol (50mg) + Glycopyrronium (110 mg)	70	86.9	24%
Iron ferric	Mineral	210 mg tab	25	30.5	22%
Isotretinoin	Skin	10mg tab	40	17.9	-55%
Ivabradine	Cardiac	5mg tab	25.8	30.9	20%
Ketorolac	Pain	10 mg tab	12	10.5	-13%
Levetiracetam	Epileptic	500 mg tab	30	19.2	-36%
Linagliptin	Diabetic	5 mg tab	18	39.8	121%
Mirabegron	Urinary	50 mg tab	55	50.0	-9%
Nitroglycerin	Cardiac	2.6 mg tab	7.05	8.5	20%
Pirfenidone	Respiratory	267 mg tab	45	40.1	-11%
Repaglinide	Diabetic	1 mg tab	3	20.9	596%
Tacrolimus	Skin	1 mg capsule	50	42.4	-15%
Tiotropium bromide	Respiratory	18 mcg Inhalation capsule	8	15.9	99%
Tolperisone	Pain	100 mg tab	5	14.5	189%

Source: Drug names were gathered during interviews. Note: The Maximum Retail Price (MRP) per unit was used to estimate the price difference. The exchange rate used was 1 INR = 1.3266 BDT. Medicine prices in Bangladesh were collected from Medex, while prices in India were sourced from Netmeds and Pharmeasy. Accessed on March 4, 2024.

Figure 0.2: Price comparison of patented drugs between Bangladesh and India by diseases



Source: Drug names were gathered during interviews. Note: The graph illustrates the average price difference of patented drugs between Bangladesh and India based on disease. A positive percentage indicates that the drug price for a particular disease is higher in India compared to Bangladesh, while a negative percentage indicates that the drug price for the disease is lower in India compared to Bangladesh.

Table 0.4: Price comparison of off-patented drugs between Bangladesh and India by disease

Disease Name	Average price in Bangladesh (BDT)	Average price in India (BDT)	Difference
Allergy	23.10	38.96	69%
Anaesthetic	250.00	660.98	164%
Antibiotic	65.19	79.64	22%
Antifungal	20.00	15.22	-24%
Antiseptic	68.00	114.09	68%
Cardiovascular	14.76	19.12	30%
Diabetic	11.60	13.65	18%
Gastrointestinal	46.25	42.96	-7%
Hematologic disorders	107.47	101.76	-5%
HIV	85.00	68.09	-20%
Infections	65.29	122.74	88%
Kidney	27.50	34.16	24%
Metabolic Disorders	39.01	44.57	14%
Miscellaneous	24.92	34.83	40%
Neurological	9.80	13.42	37%
Osteoarthritis	29.20	92.03	215%
Pain	45.16	51.29	14%

Respiratory	100.53	126.46	26%
Sex	38.38	52.53	37%
Skin	227.80	170.54	-25%
Urinary	12.61	32.05	154%
Vitamins	6.90	13.79	100%

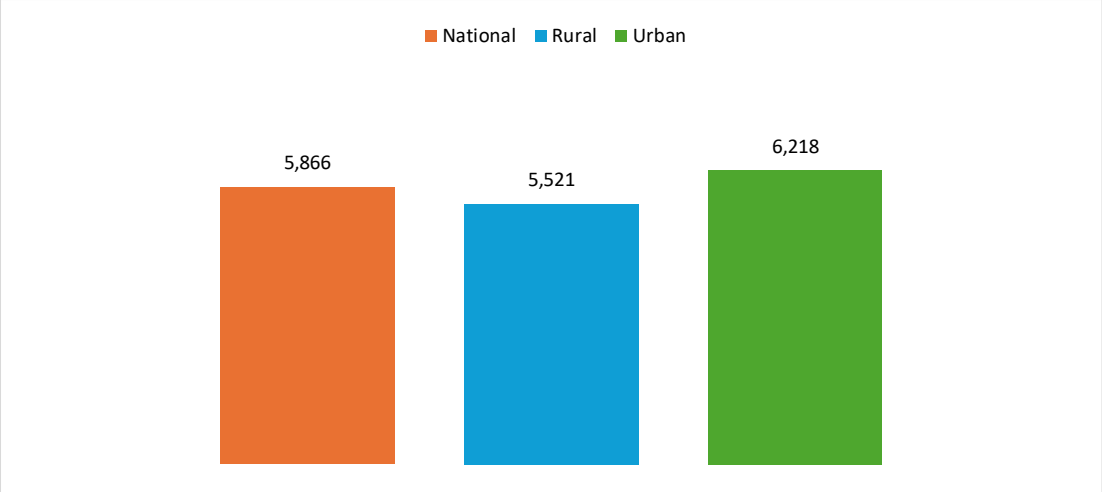
Source: Drug names were gathered during interviews. Note: The Maximum Retail Price (MRP) per unit was used to estimate the price difference. The exchange rate used was 1 INR = 1.3266 BDT. Medicine prices in Bangladesh were collected from Medex, while prices in India were sourced from Netmeds and Pharmeasy. Accessed on 04 March 2024.

5.2 Impact Assessment

5.2.1 Some descriptive statistics on medicine expenditure from HIES 2022

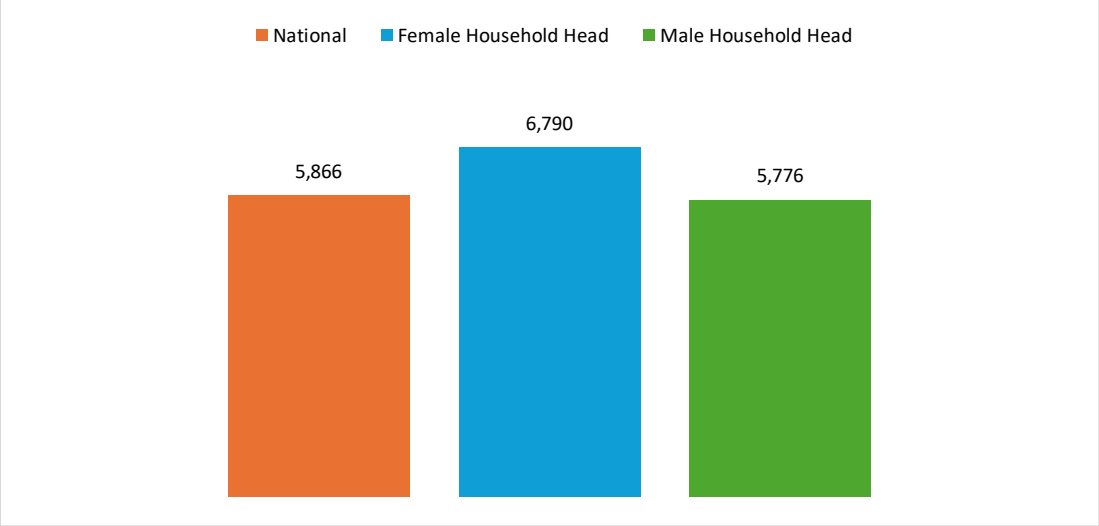
Figure 0.3 and Figure 0.4 present per person the total annual out-of-pocket expenditure on medicine in 2022 in Bangladesh, derived from data gathered through the Bangladesh Household Income and Expenditure Survey (HIES) 2022. Total expenditure on medicines includes expenditure on chronic routine medicines, outpatient medicines, and inpatient medicines. These medicine expenditures only include individuals who had incurred some spending on medicines. The figures are categorised based on various demographic factors. The national average indicates an expenditure of BDT 5,866 per person. Further insights are provided by distinguishing between rural and urban areas, with rural households spending BDT 5,521 per person and urban households spending BDT 6,218 per person annually on medicine. Additionally, the data is stratified by the gender of the household head, revealing that female-headed households spend BDT 6,790 per person, while male-headed households incur an annual expense of BDT 5,776 per person on medicine. These figures provide a snapshot of the variation in out-of-pocket medical expenditures across different demographic segments in Bangladesh. Here, the total per-person medicine expenditure is larger for female-headed households and households residing in urban areas.

Figure 0.3: Per-person annual total medicine expenditure (BDT) in Bangladesh in 2022



Source: Authors' illustration using HIES 2022.

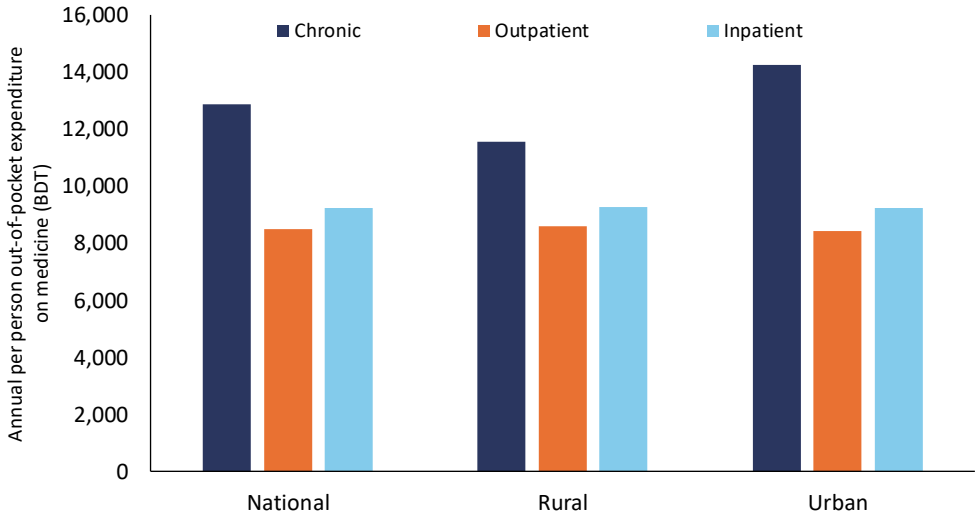
Figure 0.4: Per-person annual total medicine expenditure (BDT) in Bangladesh in 2022 by household's head type



Source: Authors' illustration using HIES 2022.

The disaggregation of the total annual per-person medicine expenditure is shown in **Error! Reference source not found.**. The most significant component in the total medicine expenditure is the expenditure on routine medicines for chronic diseases. About BDT 13,000 is spent on medicines for individuals with some chronic conditions, and this figure is even higher for individuals living in urban areas or having female household heads. Per-person outpatient medicine expenditure for some non-chronic conditions is also substantial, more than BDT 8,500 annually at the national level, while the inpatient medicine expenditure is even higher than the outpatient medicine expenditure. Interestingly, both inpatient and outpatient medicine expenditures are slightly higher in rural areas compared to urban areas.

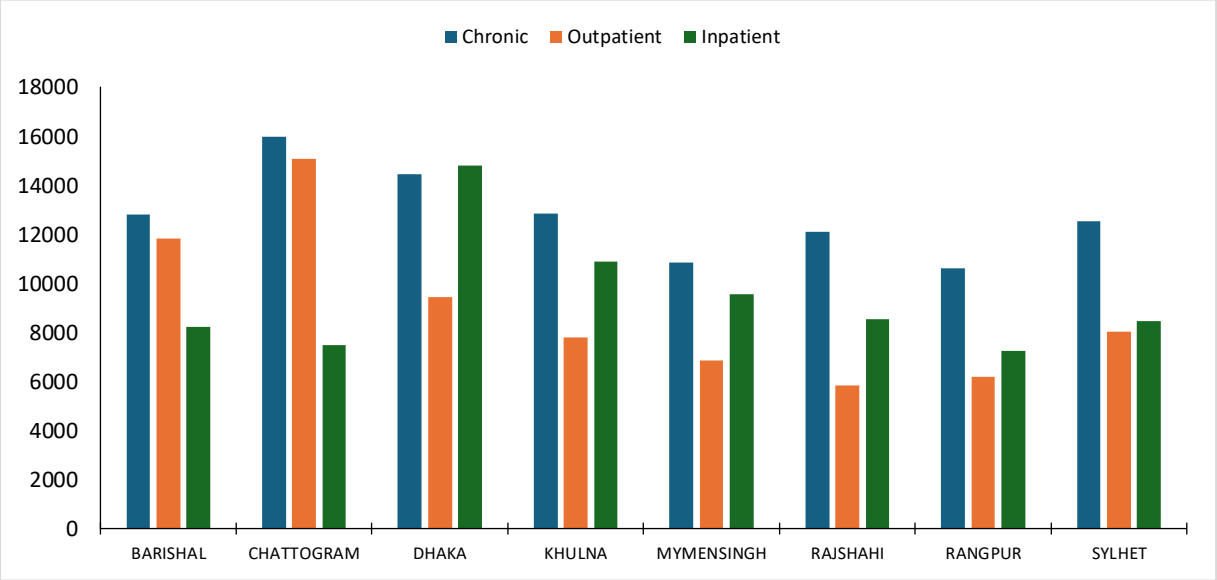
Figure 0.5: Annual per person out-of-pocket expenditure on medicines for individuals reporting illness (BDT)



Source: Authors' estimates using HIES 2022.

These three types of medical expenditures are further categorised by division (Figure 0.6). Here, Barishal exhibits notable spending on chronic medicines, with the highest expenditure in this category. Chattogram leads in both chronic and outpatient medicine expenditures, while Dhaka has the highest inpatient medicine expenditure. Khulna, Mymensingh, Rajshahi, Rangpur, and Sylhet also display varying patterns of expenditure across the three medicine categories, providing a comprehensive overview of regional differences in healthcare spending.

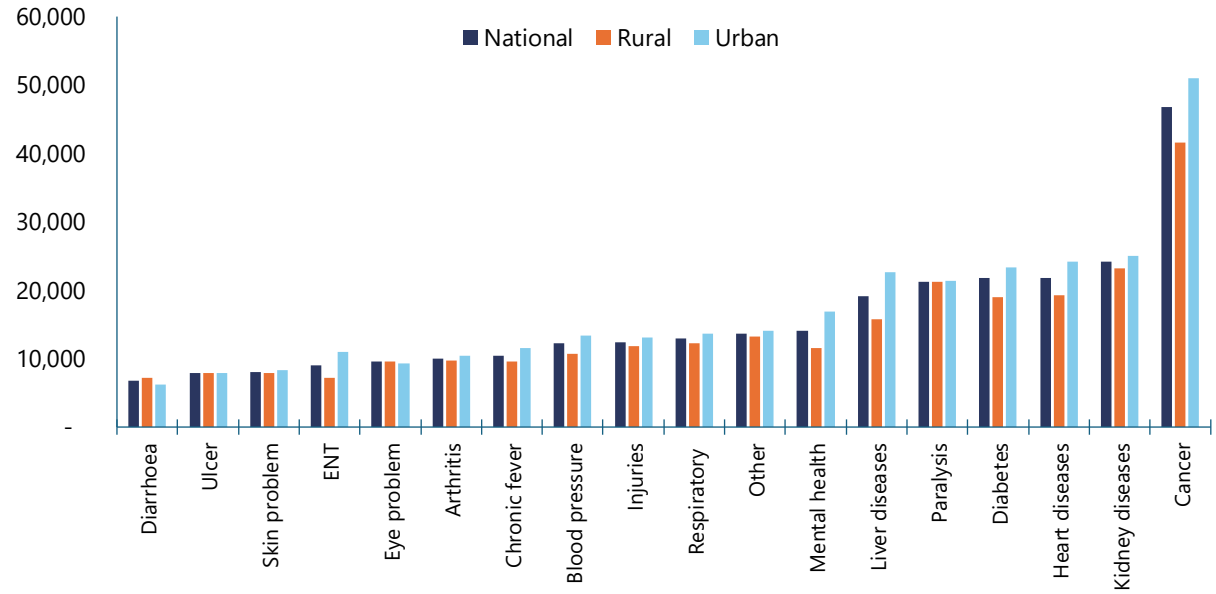
Figure 0.6: Division-wise per-person annual medicine expenditure (BDT)



Source: Authors' illustration using HIES 2022.

Per-person annual medicine expenditures on routine medicines are shown chronic illness-wise in Figure 0.7. Notable observations include variations in spending across different chronic diseases, with Cancer and Kidney Diseases showing higher expenditures compared to other conditions. Additionally, differences in expenditure patterns are evident based on the geographical location and gender of the household head, providing insights into the diverse healthcare spending landscape for chronic illnesses in Bangladesh (See Annex A4).

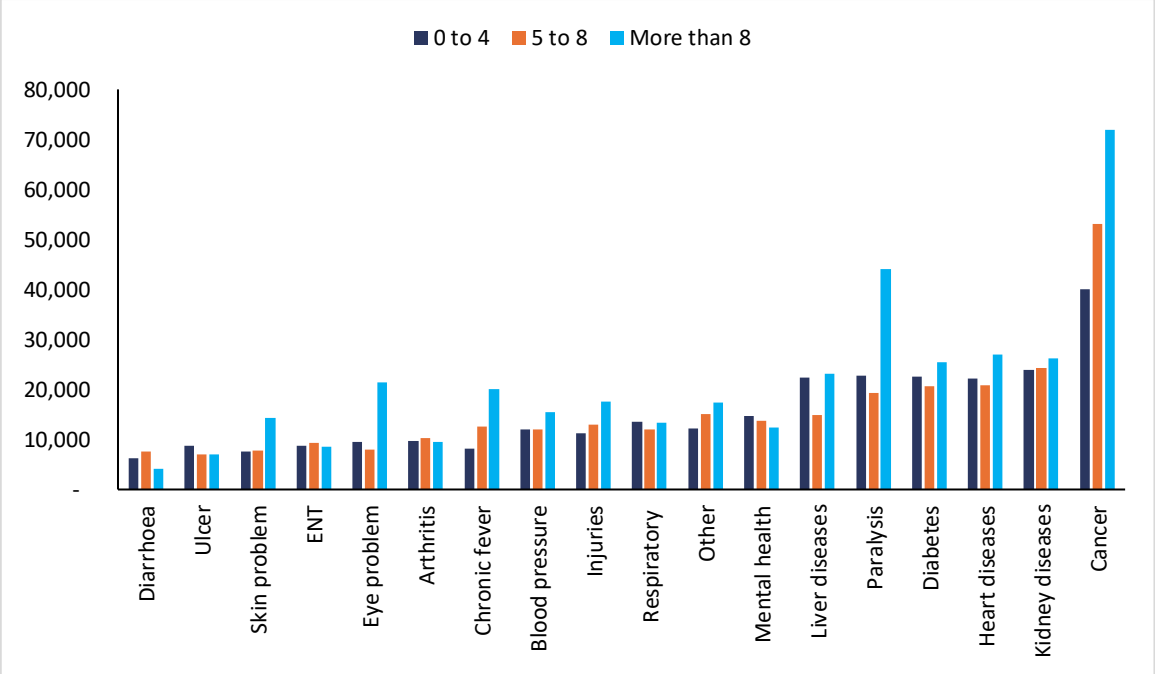
Figure 0.7: Annual out-of-pocket expenditure on medicines for chronic diseases (BDT)



Source: Illustration using HIES 2022. Note: ENT stands for ear, nose, and throat.

Additionally, Figure 0.8 displays the medicine expenditures for various chronic illnesses based on the size of the household. The figure illustrates that larger households, with more than 8 members, tend to incur higher expenditures across several chronic diseases, such as Chronic Heart Disease, Diabetes, Cancer, and Paralysis. Conversely, households with 0 to 4 members often show lower expenditures in comparison. These insights provide a better understanding of how household size influences healthcare spending patterns for chronic illnesses in Bangladesh.

Figure 0.8: Larger households generally incur higher per-person annual medicine expenditure



Source: Authors' illustration using HIES 2022. Note: ENT stands for ear, nose, and throat.

5.2.2 Market demand elasticities of medicine

Using the HIES 2022 data, we computed the market demand elasticities, E_D, for a group of medicines treating a chronic condition (Table 0.5). Expenditure elasticities are income elasticities showing how demand for medicines treating a chronic disease changes when household income changes. These elasticities are small and less than one in absolute value, which makes sense as the current market for medicines is oligopolistic, and in an oligopolistic market, the market demand curve is kinked, and all firms in the industry operate at the inelastic portion of this kinked demand curve.

Table 0.5: Compensated, uncompensated, and expenditure elasticities of medicines in Bangladesh

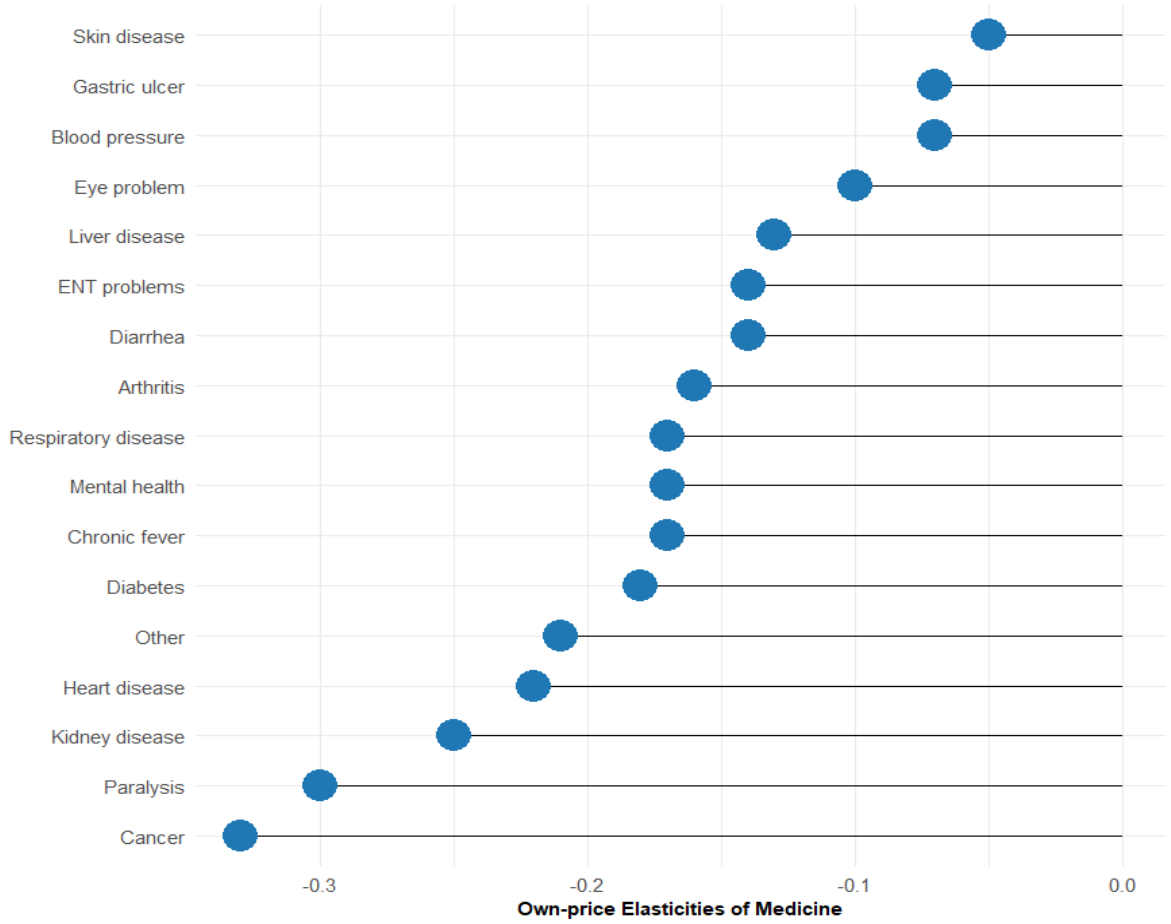
Chronic disease	Compensated	Uncompensated	Expenditure
Chronic fever	-0.08***	-0.17***	0.46***
Heart disease	-0.14***	-0.22***	0.29***
Respiratory	-0.13***	-0.17***	0.21***
Diarrhoea	-0.11***	-0.14**	0.20***
Ulcer	-0.06**	-0.07***	0.14***
Blood pressure	-0.05***	-0.07***	0.10***
Arthritis	-0.13***	-0.16***	0.18***
Skin disease	-0.03***	-0.05***	0.12***
Diabetes	-0.12***	-0.18***	0.24***
Cancer	-0.21***	-0.33***	0.32***
Kidney disease	-0.17***	-0.25***	0.29***

Liver disease	-0.10***	-0.13***	0.11***
Mental health	-0.14***	-0.17***	0.11***
Paralysis	-0.20***	-0.30***	0.30***
ENT problems	-0.11***	-0.14***	0.24***
Eye problem	-0.06***	-0.10***	0.24***
Other	-0.16***	-0.21***	0.25***

Source: Authors' estimate using HIES 2022. Note: Compensated elasticities show only the substitution effect of a price change, whereas uncompensated elasticities incorporate both the substitution effect and the income effect. ENT stands for ear, nose, and throat.

Since we need the marginal revenue to equal marginal cost for the profit maximisation condition, we use the uncompensated demand elasticities, which are related to the market demand. Figure 0.9 contrasts the uncompensated elasticities for various non-communicable (Chronic) diseases.

Figure 0.9: Own-price elasticities of medicines for non-communicable diseases



Source: Authors' illustration using estimated elasticities in Table 0.5.

Now if there is a single firm, i.e., a monopoly market, the markup equation from the profit maximisation condition implies that:

$$\frac{P - MC}{P} = -\frac{1}{E_d}$$

Here, E_d is the firm's price elasticity of demand. Note that this equation can be rewritten as:

$$P = \frac{MC}{1 + (\frac{1}{E_d})}$$

If the firm is a monopolist, then the relevant elasticity is the market elasticity of demand, which is denoted by E_D. Obtaining an estimate of this market elasticity of demand may or may not be difficult, but for the moment, let's assume that we have such an estimate. Given this estimate ofE_D, how can we obtain an estimate of the firm's price elasticity of demand, E_d.

If the firm is not the monopoly, rather several firms are competing with each other according to Cournot (which is a reasonable assumption as there is no clear market leader for the pharmaceutical industry in Bangladesh), we need to obtain the firm-level elasticities, E_d, from the market elasticities, E_D, estimated using the HIES data, for each type of medicine treating some chronic conditions. Suppose that there are n equal-sized firms in the market and that they all have the same marginal cost, c. In the Cournot model, each firm chooses its profit-maximizing output, taking the outputs of its competitors as fixed. For Firm i, profit is given by:

$$\Pi_i = [P(Q) - c]Q_i$$

where Q is the total output of the industry. We want to maximize this profit with respect to Q_i, treating the Q_j's for the other firms as fixed:

$$\frac{\delta \Pi_i}{\delta Q_i} = P(Q) - c + Q_i \frac{dP}{dQ}\frac{\delta Q}{\delta Q_i} = 0$$

Here $\frac{\delta Q}{\delta Q_i} = 1$ and $\frac{\delta Q_j}{\delta Q_i} = 0$. Thus, the reaction curve for firm *i* is:

$$P(Q) + Q_i \frac{dP}{dQ} = c$$

If there are n equal-sized firms, $Q_i = \frac{Q}{n}$, so:

$$P(Q) + \frac{Q}{n}\frac{dP}{dQ} = c$$

This implies that:

$$\frac{P - c}{P} = -\frac{1}{n}\frac{Q}{P}\frac{dP}{dQ} = -\frac{1}{nE_D}$$

Thus, we have:

$$E_d = nE_D$$

Thus, with n equal-sized firms, to obtain demand elasticity for a single firm, E_d, one needs to multiply the market demand elasticity, E_D, with the number of firms, n. However, in the pharmaceutical market in Bangladesh, all firms are not equal-sized. Some firms have significantly higher market share than others. Nevertheless, these firms appear to be involved in a Cournot competition. Hence, to compute the firm-level demand elasticity for some particular medicines treating a chronic condition, we need to compute the market concentration first for the pharmaceutical industry, which is measured by the Herfindahl-Hirschman index (HHI). Here, HHI for an industry is defined as:

$$HHI = \sum_{i=1}^{m} S_i^2$$

Where S_i is the market share of Firm *i*. Next, we define n^*, the equivalent number of equal-sized firms that yields the same value of the HHI calculated from the actual market share as above. So, $n^*$is defined as:

$$\sum_{i=1}^{n^*} \left(\frac{1}{n^*}\right)^2 = n^* \left(\frac{1}{n^*}\right)^2 = \frac{1}{n^*} = HHI$$

Thus, n^* is simply the reciprocal of the HHI, i.e., $n^* = 1/HHI$. Now, we use this n^* to obtain E_d:

$$E_d = n^* E_D$$

We gathered the market share data for each pharmaceutical firm in Bangladesh and computed the n^*= 13.27. Detailed market share information is provided in Annex A9. Using the equivalent equal-sized number of firms, we compute the current markups for each chronic disease, which are shown in Table 0.6.

Table 0.6: Estimated markups for chronic medicines in Bangladesh under the oligopolistic market structure

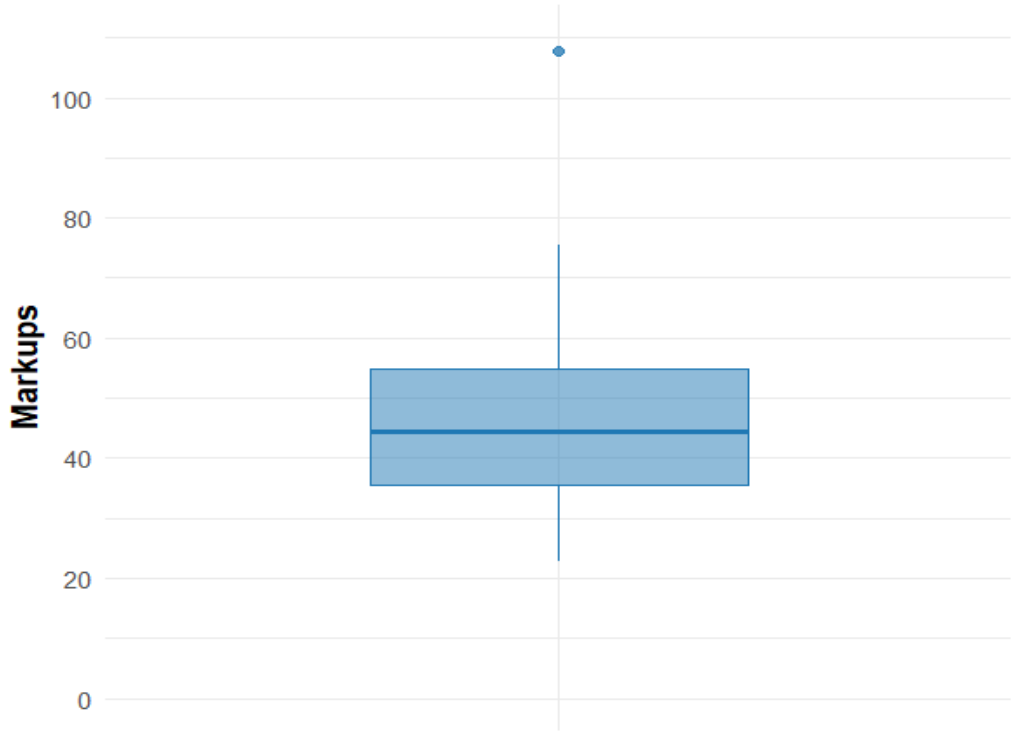
Chronic disease	Market elasticities	Firm-level elasticities	Oligopoly markup (%)
Chronic fever	-0.17	-2.26	44.33
Heart disease	-0.22	-2.92	34.25
Respiratory disease	-0.17	-2.26	44.33
Diarrhoea	-0.14	-1.86	53.83
Ulcer	-0.07	-0.93	107.65
Blood pressure	-0.07	-0.93	107.65
Arthritis	-0.16	-2.12	47.10
Skin disease	-0.05	-0.66	150.72
Diabetes	-0.18	-2.39	41.87

Cancer	-0.33	-4.38	22.84
Kidney disease	-0.25	-3.32	30.14
Liver disease	-0.13	-1.73	57.97
Mental health	-0.17	-2.26	44.33
Paralysis	-0.30	-3.98	25.12
ENT problems	-0.14	-1.86	53.83
Eye problem	-0.10	-1.33	75.36
Other	-0.21	-2.79	35.88
n*	13.27		

Source: Authors' estimation using HIES 2022. Note: ENT stands for ear, nose, and throat.

The distribution of the estimated markup is illustrated in Figure 0.10. The estimated markups span from approximately 20 per cent to around 150 per cent over the marginal costs. Notably, the highest markup is observed for medicines targeting chronic skin diseases, a logical correlation given the visible nature of skin conditions. Consequently, the demand for medications to address such ailments may exhibit greater inelasticity compared to those for other chronic diseases. The median markup hovers around 44 per cent, indicative of the pricing latitude available to pharmaceutical firms. This implies that for half of the chronic disease medications, these firms have the capacity to augment prices by more than 44 per cent above the marginal costs, thereby determining the final prices of their medicines.

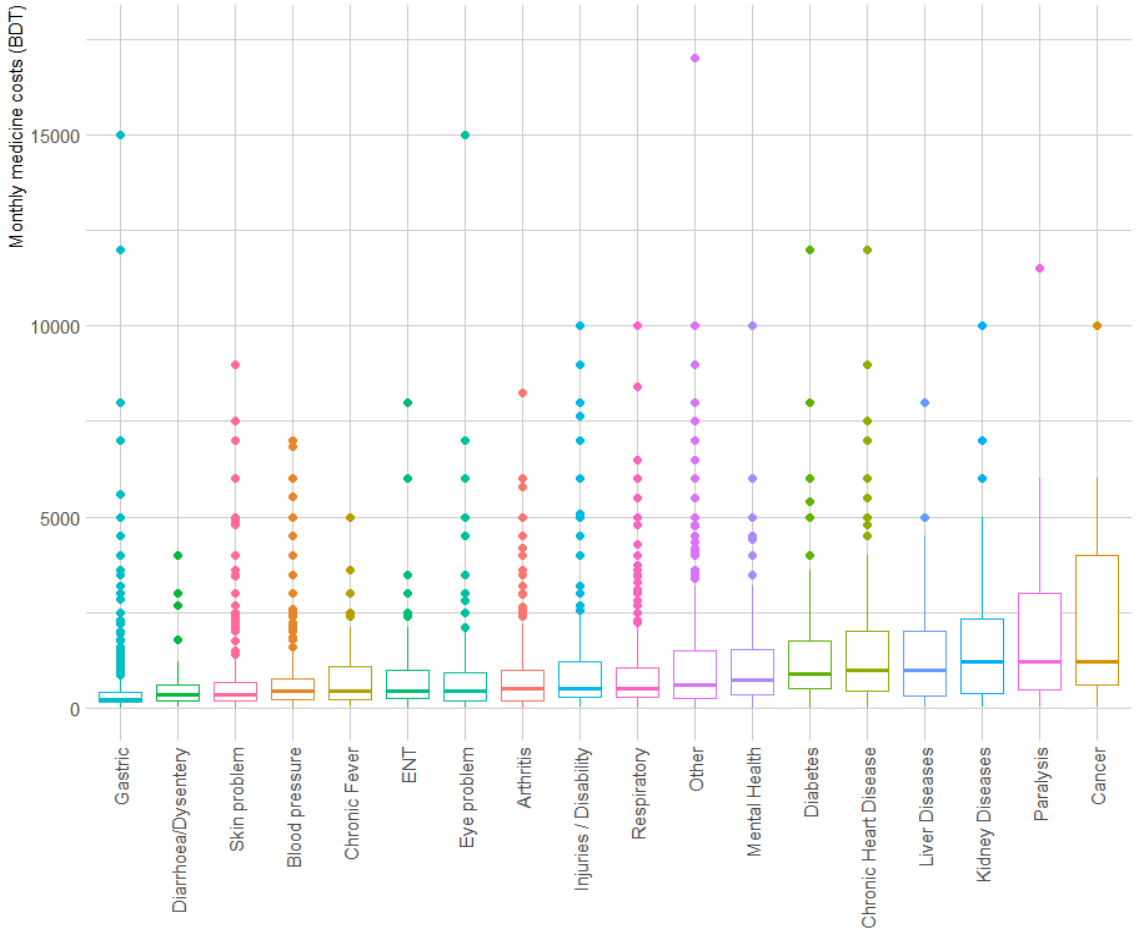
Figure 0.10: Distribution of the estimated markups of chronic disease medicines in Bangladesh



Source: Authors' illustration using estimated markups.

In order to compute the implied marginal cost of producing medicines for chronic diseases, we need information regarding the current prices of these medications. To achieve this, we calculate the average, median, minimum, maximum, and standard deviation of the monthly costs associated with each chronic disease, as reported by households in HIES 2022 (See Annex A5). These costs are considered indicative of the prices faced by consumers for a month. Observing the data, it becomes evident that the average costs of medicines for almost all chronic diseases surpass their respective median costs. This discrepancy suggests that while most households incur moderate expenses for monthly medications treating chronic diseases, some face significantly higher costs. Notably, the average monthly cost for cancer medications exceeds 3300 BDT, making it the highest among all chronic diseases, whereas the smallest average cost pertains to gastric medicines, at approximately 400 BDT. The significant disparity in household expenditure on chronic disease medications is underscored by the substantial standard deviations observed. Indeed, there exists considerable variability among households in terms of their monthly spending on these essential medicines. The discrepancy between the maximum and minimum monthly costs for most chronic diseases spans several hundredfold, further highlighting the diversity in household financial burdens associated with managing chronic ailments. These insights are visually depicted in Figure 0.11, which illustrates the distribution of prices (monthly costs) across various chronic diseases, providing a comprehensive overview of the financial burden surrounding the procurement of medications for chronic conditions.

Figure 0.11: Distributions of prices (monthly costs) of medicines for chronic illness in 2022 in Bangladesh.



Source: Authors' illustration using HIES 2022 data. Note: ENT stands for ear, nose, and throat.

Using the price information for chronic disease medicines and the estimated markups for these medicines, as reported in Table 0.6, we can compute the implied marginal costs of producing these medicines using the following formula:

$$P = MC(1 + \mu),$$

$$or\ MC = \frac{P}{1+\mu},$$

where μ is the estimated markup. The estimated marginal costs derived from average prices are detailed in Table 0.7. It is evident that the highest marginal cost is associated with medications for cancer, followed by those for paralysis and kidney diseases. Conversely, the lowest marginal costs are attributed to the production of medicines for gastric ulcers, followed by medications for skin diseases and blood pressure.

Table 0.7: Implied marginal costs of producing medicines for chronic diseases in Bangladesh

Chronic disease	Average price (P)	Oligopoly markup (%)	Marginal cost (MC)
Chronic fever	752.59	44.33	521.44
Heart disease	1445.94	34.25	1077.02
Respiratory	983.72	44.33	681.58
Diarrhoea	608.60	53.83	395.64
Ulcer	414.19	107.65	199.46
Blood pressure	647.51	107.65	311.82
Arthritis	779.81	47.10	530.13
Skin problem	707.57	150.72	282.22
Diabetes	1316.77	41.87	928.18
Cancer	3366.46	22.84	2740.62
Kidney diseases	1680.85	30.14	1291.54
Liver diseases	1438.73	57.97	910.78
Mental health	1282.14	44.33	888.35
Paralysis	1719.20	25.12	1374.05
ENT problem	756.14	53.83	491.56
Eye problem	872.99	75.36	497.84
Other (specify)	1234.27	35.88	908.32

Source: Authors' estimation using HIES 2022 data. Note: ENT stands for ear, nose, and throat.

5.2.3 Effects of LDC graduation on access to medicine

The effects of Bangladesh's LDC graduation on access to medicines will be diverse and depend on public policy about protecting the domestic industry from foreign competition and the nature of the intellectual property rights provisions. Hence, we discuss the accessibility of essential medicines under these various scenarios.

Scenario 1: Accessibility of patented medicines that cannot be produced domestically will not affected by Bangladesh's LDC graduation.

Pharmaceutical firms continue to encounter challenges in producing generic versions of several new and innovative medicines, particularly advanced biological medicines. This limitation stems from a lack of technological prowess and capacity to replicate these complex formulations. Even in cases where a generic version is successfully manufactured, domestic firms often lack the capability to conduct efficacy testing. Presently, for chronic diseases such as cancer, diabetes, and respiratory conditions, access to innovative patented medicines remains restricted to purchasing from their original creators, often at exorbitant prices. Consequently, only households from higher-income brackets can afford these vital medications, while lower-income households are compelled to seek alternative, cheaper treatment options.

Following Bangladesh's graduation from LDC status, the scenario is unlikely to change significantly. These medicines will continue to be imported from patent holders at substantial costs, rendering accessibility confined primarily to higher-income households, as is the case presently. Therefore, the LDC graduation is unlikely to alter the accessibility of these innovative patented medicines across different income groups in Bangladesh.

Nevertheless, there exists a glimmer of hope for Bangladesh's pharmaceutical industry. If Bangladeshi firms can successfully develop the capacity to produce or register to manufacture generic versions of some or most of these patented medicines by 2026 (and possibly by 2029), a new era of opportunity may emerge. This pivotal timeline delineates the window within which Bangladeshi producers must seek permission to produce generic versions of patented medicines. Therefore, concerted efforts from the Government of Bangladesh, the pharmaceutical industry, and other stakeholders are imperative. Collaborative endeavours aimed at bolstering domestic production capacities and fostering innovation are paramount. By working together, these entities can pave the way for Bangladesh to not only produce these generics beyond 2029 but also emerge as a significant player in the global pharmaceutical arena, thereby ensuring sustainable access to essential medicines for the populace.

Scenario 2: Most of the generic medicines manufactured in Bangladesh operate without the burden of patent protection across global jurisdictions. Nevertheless, a notable fraction, roughly ranging between 5 to 10 per cent, of these generic medicines from Bangladesh currently fall under patent protection in foreign domains.[7] Even with Bangladesh's impending graduation from the category of LDCs, the country retains the ability to continue producing these patented medicines, thanks to the removal of the mailbox provision. Had this provision not been abolished, Bangladesh would have found itself compelled to extend patent protection to these medications post-LDC graduation, potentially paving the way for monopolistic pricing structures. This scenario could have led to inflated prices for essential medicines. Consequently, our analysis extends to estimating the extent of monopoly markups and pricing dynamics, particularly concerning chronic disease medications, illustrating the ramifications of pharmaceutical market monopolisation on access and affordability (Table 0.8).

Table 0.8: Monopoly prices of on-patented medicines for which generic versions are currently produced in Bangladesh.

	Current market condition			Market condition under a monopoly		
Chronic disease	Oligopoly markup	Average initial price (BDT)	MC	Monopoly markup	Monopoly price (BDT)	Increase in price (%)
Chronic fever	44.33	752.59	521.44	588.24	5179.59	588.24
Heart disease	34.25	1445.94	1077.02	454.55	8018.38	454.55

[7] The proportion of medicines produced in Bangladesh that have patent protection in other countries is about 5 to 10 per cent. This figure is reported in our KIIs with pharmaceutical industry stakeholders and experts.

Respiratory disease	44.33	983.72	681.58	588.24	6770.29	588.24
Diarrhoea	53.83	608.60	395.64	714.29	4955.78	714.29
Ulcer	107.65	414.19	199.46	1428.57	6331.17	1428.57
Blood pressure	107.65	647.51	311.82	1428.57	9897.69	1428.57
Arthritis	47.10	779.81	530.13	625.00	5653.64	625.00
Skin disease	150.72	707.57	282.22	2000.00	14858.92	2000.00
Diabetes	41.87	1316.77	928.18	555.56	8632.16	555.56
Cancer	22.84	3366.46	2740.62	303.03	13567.83	303.03
Kidney disease	30.14	1680.85	1291.54	400.00	8404.25	400.00
Liver disease	57.97	1438.73	910.78	769.23	12505.89	769.23
Mental health	44.33	1282.14	888.35	588.24	8824.14	588.24
Paralysis	25.12	1719.20	1374.05	333.33	7449.87	333.33
ENT problems	53.83	756.14	491.56	714.29	6157.18	714.29
Eye problem	75.36	872.99	497.84	1000.00	9602.93	1000.00
Other	35.88	1234.27	908.32	476.19	7111.76	476.19

Source: Authors' estimation using HIES 2022 data. Note: ENT stands for ear, nose, and throat.

Scenario 3: Costs of producing generic of the currently on-patent medicines could increase after the LDC graduation due to the higher import prices of APIs needed for the production of these medicines, reducing their access and affordability.

It is improbable that currently patented medications will be granted monopoly marketing rights in Bangladesh after the LDC graduation, given the country's ability to issue compulsory licenses to domestic firms, thereby enabling them to produce these medicines. Consequently, the market can sustain the availability of generic versions of these vital medications. However, amidst this regulatory flexibility, a concerning trend looms—the potential escalation of production costs for these medicines. Domestic firms may find themselves facing heightened import costs, particularly concerning raw materials such as API prices. This scenario paints a challenging picture, where despite domestic firms maintaining their existing markup rates, the fundamental cost structure of medicine production is poised to increase. Consequently, the marginal costs associated with manufacturing these medicines are anticipated to rise post-LDC graduation.

This inevitable rise in production costs is a pivotal concern, especially considering its trickle-down effect on medication pricing. As the production expenses soar, the burden ultimately falls on consumers, particularly low-income households, who may find themselves increasingly priced out of essential medications. The ensuing rise in prices poses a tangible threat to the accessibility and affordability of vital treatments for those already facing economic hardship. In light of these potential challenges, it becomes imperative to assess the likely trajectory of medication prices in the post-LDC era for these medicines. Through simulation exercises, we aim to anticipate the plausible scenarios, particularly focusing on two key parameters: a conservative 10 per cent increase in marginal cost (MC) and a more drastic 20 per cent surge in MC post-LDC graduation. Results are shown in the following Table 0.9. From the

table, it is evident that the average prices of medicines are poised to increase in proportion to the rise in marginal costs. That is to say, if marginal costs escalate by 10 per cent, the prices of these medicines will correspondingly increase by 10 per cent, and so forth. Our assumption here rests on the premise that pharmaceutical firms will maintain their current level of markups despite facing heightened marginal costs, effectively transferring the entire burden of the LDC-induced increase in marginal costs onto consumers. Given the highly inelastic market elasticities of these medicines, this assumption appears reasonably credible. Consequently, consumers are likely to shoulder the weight of escalating production costs, encountering elevated prices for these indispensable medications post-LDC graduation. This impending scenario underscores the potential ramifications of heightened import costs for APIs and other essential inputs, which could, in turn, hinder access to these medicines for economically disadvantaged households.

Table 0.9: Scenarios of increased marginal cost (MC) of producing on-patent generic medicines after Bangladesh's LDC graduation.

	Current market condition			10 per cent increase in MC		20 per cent increase in MC	
Chronic disease	Markup (oligopoly)	Average initial price (BDT)	Initial MC	New MC	New price (BDT)	New MC	New price (BDT)
Chronic fever	44.33	752.59	521.44	573.59	827.85	625.73	903.11
Heart disease	34.25	1445.94	1077.02	1184.72	1590.53	1292.42	1735.13
Respiratory	44.33	983.72	681.58	749.74	1082.09	817.90	1180.46
Diarrhoea	53.83	608.60	395.64	435.21	669.47	474.77	730.33
Ulcer	107.65	414.19	199.46	219.41	455.61	239.35	497.03
Blood pressure	107.65	647.51	311.82	343.00	712.26	374.19	777.02
Arthritis	47.10	779.81	530.13	583.14	857.79	636.15	935.78
Skin disease	150.72	707.57	282.22	310.44	778.32	338.66	849.08
Diabetes	41.87	1316.77	928.18	1021.00	1448.45	1113.82	1580.12
Cancer	22.84	3366.46	2740.62	3014.68	3703.10	3288.74	4039.75
Kidney disease	30.14	1680.85	1291.54	1420.69	1848.94	1549.85	2017.02
Liver disease	57.97	1438.73	910.78	1001.85	1582.60	1092.93	1726.48
Mental health	44.33	1282.14	888.35	977.19	1410.35	1066.02	1538.57
Paralysis	25.12	1719.20	1374.05	1511.45	1891.12	1648.86	2063.04
ENT problems	53.83	756.14	491.56	540.71	831.76	589.87	907.37
Eye problem	75.36	872.99	497.84	547.62	960.29	597.40	1047.59
Other	35.88	1234.27	908.32	999.16	1357.70	1089.99	1481.13

Source: Authors' estimation using HIES 2022 data. Note: ENT stands for ear, nose, and throat.

Scenario 4: Medicines invented and patented after 2029 require permission and royalties to produce generic versions, which will increase prices and reduce accessibility for lower-income households.

Bangladesh faces the imperative of extending patent protection to all new and innovative medicines emerging post-2029. For a significant portion of these medicines, particularly biological ones, the LDC status holds little sway over accessibility. Bangladeshi pharmaceutical firms lack the requisite capacity and technology to produce such medicines, necessitating their procurement from patent holders at elevated prices. This dynamic remains unaltered post-LDC graduation, perpetuating the dependency on patent holders for these biological medicines. However, a subset of medications entering the market post-2029 presents a different scenario. Bangladeshi pharmaceutical firms could potentially produce generic versions of these medicines, provided they secure the necessary permissions from patent holders. Negotiations would ensue, with firms obligated to pay royalties to acquire the rights to produce and distribute these medicines within Bangladesh. Consequently, the accessibility of this particular set of medicines becomes contingent upon Bangladesh's LDC graduation.

Bangladesh's existing patent laws stipulate a royalty rate of four per cent to patent holders for the production and sale of these medicines. Nonetheless, many patent holders may baulk at this rate, preferring higher royalties in exchange for granting production and marketing rights to local pharmaceutical firms. This divergence in royalty demands could potentially hinder the ability of Bangladeshi firms to access and produce generic versions of these crucial medicines, consequently impacting healthcare accessibility within the country.

To investigate the ramifications of incurring royalty payments for the production of new, innovative patented medicines post-2029, we undertake an assessment of the counterfactual prices of chronic disease medications under two royalty payment scenarios: 4 per cent and 10 per cent, as delineated in Table 0.10. Our assumption posits that firms will incorporate these royalty payments into their existing markups, thereby elevating the prices of these medicines.

Under the provision of a 4 per cent royalty fee for producing generic versions of medicines slated for market entry after 2029, we observe a marginal increase in market prices, typically around 2 to 3 per cent. However, should a higher royalty fee, such as 10 per cent, be stipulated for the production of these generic medicines, the resultant price hike would be more pronounced, with generic medicine prices escalating by approximately 5 to 8 per cent compared to the absence of a royalty fee regime.

Consequently, the imposition of royalty payments for new, innovative medicines post-2029 is anticipated to exert a moderating influence on the accessibility and affordability of these medications for lower-income households. Notably, domestic pharmaceutical firms must possess the requisite capacity and technological infrastructure to produce these generic medicines.

Table 0.10: Effects of royalty payments on the prices of new patented medicines after 2029 in Bangladesh.

	Current market condition			4 per cent royalty			10 per cent royalty		
Chronic disease	Initial markup	Average initial price (BDT)	MC	New markup	New price (BDT)	Increase in prices (%)	New markup	New price (BDT)	Increase in prices (%)
Chronic fever	44.33	752.59	521.44	48.33	773.45	2.77	54.33	804.73	6.93
Heart disease	34.25	1445.94	1077.02	38.25	1489.0	2.98	44.25	1553.6	7.45
Respiratory	44.33	983.72	681.58	48.33	1010.9	2.77	54.33	1051.9	6.93
Diarrhoea	53.83	608.60	395.64	57.83	624.43	2.60	63.83	648.17	6.50
Ulcer	107.65	414.19	199.46	111.65	422.17	1.93	117.65	434.13	4.82
Blood pressure	107.65	647.51	311.82	111.65	659.99	1.93	117.65	678.69	4.82
Arthritis	47.10	779.81	530.13	51.10	801.02	2.72	57.10	832.83	6.80
Skin disease	150.72	707.57	282.22	154.72	718.86	1.60	160.72	735.79	3.99
Diabetes	41.87	1316.77	928.18	45.87	1353.9	2.82	51.87	1409.6	7.05
Cancer	22.84	3366.46	2740.62	26.84	3476.1	3.26	32.84	3640.5	8.14
Kidney disease	30.14	1680.85	1291.54	34.14	1732.5	3.07	40.14	1810.0	7.68
Liver disease	57.97	1438.73	910.78	61.97	1475.5	2.53	67.97	1529.8	6.33
Mental health	44.33	1282.14	888.35	48.33	1317.7	2.77	54.33	1370.9	6.93
Paralysis	25.12	1719.20	1374.05	29.12	1774.2	3.20	35.12	1856.6	7.99
ENT problems	53.83	756.14	491.56	57.83	775.81	2.60	63.83	805.30	6.50
Eye problem	75.36	872.99	497.84	79.36	892.91	2.28	85.36	922.78	5.70
Other	35.88	1234.27	908.32	39.88	1270.6	2.94	45.88	1325.1	7.36

Source: Authors' estimation using HIES 2022 data. Note: ENT stands for ear, nose, and throat.

Scenario 5: Access to off-patent generic medicines will be enhanced if the import of medicine is allowed without any tariff.

Currently, the importation of medicines produced domestically is prohibited in Bangladesh, a measure implemented to safeguard domestic pharmaceutical firms from foreign competition. However, following the graduation from LDC status, Bangladesh will no longer have the authority to prohibit the importation of generic off-patent medicines. Nonetheless, Bangladesh

retains the option to levy tariffs on the importation of such medicines.[8] Should Bangladesh choose to impose sufficiently high tariffs on the importation of off-patent generic medicines, which are already manufactured by domestic firms, there will likely be no alteration in access to these medicines post-LDC graduation.

However, if Bangladesh opts to permit the unrestricted importation of these medicines, it may lead to a reduction in market concentration among domestic firms. Consequently, this reduction in market concentration could diminish the markup that domestic firms can impose on these medicines, thereby potentially lowering their prices. Consequently, this policy shift may enhance the affordability and accessibility of these medicines for the general populace. To quantify the potential impact, we conduct simulations to estimate the reduction in average prices of various chronic disease medicines corresponding to different levels of decrease in market concentration for domestic pharmaceutical firms facing foreign competition (Table 0.11). From the table, it becomes evident that should free importation be permitted for off-patent generic medicines following Bangladesh's graduation from LDC status, the prices of these medicines are expected to decrease, given the anticipated reduction in market concentration under the free import regime. As indicated by the HHI, a 10 per cent decrease in market concentration is associated with price reductions ranging from approximately 2 per cent for paralysis medications to around 6 per cent for treatments related to skin diseases. Similarly, for a 30 per cent reduction in market concentration, the corresponding price reductions are approximately three times higher, ranging from about 6 per cent to around 18 per cent across various chronic disease medications.

The decrease in prices of chronic disease medicines is poised to enhance their accessibility and affordability, particularly for lower-income households. Additionally, the perceived higher quality and efficacy of imported off-patent generic medicines may catalyse an improvement in the standards of domestically produced counterparts. Should imported off-patent generic medicines maintain a reputation for superior quality, domestic producers may be incentivised to enhance their own standards to remain competitive. Failure to do so could result in a further loss of market share for domestic producers, potentially exacerbating the reduction in market concentration. Thus, this dynamic presents an opportunity for domestic pharmaceutical

[8] Bangladesh is not a party of the Pharma Agreement of Uruguay round 1994, which has eliminated has eliminated tariffs, as well as other duties and charges, on a long list of pharmaceutical products and on the ingredients and other substances used to produce them, permanently binding them at duty-free levels (Cato Policy Analysis, No. 918, 2021, https://www.cato.org/sites/cato.org/files/2021-06/policy-analysis-918-updated.pdf. So, Bangladesh can impose tariff on the importation of medicines after its LDC graduation in 2026.

firms to elevate their offerings, thereby contributing to an overall enhancement in the quality and effectiveness of off-patent generic medicines available in the market.

Nevertheless, the assurance of increased accessibility and affordability for off-patent generic medicines cannot be guaranteed solely by allowing free importation after Bangladesh's graduation from LDC status unless significant changes are made to the marketing practices of domestic pharmaceutical firms. Presently, pharmaceutical companies in Bangladesh employ an aggressive marketing strategy whereby they directly engage with physicians and doctors through an extensive network of sales representatives. This approach aims to persuade and incentivise healthcare professionals to prescribe their medicines over alternatives. In such a scenario, imported medicines may struggle to compete with domestically produced counterparts, at least in the short term. Furthermore, the relentless pursuit of aggressive marketing strategies by domestic pharmaceutical firms is likely to escalate their marginal costs, subsequently driving up the prices of their medicines. This, in turn, could lead to a reduction in the accessibility and affordability of these medicines compared to the current state. Therefore, it becomes imperative to regulate these marketing practices to ensure that the benefits of free importation translate into tangible improvements in accessibility and affordability for consumers.

Another pertinent issue arises from the heightened costs associated with producing off-patent generic medicines domestically, particularly when contending with competition from higher-quality imported alternatives. Should the imported medicines boast superior quality, domestic pharmaceutical firms would be compelled to utilise better quality raw materials, such as Active Pharmaceutical Ingredients (APIs), and adopt more advanced technology in the manufacturing process to produce medicines that can effectively rival their imported counterparts. However, this upgrading of production standards is likely to drive up production costs and subsequently inflate the prices of these medicines. Consequently, there exists a potential risk of diminished accessibility and affordability for lower-income households. Nevertheless, such an endeavour would lead to an overall enhancement in the quality and efficacy of domestically produced medicines, thereby aligning with the overarching goal of improving healthcare outcomes for all segments of society.

Table 0.11: Reduction in prices of off-patent generic medicines if free import is allowed for these medicines after the LDC graduation.

	Current market concentration (HHI)			10 per cent fall in HHI			20 per cent fall in HHI			30 per cent fall in HHI		
Chronic disease	Markup (%)	Average initial price (BDT)	MC	Markup (%)	Average price (BDT)	Reduction in price (%)	Markup (%)	Average price (BDT)	Reduction in price (%)	Markup (%)	Average price (BDT)	Reduction in price (%)
Chronic fever	44.33	752.59	521.44	39.93	729.68	3.04	35.48	706.44	6.13	31.06	683.39	9.19
Heart disease	34.25	1445.94	1077.02	30.86	1409.37	2.53	27.42	1372.29	5.09	24.00	1335.50	7.64
Respiratory disease	44.33	983.72	681.58	39.93	953.77	3.04	35.48	923.40	6.13	31.06	893.27	9.19
Diarrhoea	53.83	608.60	395.64	48.49	587.50	3.47	43.08	566.09	6.99	37.71	544.85	10.48
Ulcer	107.65	414.19	199.46	96.98	392.91	5.14	86.16	371.32	10.35	75.43	349.91	15.52
Blood pressure	107.65	647.51	311.82	96.98	614.24	5.14	86.16	580.50	10.35	75.43	547.02	15.52
Arthritis	47.10	779.81	530.13	42.43	755.07	3.17	37.70	729.97	6.39	33.00	705.07	9.59
Skin disease	150.72	707.57	282.22	135.78	665.41	5.96	120.63	622.65	12.00	105.60	580.23	18.00
Diabetes	41.87	1316.77	928.18	37.72	1278.25	2.93	33.51	1239.19	5.89	29.33	1200.44	8.83
Cancer	22.84	3366.46	2740.62	20.57	3304.42	1.84	18.28	3241.51	3.71	16.00	3179.10	5.57
Kidney disease	30.14	1680.85	1291.54	27.16	1642.26	2.30	24.13	1603.13	4.62	21.12	1564.30	6.93
Liver disease	57.97	1438.73	910.78	52.22	1386.40	3.64	46.40	1333.33	7.33	40.61	1280.68	10.99
Mental health	44.33	1282.14	888.35	39.93	1243.11	3.04	35.48	1203.52	6.13	31.06	1164.25	9.19
Paralysis	25.12	1719.20	1374.05	22.63	1684.99	1.99	20.10	1650.29	4.01	17.60	1615.87	6.01
ENT problems	53.83	756.14	491.56	48.49	729.92	3.47	43.08	703.32	6.99	37.71	676.94	10.48
Eye problem	75.36	872.99	497.84	67.89	835.81	4.26	60.31	798.10	8.58	52.80	760.68	12.86
Other	35.88	1234.27	908.32	32.33	1201.97	2.62	28.72	1169.20	5.27	25.14	1136.69	7.91

Source: Authors' estimation using HIES 2022 data. *Note: ENT stands for ear, nose, and throat.*

5.2.4 Impact on poverty

The impact of Bangladesh's LDC graduation on the poverty rate among households with members suffering from chronic diseases is estimated using HIES data. The poverty rates are estimated based on both upper and lower-poverty-line incomes. Currently, in HIES 2022 data, the poverty rates among households with members suffering chronic diseases are 15.98 per cent and 4.71 per cent under the upper and lower poverty line income, respectively. These figures are slightly smaller than the national poverty rates, which are 18.7 and 5.6 per cent, respectively. The detailed table can be found in Annex A6.

The simulated prices in the previous section indicate minimal increases, suggesting that the poverty impacts–are likely to remain low. In Scenarios 2, 3, 4, and 5 the pricing dynamics of essential medicines for chronic diseases are forecasted to estimate the impact on household poverty.

Under Scenario 2, the poverty rate under the upper poverty line would have more than doubled, rising from approximately 16 percent to over 36 percent if Bangladesh had lost the ability to produce these drugs post-graduation. Similarly, the poverty rate under the lower poverty line would have increased more than fourfold, from below 5 percent to above 22 percent. The impact would have been particularly severe for households with members suffering from chronic diseases such as kidney disease, hypertension, cancer, or liver disease. For these households, poverty rates under the upper poverty line could rise 3 to 4 times, and under the lower poverty line, more than 5 times compared to current rates. However, the likelihood of this scenario materialising is extremely low, as there is no prospect of establishing monopoly rights for on-patent medicines that Bangladesh currently produces in generic form to the abolishment of mailbox system. Following LDC graduation, Bangladesh can continue producing these generic versions without granting monopoly rights to patent holders, thereby avoiding the projected adverse impacts on poverty.

In Scenario 3, which models increased marginal costs due to higher API import prices post-LDC graduation, the impact on poverty is not substantial. Under the upper poverty line, poverty rates are projected to increase by approximately 0.3 and 0.45 percentage points for a 10 percent and 20 percent increase in marginal costs, respectively. Similarly, under the lower poverty line, poverty rates would rise by about 0.15 and 0.25 percentage points, respectively.

The impact under Scenario 4, involving royalty payments for new patented medicines after 2029, is even smaller. If pharmaceutical firms allocate 4 percent of the markup as royalty payments to patent holders, as stipulated in the new patent act, poverty rates under both the upper and lower poverty lines are projected to increase by only 0.1 percentage points. If the royalty fee increases to 10 percent of the markup, poverty rates still rise only marginally.

In Scenario 5, where the costs of off-patent generic medicines decline due to heightened competition from imported medications, poverty rates are anticipated to decrease. For every 10 percent reduction in market concentration, measured by the Herfindahl-Hirschman Index (HHI), poverty rates among households with members afflicted by chronic illnesses are projected to decline by approximately 0.5 percentage points under the upper poverty line and about 0.2 percentage points under the lower poverty line. Households with members suffering from specific chronic ailments, such as chronic fever and mental health issues, are expected to experience more substantial reductions in poverty rates, potentially up to 4 percentage points under the upper poverty line and up to 1 percentage point under the lower poverty line. Overall, the impact of LDC graduation on household poverty is expected to be insignificant, as drug prices are unlikely to increase significantly.

5.2.5 Effects of LDC graduation on medicine and API export

To investigate the effects of Bangladesh's LDC graduation on medicine exports, we first estimate the relationship between the volume of medicine exports and the unit price of medicines. We used custom data from all medicine exports from Bangladesh from 2015 to 2019 and converted them into quarterly data. To estimate the relationship between the unit price of medicine and the volume of medicine exported from Bangladesh consistently, we control various types of fixed effects.

The following table presents the results of regression analyses, with the dependent variable being the natural logarithm of the net volume of medicine exports from Bangladesh. The independent variables include the natural logarithm of unit price, the natural logarithm of the exchange rate (BDT per importing country's currency), and the natural logarithm of world GDP. The table is structured to display three different regression specifications: the first column without any fixed effect, the second column including only the product-fixed effect, and the third column adding both product and importing country fixed effects.

Table 0.12: Estimated impact of medicine prices on medicine export from Bangladesh

	Dependent Variable = ln(Net Volume of Medicine)		
	(1)	(2)	(3)
ln(unit price)	-0.576***	-0.676***	-0.688***
ln(exchange rate)	-0.635***	-0.761***	-0.969***
ln(world GDP)	5.453***	1.547***	1.401***
Constant	-51.027***	-10.448***	-7.438**
Product fixed effect	No	Yes	Yes
Destination fixed effect	No	No	Yes
Year fixed effect	No	No	No
Observations	19515	19515	19515
Adjusted R-squared	0.2154	0.5438	0.6542

F-statistics	1787.08***	448.40***	181.08***

Source: Authors' estimation using Bangladesh Customs data.

In the first regression (Column 1 in Table), the negative coefficient for ln(unit price) suggests an inverse relationship between the unit price and the net volume of medicine exports. Here a one per cent increase in unit prices will lead to more than 0.5 per cent loss in the export volume of medicine. The negative coefficients for ln(exchange rate) and positive for ln(world GDP) indicate that an appreciation of the BDT against the importing country's currency and an increase in the world GDP contribute to higher net volumes of medicine exports. However, the constant term is large and negative, implying a substantial baseline impact that is not explained by the included variables. The adjusted R-squared is 0.2154, indicating a moderate explanatory power, and the F-statistic is highly significant at 1787.08.

The second regression (Column 2) introduces a product-fixed effect, which accounts for unobserved product-specific factors. The coefficients for ln(unit price) and ln(exchange rate) remain negative but have increased in magnitudes, suggesting their significant negative impact on the export volume of medicine. The inclusion of the product fixed effect substantially increases the adjusted R-squared to 0.5438, indicating improved model fit.

In the third regression (Column 3), destination-fixed effects are added to control for unobserved factors related to the importing countries. The coefficients maintain their signs, but the magnitudes have increased more, and the adjusted R-squared increases further to 0.6542. This suggests that accounting for both product and importing country fixed effects enhances the model's explanatory power.

A similar analysis has been conducted for API export (Table). In the first regression (column 1), the negative coefficient of ln(unit price) indicates an inverse relationship between the unit price and net volume of API exports. Here, a one per cent increase in price will lead to more than 0.80 per cent loss in the export volume of API. The negative coefficients for ln(exchange rate) indicate that an appreciation of the BDT against the importing country's currency decreases the API export, whereas the positive coefficient of ln (world GDP) increases the API export. The adjusted R squared value of 0.8102 indicates a strong explanatory power, with the F-statistic highly significant at 1580.

After introducing the product fixed effects in column (2), the sign of the coefficients remains the same, but their magnitude change. The unit price coefficients show that price changes have a lesser impact on the API export volume. The inclusion of the product fixed effect substantially increases the adjusted R-squared to 0.8941, suggesting the improved model fit. However, after introducing the product and country fixed effect, the coefficient of ln (unit price)

increased, whereas the coefficient of the other two variables decreased. The adjusted high R square value indicates the model exploratory power substantially increased after including the product and country fixed effects.

Table 0.13: Estimated impact of API prices on API export from Bangladesh

	Dependent Variable = ln(Net Volume of API)		
	(1)	(2)	(3)
ln(unit price)	-0.801***	-0.580***	-0.773***
ln(exchange rate)	-21.540***	-22.370***	-5.119*
ln(world GDP)	21.798***	14.887***	4.201
Constant	-142.051***	-61.856**	-18.044
Product fixed effect	No	Yes	Yes
Destination fixed effect	No	No	Yes
Year fixed effect	No	No	No
Observations	1111	1111	1111
Adjusted R-squared	0.8102	0.8941	0.9394
F-statistics	1580.53***	196.14***	203.40***

Source: Authors' estimation using Bangladesh Customs data.

Using the estimated price result, a simulation exercise has been conducted to assess the impact of reduced cash incentives on exports. Previously, the exporters of pharmaceuticals and API received cash incentives of 10 per cent and 20 per cent, respectively, based on exports.[9] However, these incentives have been reduced to 8 per cent for pharmaceuticals and 10 per cent for APIs.[10] This reduction of cash incentives will increase production costs.

To simulate the impact on exports, elasticity coefficients from three regression models were considered. For medicine exports, a 2 per cent reduction in cash incentives translates to a 1.2 to 1.4 per cent decrease in exports. Based on current medicine exports, this loss amounts to approximately $2 to $2.4 million. If incentives are completely discontinued, exports could decline by 5.8 to 6.9 per cent, equivalent to $10 to $12 million.

Similarly, a 10 per cent reduction in cash assistance for API exports could lead to a 6 to 8 per cent decline, while a complete cessation of cash assistance may result in a reduction of 11.6 to 16 per cent. However, exporters can mitigate export losses by absorbing additional costs and having lower profits.

[9] Circular No: FE 13, published on 24 August 2023. For details: https://www.bb.org.bd/en/index.php/mediaroom/circular

[10] Circular No FE 05 published on 12 February 2024. For details: https://www.bb.org.bd/en/index.php/mediaroom/circular

Table 0.14: Simulation of potential export loss based on estimated price elasticity

Products	Medicine		API	
Cash incentive reduction (percentage point)	2%	10%	10%	20%
Percentage loss	-1.2% to -1.4 %	-5.8% to -6.9%	-5.8% to -8.0%	-11.6% to 16.0%
Export in FY23 (million)	$175.42		$8.27	
Export loss (million)	$-2.0 to $-2.4	$-10.1 to $-12.1	$-0.5 to -0.7	$-1.0 to -1.3

Source: Author's estimation based on regression results and based on data from the EPB.

The potential increase in the cost of producing medicines, attributed to the strengthened IPR regime, is a key factor contributing to the rise in unit prices. As pharmaceutical companies face more stringent regulations and intellectual property constraints, the costs associated with research, development, and compliance are likely to escalate. Consequently, these elevated costs are transferred to the final product - medicines - leading to an increase in their prices.

The negative impact on medicine exports is a direct consequence of this price hike. As the cost of Bangladeshi medicines rises, they become less competitive in the international market. Importing countries seeking cost-effective solutions for their healthcare needs may turn to alternative suppliers with more competitive pricing. This shift in market dynamics, coupled with the negative coefficient of the unit price, suggests a potential decline in the export volume of medicines from Bangladesh.

Furthermore, this scenario underscores the delicate balance that countries like Bangladesh must navigate as they strive to meet international standards and obligations associated with the loss of LDC status. While strengthening the IPR regime is a step towards global economic integration, policymakers must carefully consider the implications for critical sectors like pharmaceuticals. Balancing the need for innovation and compliance with the imperative of maintaining affordable and accessible healthcare solutions is crucial for sustaining Bangladesh's competitiveness in the global pharmaceutical market. Policymakers may need to explore strategies such as targeted support for research and development, capacity building, and negotiating flexibilities within international agreements to ensure a sustainable and thriving pharmaceutical industry in the post-LDC graduation era.

5.2.6 Impact of LDC graduation on the pharmaceutical industry

A general equilibrium framework has been utilised to analyse the impact of LDC graduation on Bangladesh's pharmaceutical industry. A general equilibrium framework allows inter-sectoral interactions in an economy. It captures the linkages between markets in which goods from

one sector can be used as inputs for production, as well as forward and backward linkages. The impact of the reallocation of resources between sectors as a result of tariff/subsidy changes in one or more sectors can also be studied under this framework. In exploring the possible effects of tariff/subsidy and trade policy changes as a result of LDC graduation, one of the most useful Computable General Equilibrium (CGE) frameworks is the Global Trade Analysis Project (GTAP) model.

The GTAP database, which is used for this analysis, is built from several internationally renowned data sources, including national input-output (I-O) tables, FAO, IMF, IEA, OECD, etc. It also takes input from individual contributors who specialise in building IO tables for their regions/countries. The GTAP 11.0 database is the latest publicly available source and has global data for 160 regions/countries and 65 sectors referenced to the year 2017. There are 65 sectors (45 goods and 20 services sectors), 160 regions/countries and 7 factors. The 65-commodity classification is kept unchanged, but the GTAP regions are aggregated into 9, and factors are classified into 5 (land, skilled labour, unskilled labour, capital and natural resource). To look at the current global scenario, we first adjust the model using GTAPAdjust program developed by COPS to reflect the reality in 2023 using GDP data from the World Bank Development Indicators. The detail GTAP regional aggregation and GTAP commodity classification can be found in in Annex A7 and A8.

Simulation design

As an LDC, Bangladesh enjoys advantages such as duty-free market access and relaxed rules of origin in many developed and developing nations through their generalised system of preference (GSP) programs. It also benefits from the policy flexibility in adhering to the WTO rules. The pharmaceutical industry, in particular, benefits from duty-free market access and policy flexibilities in implementing the Agreement on SCM and the TRIPS under the S&DT for LDCs. Upon graduating from the LDC status, the country will no longer benefit from the existing duty-free market access designed for LDCs, which will be replaced by either a less favourable GSP scheme or no preference. This will result in a hike in tariff rates. Bangladesh currently provides a 10 per cent export incentive for API exports and 8 per cent for other medicinal exports.[11] In post-graduation, it will also no longer be able to provide export subsidies, as it will be non-compliant with the Agreement on SCM. The loss of preferential

[11] Previously, the exporters of pharmaceuticals and API received cash incentives of 10 per cent and 20 per cent, respectively, based on exports. However, these incentives have been reduced to 8 per cent for pharmaceuticals and 10 per cent for APIs.

market access and export subsidy could affect the industry's export competitiveness and reduce incentives for exporting.

In addition, after graduation, Bangladesh will be required to adhere to TRIPS regulations, necessitating the reinstatement of pharmaceutical patents and a review of pertinent laws. This adjustment may potentially result in an increase in drug prices and healthcare expenditures. The post-graduation landscape may present challenges such as a rise in Active Pharmaceutical Ingredients (API) prices, potential industry consolidation, increased import competition, and impacts on exports due to higher production costs and the need to comply with TRIPS. A literature review suggests a potential 2-4 per cent rise in capital costs for patent-protected pharmaceutical production due to TRIPS enforcement. Discussions with the stakeholders reveal that the price of imported API will rise by 20-40 per cent after LDC graduation and the loss of TRIPS waiver. This will also affect domestic production, employment, exports, and imports in the pharmaceutical sector.

Shock scenarios

To analyse the impact of LDC graduation and loss of TRIPS waiver, four sets of shock scenarios are designed. Under each scenario, a low shock and a high shock have been considered, which are discussed below:

Scenario 1: Modelling LDC graduation-induced tariff hikes and export subsidy reduction for pharmaceuticals exports

In this scenario, the loss of LDC graduation-induced tariff hike and removal of export subsidy have been modelled. Shocks have been introduced by replacing the current tariff (preferential tariff) with post-graduation tariff rates for the pharmaceutical sector in major preference-granting countries. Another shock has been introduced to remove the export subsidy on pharmaceutical sectors. Under low shock, it is considered that the domestic producers have some capacity to absorb the removal of subsidies on pharmaceuticals and API exports.

Scenario 2: Modelling the impact of the loss of TRIPS wavier

In this scenario, shocks are introduced to analyse the impact of the loss of TRIPS waiver on the pharmaceutical sector. Based on the review of secondary literature and discussions with the stakeholders, two channels of impact are considered - (i) a rise in capital costs for patent-protected pharmaceutical production (2-4 per cent increase in capital costs), and (ii) a rise in the prices of API imports used for pharmaceuticals production sectors (20-40 per cent increase in API imports) - due to TRIPS enforcement. The lower bound of the potential increase in

capital cost and API imports are considered for low shock, while the upper bounds are considered for high shock.

Scenario 3: Modelling the combined effect of tariff hikes, removal of subsidies, and the loss of TRIPS waiver on the pharmaceutical sector

The above two scenarios are combined to understand the complete effect of LDC graduation on the pharmaceutical sector in Bangladesh, including those arising from tariff hikes, subsidy removal, and loss of TRPIS waiver.

Scenario 4: Modelling the effect of tariff hikes, removal of subsidies for all sectors and the loss of TRIPS waiver on the pharmaceutical sector

In this scenario, along with the pharmaceutical sector, tariff and subsidy shocks are generated to all other sectors that enjoy preferential tariffs and/or export subsidies. Production and exports of pharmaceutical sectors are linked with other sectors through forward and backward linkages resulting from a general equilibrium effect. Therefore, to capture the general equilibrium dynamics, the current tariff preferences are replaced by post-graduation tariffs for all sectors, including pharmaceuticals. In addition, as Bangladesh will not be able to provide export subsidies to any sectors, this shock removes export incentives for all sectors, including those for pharmaceuticals and API exports. Furthermore, this scenario considers the loss of the TRIPS waiver and the resultant increase in capital cost and API imports. Therefore, this scenario implies a combined impact of LDC graduation for all sectors, including pharmaceuticals. We consider the low and high shocks based on the lower and upper bounds, as discussed above.

Estimated results

The estimated results based on GTAP simulations using the shock scenarios discussed above are summarised below:

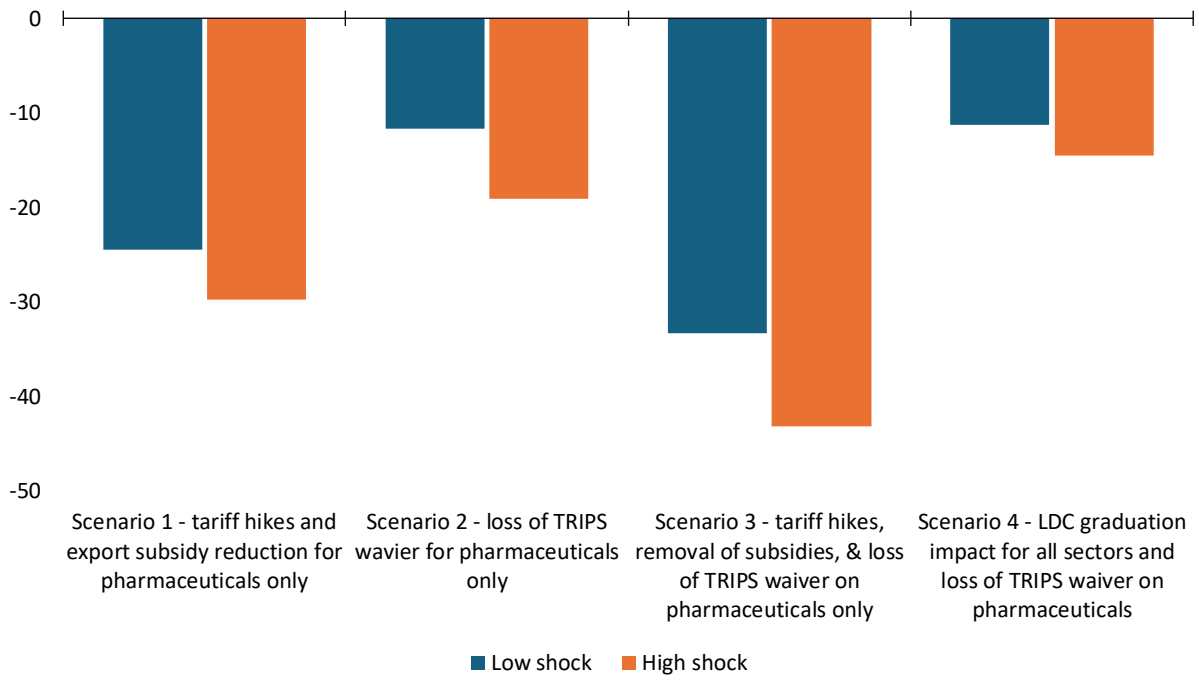
Exports of pharmaceuticals

Figure 0.12 summarises the impact of LDC graduation on Bangladesh's pharmaceutical exports.

- Under scenario 1, if the current tariff preferences in destination countries are eroded and Bangladesh removes cash subsidy after LDC graduation, pharmaceutical exports would decline 24.5-29.8 per cent.
- If Bangladesh loses the TRIPS waiver and complies with the WTO agreement, the rise in capital cost for patent-protected pharmaceutical production and increase in API prices could result in an 11.7-19.1 per cent reduction in pharmaceutical exports.

- If Bangladesh faces a tariff hike due to preference erosion, removes export subsidy for pharmaceuticals, and loses TRIPS waiver after LDC graduation, pharmaceutical exports could decline by 33.4-43.3 per cent.
- Under scenario 4, if all other sectors face an increase in tariff and removal of export subsidy, and the pharmaceutical sector complies with TRIPS requirements, the overall impact on the pharmaceuticals exports could be in the range of 11.2 per cent and 14.6 per cent. The general equilibrium effects, resulting from the other sectors through linkage effects, partly subsidies the overall impact on pharmaceutical products. It is worth noting that API exports will be affected disproportionately as the reduction in API exports is estimated to be 13.4-20.5 per cent. This is accountable for the higher rate of export subsidies provided to API exports.

Figure 0.12: Impact of LDC graduation on pharmaceuticals exports (% deviation from the baseline)



Source: Authors' estimation based on GTAP model.

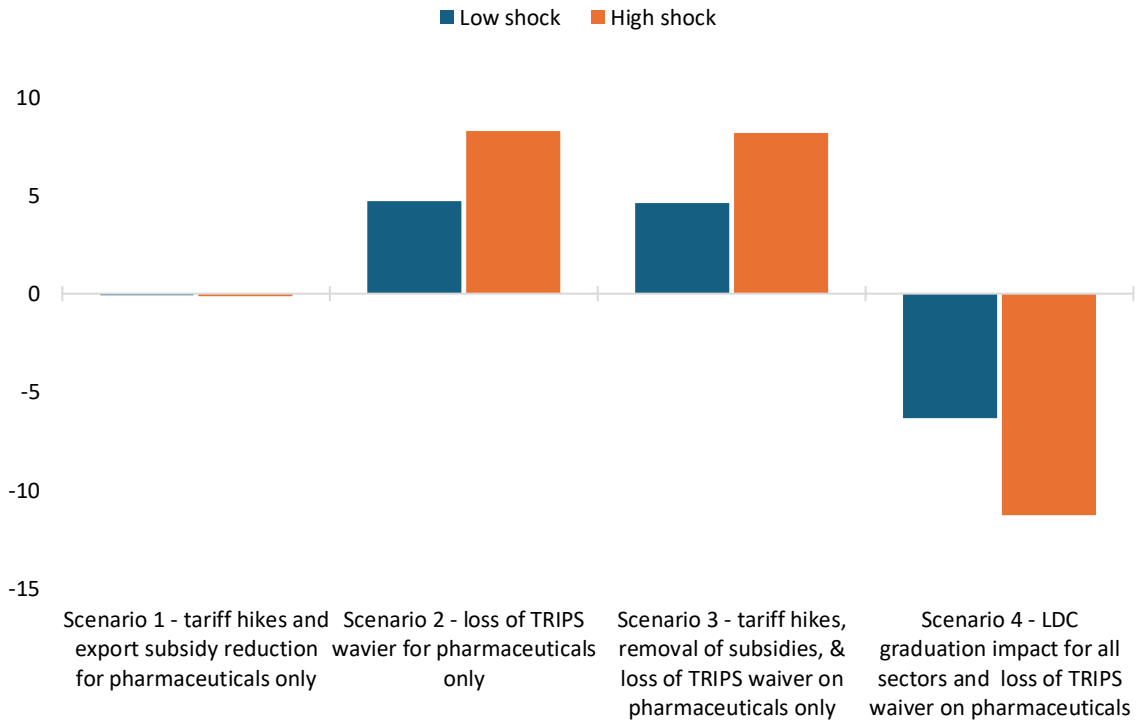
Imports of pharmaceuticals

Figure 0.13 summarises the impact of LDC graduation on pharmaceutical imports.

- Under scenario 1, Bangladesh's pharmaceutical imports are estimated to not be affected as a result of the post-graduation tariff hikes and the removal of export incentives.

- The loss of TRIPS waiver is expected to cause a 4.7-8.3 per cent rise in pharmaceuticals import value. This is accountable for the rise in capital costs and patent protection, which has caused a decline in domestic pharmaceutical production. API imports are estimated to decline by around 1 per cent under scenario 2 - the high cost of API after DC graduation will result in an increase in domestic production of API.
- Under scenario 3, pharmaceutical imports are estimated to increase by 4.6-8.2 per cent if Bangladesh faces a tariff hike, export subsidy removal and loss of TRIPS waiver.
- Under scenario 4, if all other sectors, along with the pharmaceutical sector, face a tariff hike and removal of export subsidy as a result of LDC graduation, and Bangladesh complies with TRIPS requirements, pharmaceutical imports are estimated to decline by 6.3-11.3 per cent. The rise in tariff for Bangladesh's major exports, i.e. RMG, Leather and footwear, etc., to major markets will result in a significant decline in Bangladesh's overall export earnings, which will, in turn, adversely affect imports of all sectors, including pharmaceuticals.

Figure 0.13: Impact of LDC graduation on pharmaceuticals imports (% deviation from the baseline)



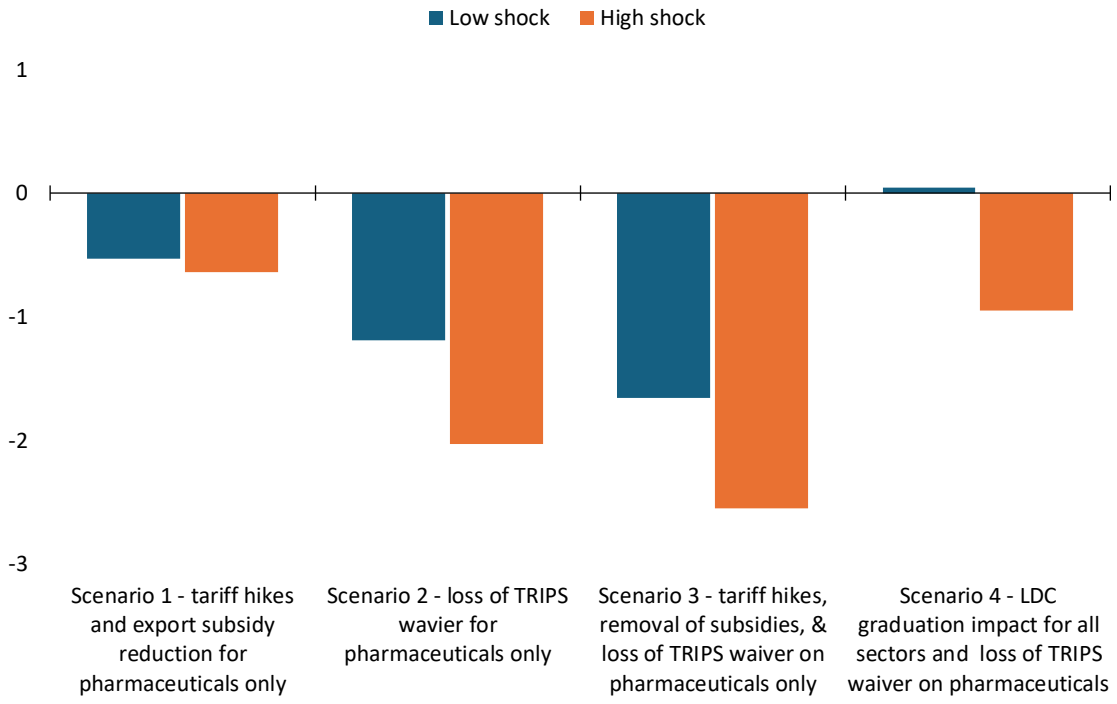
Source: Authors' estimation based on GTAP model.

Domestic production of pharmaceuticals

Figure 0.14 summarises the impact of LDC graduation on the domestic production of pharmaceuticals.

- The loss of preferential market access and removal of export subsidies for pharmaceuticals will adversely affect pharmaceutical exports, which will affect the domestic production of pharmaceuticals. The pharmaceutical production in Bangladesh could decline by 0.5-0.6 per cent under scenario 1.
- If Bangladesh loses access to the TRIPS waiver after LDC graduation, its pharmaceutical production is estimated to shrink by 1.2-2.3 per cent. The rise in capital cost and increase in API import prices as a result of patent protection are attributable to this decline in domestic production. It is important to note that although the overall production of pharmaceuticals in Bangladesh will decline, production of API is estimated to expand by 2.6-5.1 per cent. The rise in the price of API imports will result in an increase in locally produced API.
- Under scenario 3, if the loss of the TRIPS waiver is combined with the loss of preferential market access and removal of export incentives for pharmaceuticals and API exports, domestic production of pharmaceuticals will reduce by 1.7-2.6 per cent.
- If all sectors experience tariff increases and subsidy removal, coupled with the removal of TRIPS waivers for pharmaceuticals, domestic production would remain relatively stable under low shocks in scenario 4. This resilience is attributable to the inelastic demand for medicine products. Nonetheless, in the event of high shocks within this scenario, domestic pharmaceutical production could potentially decline by approximately 1 per cent. Conversely, the production of API is estimated to grow by 12-14.5 per cent due to the escalation in API import prices.

Figure 0.14: Impact of LDC graduation on pharmaceuticals production (% deviation from the baseline)



Source: Authors' estimation based on GTAP model.

6 Policy Implication and Recommendations

Bangladesh is unique amongst LDCs due to its modern and well-developed pharmaceutical sector, which has benefited from special privileges that allow domestic firms to enjoy non-compliance with global patent laws, backed by domestic policy support that limits competition from foreign sources and enables the government to provide export subsidies otherwise prohibited under WTO rules and regulations. As Bangladesh does not produce many of the patented drugs, the introduction of patent protection is unlikely to cause major disruptions, and recent changes to the patent act have taken advantage of accessing most benefits by not granting patent protection for drugs already manufactured locally under international patent protection. Consequently, LDC graduation per se is unlikely to cause drug prices to rise; however, in the future, any newly patented drugs cannot be produced locally, even if there is domestic capacity to do so, without the permission of patent holders and paying the appropriate royalty fees, as per the provisions allowed within the Bangladesh legal framework. However, exports could suffer due to the discontinuation of export subsidies, and the cost of imported APIs could rise, adversely impacting pharmaceutical production in the country. Under the new regime, there are opportunities for import liberalisation that can enhance competition and help consumers access medicines from foreign sources, having positive effects on accessing drugs and improving efficacy, giving consumers expanded choices. Overall, the impact is expected

to be limited on medicine accessibility, although the domestic pharmaceutical sector may be subject to some competition given the actual use of policy options available. Given the analysis undertaken in the study, a subsequent set of recommendations can be considered further to boost medicine accessibility and bolster the local industry's competitiveness.

1. Making full use of pharmaceutical waivers and deepening the support for the pharmaceutical industry: Bangladesh has approximately two and a half years until LDC graduation, and at the latest Ministerial Conference of the WTO (MC13), WTO members agreed to exercise due restraint provision for the LDC graduating members for three additional years post-graduation. This implies that Bangladesh can still have over five years to maintain its current policy regime for the pharmaceutical sector. It is crucial to leverage these flexibilities to provide effective policy support to the pharmaceutical sector, ensuring accessibility to medicines and industry competitiveness post-LDC graduation. With the opportunity to continue producing royalty-free medicines for the next five years, efforts should concentrate on enhancing capacity to produce more patented drugs and licensing them for continued production post-graduation. Special emphasis should be placed on the production of biological drugs, given their complexity and high costs. Bangladesh has already made strides in producing biological drugs (See Box 1). Augmented support for research and development, as well as clinical trials, holds the potential to significantly propel progress in this sector.

2. Continuing export subsidies for APIs and medicine to assist the industry in sustaining its export earnings during the transition period. Bangladesh has recently slashed its export subsidies for both API and medicine exports, with the API export subsidy reduced from 20 per cent to 10 per cent, and the medicine export subsidy reduced from 10 per cent to 8 per cent. The curtailing of export subsidies is likely to have rendered Bangladeshi pharmaceutical products less competitive, resulting in lower export earnings than their potential level. Although maintaining export subsidies indefinitely is not feasible, especially with the impending LDC graduation, it would be strategic to continue them for the next five years, a period which should align with the rules of the WTO, particularly in light of outcomes from the 13th WTO ministerial conference.

Furthermore, supporting exporters in establishing and strengthening networks with buyers in both existing and new markets is crucial for expanding exports. Over the next five years, there should be a concerted effort to penetrate high-value medicine markets such as those in Europe and North America. To achieve this, firms should receive support in developing capacities compliant with the regulatory standards of developed markets, including securing the necessary administrative approvals. This dual approach of sustaining subsidies and

enhancing compliance capabilities will provide a much-needed buffer and growth trajectory for Bangladesh's pharmaceutical industry during its crucial phase of LDC graduation.

Box 1: Breakthrough in Biotechnology: Bangladesh Develops First Biological Medicine

A groundbreaking achievement has emerged from Bangladesh's scientific community with the development of the country's inaugural medicine crafted through genetic engineering and biotechnology. This pioneering advancement, spearheaded by cytologist Kakan Nag and geneticist Nazneen Sultana, marks a monumental stride in the nation's pharmaceutical landscape. Led by the inventors of the renowned 'Bangavax' corona vaccine, this scientific duo, accompanied by 10 young researchers, has unveiled 'Erythropoietin', the nation's premier biological drug. This monumental feat, realised with the support of pharmaceutical entity Globe Biotech Limited, signals a new era in Bangladesh's pharmaceutical prowess.

What are Biologic Drugs?

Distinguishing between chemical and biologic drugs, the latter, exemplified by 'Erythropoietin', harnesses living cells or DNA for its formulation. As opposed to chemical counterparts like 'Paracetamol', which utilise additional excipients, biologic drugs emerge from cutting-edge biotechnological processes.

Domestic Production of Biologic Drugs

Erythropoietin, a protein hormone pivotal in red blood cell production, offers a lifeline for individuals grappling with anaemia due to kidney or liver impairment. Unlike its chemical counterparts, this biological marvel stands as Bangladesh's first indigenous remedy for such ailments.

Elucidating the intricacies of production, Kakan Nag and his team divulge a meticulous process reliant on genetic engineering. From isolating the gene responsible for Erythropoietin production to cloning and multiplication, each step underscores Bangladesh's burgeoning biotechnological acumen. Rigorous clinical trials, greenlit by government authorities, affirm the safety and efficacy of this homegrown remedy. With regulatory approval secured, the drug's deployment, albeit in limited capacity, marks a watershed moment in Bangladesh's pharmaceutical landscape.

Path Ahead: Unlocking Potential in Biotechnology

As Bangladesh charts a course towards LDC graduation in 2026, the spotlight shines on harnessing domestic ingenuity to circumvent potential IP hurdles. With Kakan Nag's optimistic vision for a biotech-driven future, Bangladesh stands poised to unlock a realm of possibilities in medicinal innovation. Alamgir Kabir, former Hematology Department Chairman at Dhaka Medical College, underscores the significance of this domestic breakthrough, affirming its positive reception among patients. Kakan Nag, echoing the sentiment, advocates for an enabling environment and policy support to realise Bangladesh's biotech potential fully. This momentous achievement not only augments Bangladesh's pharmaceutical prowess but also underscores its capacity for innovation on the global stage.

Source: Prothom Alo, April 19. https://www.prothomalo.com/bangladesh/8tcj6uolj4

3. Supporting the pharmaceutical industry in achieving greater cost efficiency to counter the potential rise in production costs post-LDC graduation will be important. The cost of importing APIs could increase after LDC graduation. Additionally, to produce newly patented drugs, pharmaceutical firms may have to pay royalty fees. Therefore, improving the cost efficiency of the sector should be a matter of policy attention. To this end, the following issues need to be taken into consideration.

Full operationalisation of the API park: To strengthen the backward industry and reduce reliance on imported API, the government initiated the establishment of an API park in 2008. However, it has yet to achieve full operationalisation, with only a few firms currently engaged in manufacturing there. One of the primary obstacles is the lack of gas connectivity. Although alternative options, such as using fuel to produce steam, are available, these are not economically viable. Additionally, high electricity prices exacerbate the production costs of medicines. It is important to prioritize providing all utility services at rationalised costs to the API park promptly to facilitate the commencement of operations by firms.

Supporting factors in API manufacturing: API manufacturing is considered a high-volume, low-margin business reliant on economies of scale and dedicated manufacturing lines. Consultations with industry professionals highlighted the absence of a vibrant petrochemical industry in Bangladesh as a major constraint on the pharmaceutical supply response. To achieve cost leadership in API manufacturing, a robust petrochemical industry is essential to strengthen the backward linkage of the pharmaceutical sector. Moreover, API manufacturing facilities must have adequate infrastructure to achieve economies of scale. Some industry experts suggest that the size of plots allotted to firms in the API park is insufficient to build full-fledged manufacturing units. Uninterrupted utility supplies and availability of central effluent treatment plants (CETP), among other factors, must be ensured to enable firms to minimise production costs and maintain global standards. Opportunities for future API production in various industrial parks and special economic zones (SEZs) should also be explored.

Enhancing synthetic chemistry skills: Industry representatives have highlighted the need to use drug master file (DMF) grade API in medicines for export success in regulated markets. Unlike India, which has over 4000 DMF approvals for API, Bangladesh has none. Additionally, there is a need to develop domestic capabilities to produce high-value patented API molecules, reducing dependency on external markets. Collaboration between the government and BAPI

to develop institutional capabilities for strengthening synthetic chemistry skills is crucial. Improved capacities will enable the country to manufacture APIs for newly patented drugs and enhance generic drug exports as soon as the APIs come off-patent.

Establishment of a special economic zone (SEZ) for the pharmaceutical industry: Creating a dedicated SEZ for the pharmaceutical industry can enhance supply-side capacities for export success. The infrastructure and business environment within such an SEZ should meet global standards. Furthermore, SEZs should offer expedited permitting, reduced taxes or duties, and relaxed control over the movement of capital and goods, as seen in the experiences of China and India, which boosted pharmaceutical exports through numerous SEZs.

Iinfrastructure for high-end pharmaceutical products: Pharmaceutical products require stringent storage and handling conditions. To enhance the production and export of high-end products, establishing a dedicated cargo storage and handling zone exclusively for sensitive pharmaceutical products, such as biologics, insulins, and vaccines, which require a cold chain system, is crucial. Bangladesh can learn from India's 'Pharma Zone' for such products and seek assistance from the World Health Organization (WHO) to ensure compliance with international standards.

4. Establishing bioequivalence testing capabilities should be prioritised to enable the industry to produce generic versions of newly patented drugs by leveraging various TRIPS flexibilities. This is crucial to ensuring that generic drugs match the efficacy of the original branded medicines. Currently, Bangladeshi pharma firms spend between $50,000 and $200,000 per product on testing abroad, with additional taxes exacerbating expenses. Reducing or removing these taxes can alleviate financial burdens and foster the production of more effective medicines. Although Bangladesh has initiated the Institute of Bioequivalence Studies and Pharmaceutical Sciences (IBSPS) project, progress has been minimal. Fast-tracking this project to meet global standards and gain international acceptance is essential. Lessons from the challenges faced by India's government facilities should guide the development of Bangladesh's testing infrastructure.

5. Restricting the API import in the post-LDC period needs to be examined carefully to ensure the accessibility of essential medicines. Bangladesh should consider liberalising the import of Active Pharmaceutical Ingredients (API) and refraining from imposing tariffs on both API and finished medicine imports post-LDC graduation. According to industry representatives, Bangladesh restricts API imports that are domestically producible, allowing pharmaceutical firms to import only those APIs not manufactured within the country. However, the costs of

domestically produced APIs are notably higher than those of their international counterparts. Consequently, this constraint leads to increased costs and prices for medicines employing the mandatory domestically produced APIs. Despite the lower costs of these medicines in the international market, their imports into Bangladesh are also constrained. Although the primary goal of such policies is to shield API-producing firms and encourage efficiency over time, the actual impact is a reduction in the overall competitiveness of the pharmaceutical industry in the global market and diminished accessibility of these medicines domestically. Following LDC graduation, Bangladesh will be unable to restrict the import of these medicines, rendering domestic producers incapable of competing in the local market. While imposing tariffs on both API and medicines manufactured using these APIs is an option, it would adversely affect the accessibility of these essential medicines. Therefore, rather than relying on trade policies for protection, it is advisable to provide alternative support mechanisms to foster the local production of APIs. Industry experts have emphasised that utility costs are the primary drivers of higher production costs; therefore, subsidizing utilities could help reduce production costs.

6. Expanding the insurance coverage for low-income households should be given due consideration. Also, improving the public provision of centralised procurement can be a possibile solution to minimise the financial burden healthcare. Banagladeshs low public health expenditure and high out-of-pocket expenditure limit the accessibility to healthcare. Furthermore, only 2.5 per cent of the total population is covered by medical insurance (Mostari & Mohona, 2023). The annual out-of-pocket expenditure on medicines in Bangladesh is substantial, exceeding BDT 5000 per person. This poses a significant financial burden, particularly for lower-income households.

To address this issue, the use of health insurance policies, especially among lower-income groups, should be given careful consideration. Implementing health insurance models could help enhance accessibility post-LDC graduation. This proactive step would form a crucial part of long-term planning to reduce the financial strain of medical expenses on individuals and families. By mandating health insurance, Bangladesh can fundamentally transform its healthcare landscape, ensuring that all citizens have access to essential medical services without facing financial hardship.

Also, revitalising the provision of centralised procurement of medicine could be beneficial in reducing healthcare costs. Through bulk buying, the cost of essential medicine can be reduced. Many countries follow this practice which results in significant cost reduction. For instance, in China, after introducing the pilot program of National Centralised Drug Procurement (NCDP), healthcare expenditure and drug expenditures were both reduced by 14.13 per cent and 20.75

per cent, respectively (Zhang et al., 2022). Bangladesh's Public Procurement Act of 2006 governs all public procurement processes. However, there is ongoing debate about the effectiveness of this law, particularly concerning essential medicines, as many public hospitals have reported medicine shortages, attributing these issues to factors such as insufficient budgets and delays in procurement (Tahura, 2024). Thus, revitalising the procurement policy or enacting a separate procurement policy for medicine can be a possible solution to alleviate the financial burden.

7. Introducing a support mechanism targeting low-income and most economically disadvantaged households with members suffering from chronic diseases to provide free access to essential healthcare and medicines will be an extremely helpful policy intervention in advancing affordability and accessibility to medicines. Many individuals within these groups lack stable income and permanent shelter, making it challenging for them to afford insurance premiums or even access healthcare services when needed. Despite facing chronic health issues, a notable percentage of them opt not to seek medical attention or medication due to financial constraints. The Household Income and Expenditure Survey (HIES) conducted in 2022 revealed that approximately 0.8 per cent of individuals living with chronic illnesses refrain from seeking treatment or medication altogether. For this vulnerable segment of the population, accessing healthcare services remains a distant prospect due to financial barriers and limited resources.

Some policy support measures targeting these vulnerable groups can ensure that even the most economically disadvantaged individuals can receive essential medical care. Introducing a health card system represents a promising solution in this respect. This initiative would provide eligible individuals with access to necessary treatments and medications at no cost when they visit nearby healthcare facilities, whether public or private. By implementing such a scheme, Bangladesh can take a significant step towards achieving universal healthcare coverage and improving health outcomes for all its citizens, irrespective of their socioeconomic status.

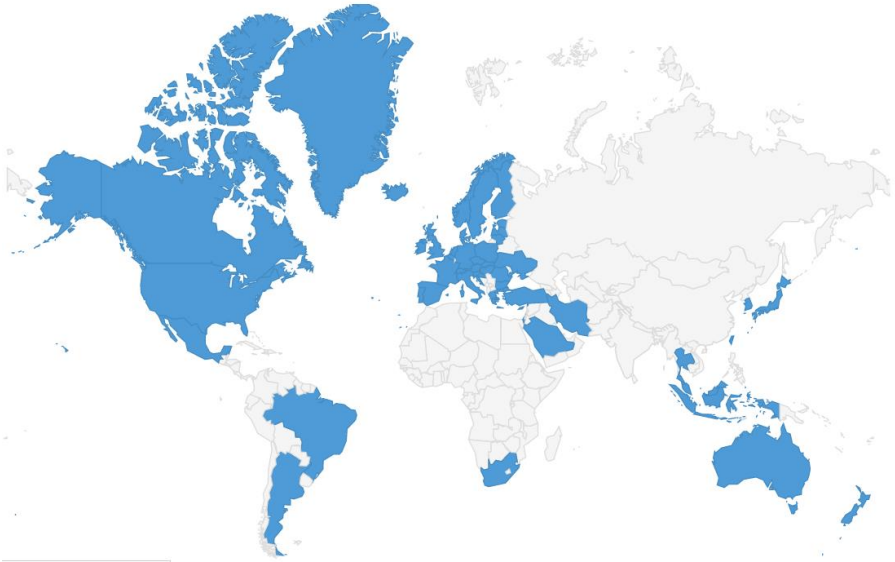
8. Strengthening institutional capacity in intellectual property-related regulatory and legal affairs now constitutes an urgent priority given the impending LDC graduation. As there is an anticipated surge in patent applications after LDC graduation, it is critical to enhance the domestic capacities to deal with intellectual property-related regulatory and legal affairs. To handle such cases, the key regulatory body for patents and trademarks—the Department of Patents, Designs, and Trademarks (DPDT)—needs to be strengthened.

Strengthening the capacity of the DGDA is crucial for enhancing and aligning quality standards.

Joining the Pharmaceutical Inspection Co-operation Scheme (PIC/S) can greatly enhance the regulatory function of the DGDA. PIC/S membership compels regulatory authorities to bolster good manufacturing practice (GMP) inspection systems and procedures, leading to improved quality standards. Membership also offers benefits such as reduced duplication of inspections, cost savings, and easier market access in member countries. The accession process involves a 'pre-accession' phase, including a gap analysis to identify differences between PIC/S requirements and the regulatory system. Although PIC/S does not oversee corrective actions during this phase, it is essential to ensure regular follow-up and prompt implementation of corrective measures.

To meet quality standards for exports, transforming DGDA drug testing laboratories into internationally accredited facilities is crucial. While the Dhaka laboratory has been modernised with assistance from the World Bank and WHO, Bangladesh lacks internationally accredited drug testing facilities. Aligning these laboratories with WHO Prequalification Programme standards can significantly enhance quality control procedures. Efforts are underway to enlist DGDA drug testing laboratories as WHO prequalified quality control laboratories, and these initiatives should be diligently pursued to elevate local laboratory standards.

Figure 6.1: List of PIC/S participating authorities



Source: https://picscheme.org/en/members, accessed on April 24, 2024.

9. Pursuing an extension for a pharmaceutical waiver through the WTO needs to be explored to mitigate the potential negative impact of pharmaceutical patents on healthcare accessibility and affordability. This initiative will be conducted in accordance with Article IX of the WTO Agreement, which allows for waivers in exceptional circumstances. Specifically, Bangladesh should submit a formal request to the TRIPS Council, highlighting the need for a

waiver on pharmaceutical patents to facilitate a smooth transition. The request should emphasise the exceptional circumstances prevalent in Bangladesh, including significant income inequality and the adverse effects of patent enforcement on healthcare access.

Upon submission of the request, the TRIPS Council will conduct a thorough review and prepare a report for consideration at the WTO Ministerial Conference within 90 days. Approval of the waiver request requires the support of three-fourths of WTO members, demonstrating a broad consensus on the necessity of the waiver. By seeking an extended pharmaceutical waiver, Bangladesh aims to safeguard public health interests and ensure continued access to affordable medicines for its population. This proactive approach aligns with Bangladesh's commitment to promoting healthcare equity and addressing the challenges posed by pharmaceutical patents in the post-LDC graduation period.

7 Concluding Remarks

The impending graduation of Bangladesh from Least Developed Country (LDC) status marks a significant turning point for the country's pharmaceutical industry, which has become a key player in the national economy and a vital component of public health. Over the past few decades, Bangladesh has made remarkable progress in pharmaceutical manufacturing, transforming from a country heavily reliant on multinational corporations for its medicine supply to one that is largely self-sufficient in producing a wide range of pharmaceutical products. This transformation has been underpinned by favourable policies and regulatory flexibilities afforded by the LDC status, particularly through exemptions from certain provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.

However, as Bangladesh prepares to graduate from LDC status in November 2026, the country’s pharmaceutical industry faces a complex and multifaceted set of challenges that could have profound implications for drug pricing and the industry's global competitiveness. The cessation of the policy flexibilities that have allowed the industry to flourish under LDC status will necessitate innovative strategies to navigate the new regulatory landscape effectively.

One of the most immediate and pressing concerns for the pharmaceutical industry in the post-LDC era is the production and availability of patented medicines. Under the current TRIPS waiver, Bangladeshi pharmaceutical companies have been able to produce generic versions of patented drugs without paying royalties. This has not only enabled the industry to keep drug prices low but has also made essential medicines more accessible to the population. To protect the accessibility to these essential medicines, one important policy change that

Bangladesh has made is its patent act, which preserves the right to produce the generic version of the medicines that are under patents in other countries. This implies that the production and accessibility of the currently patent drugs will not be impacted by the LDC graduation.

After LDC graduation, Bangladesh will lose the TRIPS waiver, and local manufacturers will be required to pay royalties to patent holders for the production of the newly patented medicines arriving in markets after Bangladesh's LDC graduation. The financial implications of these changes are not that significant as the BPA 2023 limits the royalty payment to up to 4 per cent. Also, by exploiting the MC13 decision, Bangladesh can continue with the existing patent-free regime for an additional three years after LDC graduation, and existing support measures can also be provided to this sector.

However, the potential rise in the cost of Active Pharmaceutical Ingredients (APIs) is an area of concern. APIs are the key components in drug manufacturing, and the majority of these are imported from countries like India and China. Post-graduation, the cost of importing APIs is expected to increase as per the stakeholders. This could inflate production costs, especially for generic medicines, and impact the industry's ability to maintain competitive pricing both in domestic and international markets.

Furthermore, Bangladesh's most pressing challenges lie in structural weaknesses within its healthcare system, including low public health spending, inadequate infrastructure, limited health service access, and high out-of-pocket expenditures. As evidenced by the household data, low-income people spend a significant portion of their income on medicine. Tackling these systemic issues should take priority over LDC graduation impacts, as they are the primary drivers of medicine affordability and access challenges in the country. By extending health insurance to low and middle-income households and taking advantage of the public procurement system, access to the healthcare system can be improved.

To improve the competitiveness of the pharmaceutical sector in post-LDC, some steps can be undertaken. First, the industry must also invest in research and development (R&D) to move up the value chain. Currently, the industry mostly produces and exports generic medicines, which are typically sold at lower prices and face intense competition from other low-cost producers. By investing in R&D, Bangladeshi companies can develop the capacity to produce biological drugs, which are complex and highly sought-after drugs that are coming off patent. The global market for biosimilars is also growing rapidly, and entering this market could provide Bangladeshi companies with higher profit margins and a more sustainable

competitive advantage.

Secondly, there is a need for targeted market mapping to identify niche areas within the high-end pharmaceutical markets where Bangladeshi companies can compete effectively. This could involve focusing on therapeutic areas with high demand, such as oncology, cardiovascular diseases, and diabetes, where the demand for both generic and biosimilar medicines is strong. By identifying and targeting these niches, Bangladeshi pharmaceutical companies can carve out a space for themselves in the highly competitive global market.

To further strengthen the export potential of Bangladesh's pharmaceutical industry, several areas need improvement. One critical area is the regulatory framework governing the industry. As Bangladesh transitions from LDC status, the country must align its regulatory standards with international best practices to ensure that its pharmaceutical products are accepted in high-end markets. This includes enhancing the capacity of the Directorate General of Drug Administration (DGDA) to oversee compliance with GMP standards and streamline the drug approval process.

Additionally, improving the industry's access to financing is essential for enabling the necessary investments in R&D and facility upgrades. The government could consider implementing financial incentives, such as tax breaks or low-interest loans, to encourage pharmaceutical companies to invest in these areas. Furthermore, public-private partnerships could be explored to pool resources and expertise, particularly in the development of biosimilars and other high-value pharmaceutical products.

Another area of improvement is in the development of human capital. The pharmaceutical industry requires a highly skilled workforce, particularly in areas such as R&D, quality control, and regulatory compliance. Investing in education and training programs to build a pool of skilled professionals will be crucial for the industry's long-term success. Collaborations with international pharmaceutical companies and academic institutions could also help transfer knowledge and build capacity within the industry.

While this study provides valuable insights into the potential impact of LDC graduation on Bangladesh's pharmaceutical industry, it is important to acknowledge its limitations. One of the primary limitations is the reliance on hypothetical scenario projections, which, while informative, are inherently uncertain. The actual impact of LDC graduation on the industry may differ from these projections due to a range of factors, including changes in global economic conditions, shifts in government policies, and unforeseen developments in the pharmaceutical market.

Another limitation is the scope of the data used in the analysis. The study primarily relies on available data from the Household Income and Expenditure Survey (HIES) 2022 and administrative customs data. While these sources provide a solid foundation for analysis, they may not capture the full complexity of the pharmaceutical market or the broader economic environment. As such, the findings should be interpreted with caution, and there is a need for ongoing research to monitor and assess the real-world impact of LDC graduation on the pharmaceutical industry.

Additionally, the study's focus on the economic aspects of LDC graduation means that other important dimensions, such as the social and public health implications, are not fully explored. Future research could benefit from a more holistic approach that considers the broader societal impacts of changes in drug pricing and accessibility, particularly for vulnerable populations. Despite the challenges and uncertainties associated with LDC graduation, Bangladesh's pharmaceutical industry has the potential to not only survive but thrive in the post-LDC era. By leveraging its existing strengths, addressing critical gaps, and adopting forward-looking policies, the industry can continue to contribute to public health objectives and economic development. The journey ahead will require collaboration, innovation, and a steadfast commitment to ensuring that the benefits of pharmaceutical progress are accessible to all segments of society, both at home and abroad.

The government, industry stakeholders, and international partners must work together to develop a comprehensive strategy that addresses the immediate disruptions and lays the groundwork for long-term sustainability. This includes investing in R&D, upgrading production facilities, enhancing regulatory compliance, and expanding access to high-end markets. By doing so, Bangladesh can transform the challenges of LDC graduation into opportunities for growth and development.

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9 Annex

Annex A1: Bangladesh's country wise medicine exports (million) and exports growth rate (%)

Country	FY19	FY20	FY21	FY22	FY23	Average export growth (Last three FY)
MYANMAR	20.89	19.67	22.24	27.60	25.82	10.2%

SRI LANKA	16.90	20.45	20.56	23.21	21.91	2.6%
UNITED STATES	13.69	15.19	14.97	13.44	15.25	0.6%
PHILIPPINES	9.20	13.34	13.76	22.67	15.05	11.4%
AFGHANISTAN	5.73	4.86	7.63	4.76	10.64	47.6%
KENYA	6.12	8.32	9.39	11.95	8.57	4.0%
Kampuchea Democratic	4.84	6.14	6.90	9.76	8.26	12.8%
Vietnam	5.00	5.25	5.05	2.87	5.54	15.3%
PAKISTAN	0.02	0.38	1.12	2.89	4.89	140.4%
NEPAL	3.25	2.70	5.51	5.50	4.52	28.6%
NIGERIA	2.12	1.65	2.56	3.13	3.25	27.1%
DENMARK	0.73	2.63	2.43	2.01	2.86	5.9%
SOMALIA	2.21	2.32	3.26	3.10	2.63	6.8%
Democratic Yemen	1.85	1.51	3.08	3.46	2.60	30.6%
THAILAND	0.93	0.51	0.31	0.31	2.39	211.6%

Annex A2: Quadratic Almost Ideal Demand System Framework

$$\ln V(\boldsymbol{p}, m) = \left[\left\{\frac{\ln m - \ln a(\boldsymbol{p})}{b(\boldsymbol{p})}\right\}^{-1} + \lambda(\boldsymbol{p})\right] \quad (1)$$

where ln a(p) is the transcendental logarithm function of prices or costs of individual expenditure items, p_i:

$$\ln a(\boldsymbol{p}) = \alpha_0 + \sum_{i=1}^{3} \alpha_i \ln p_i + \frac{1}{2}\sum_{i=1}^{3}\sum_{j=1}^{3} \gamma_{ij} \ln p_i \ln p_j \quad (2)$$

and b(p) is the Cobb-Douglas price aggregator, defined as follows:

$$b(\boldsymbol{p}) = \prod_{i=1}^{3} p_i^{\beta_i}$$

And $\lambda(\boldsymbol{p})$ is defined as follows:

$$\lambda(\boldsymbol{p}) = \sum_{i=1}^{3} \lambda_i \ln p_i$$

Here, we need to estimate parameters $\{\alpha_i, \beta_i, \gamma_i, \lambda_i\}$ except α_0, which is generally set to some value lower than the lowest value of *ln m* in the sample (Deaton & Muellbauer, 1980; James et al., 1997). The set of parameters satisfies some conditions:

adding up: $\sum_{i=1}^{3} \alpha_i = 1$, homogeneity: $\sum_{i=1}^{3} \beta_i = 0$, Slutsky symmetry: $\sum_{j=1}^{3} \gamma_{ij} = 0$, $\sum_{i=1}^{3} \lambda_i = 0$, and $\gamma_{ij} = \gamma_{ji}$. Now, we specify the expenditure share equation of expenditure item *i* by applying the Roy's identity to equation (1):

$$\omega_i = \alpha_i + \sum_{j=1}^{3} \gamma_{ij} ln\, p_j + \beta_i \ln\left(\frac{m}{a(\boldsymbol{P})}\right) + \frac{\lambda_i}{b(\boldsymbol{p})}\left[ln\left\{\frac{m}{a(\boldsymbol{p})}\right\}\right]^2, \qquad i\epsilon\{1,2,3\} \tag{3}$$

where ω_i is the household's budget share for expenditure category I; and here we only consider expenditure on three items: food (1), medicine (2), and education (3), ω_i is defined as follows:

$$\omega_i \equiv \frac{p_i q_i}{\sum_j p_j q_j} = \frac{p_i q_i}{m}, \quad j\epsilon\{1,2,3\}$$

Here q_i is the quantity of item *i* and p_i is the price or cost of expenditure category *j*, m is the household income spent on food, medicine, and education. Household and household head characteristics can be incorporated into the QUAIDS framework using the scaling techniques first used by Ray (1983). Poi (2002), using this scaling technique, introduces the demographic variables into the QUAIDS model. Suppose Z is the vector of demographic variables and e(p, u) is the expenditure function. Ray's scaling method decomposes the expenditure function into a scaling function, which depends on prices, level of utility, and demographics, and an expenditure function, which depends on prices and level of utility only. Specifically,

$$e(\boldsymbol{p}, u, \boldsymbol{Z}) = m_0(\boldsymbol{p}, u, \boldsymbol{Z}) \times e(\boldsymbol{p}, u)$$

Here, the scaling function $m_0(\boldsymbol{p}, u, \boldsymbol{Z})$ takes the following form:

$$m_0(\boldsymbol{p}, u, \boldsymbol{Z}) = \bar{m}_0(\boldsymbol{Z}) \times \phi(\boldsymbol{p}, u, \boldsymbol{Z})$$

where $\bar{m}_0(\boldsymbol{Z})$ is the part of the scaling function that depends on demographics only; that is, a larger family h a larger expenditure on food compared to a smaller family, and a family with more school-aged children is likely to have higher educational expenditure than a family with no school-aged children. The second part $\phi(\boldsymbol{p}, u, \boldsymbol{z})$ accounts for the interaction between the consumption pattern and demographics; that is, a family with a member with diabetes may consume a different type of food compared to a family with no such member. Ray (1983) parameterises $\bar{m}_0(\boldsymbol{Z})$ and $\phi(\boldsymbol{p}, u, \boldsymbol{z})$ as follows:

$$\bar{m}_0(\boldsymbol{Z}) = 1 + \rho' \boldsymbol{Z}$$

$$\phi(\boldsymbol{p},u,\boldsymbol{Z})=\frac{u\prod_{j=1}^{3}p_j{}^{\beta_j}\left(\prod_{j=1}^{3}p_j{}^{\eta_j'Z}-1\right)}{\frac{1}{u}-\sum_{j=1}^{3}\lambda_j\ ln\ p_j}$$

where $\rho\ and\ \eta$ are vectors of parameters to be estimated. The expenditure share equations specified in (3) become

$$\omega_i=\alpha_i+\sum_{j=1}^{3}\gamma_{ij}ln\,p_j+(\beta_i+\eta_j'\mathbf{Z})\ln\left(\frac{m}{\bar{m}_0(\boldsymbol{Z})a(\boldsymbol{P})}\right)+\frac{\lambda_i}{b(\boldsymbol{p})c(\boldsymbol{p},\boldsymbol{z})}\left[ln\left\{\frac{m}{\bar{m}_0(\boldsymbol{z})a(\boldsymbol{p})}\right\}\right]^2 \quad (4)$$

where $c(\boldsymbol{p},\boldsymbol{z})=\prod_{i=1}^{3}p_i{}^{\boldsymbol{\eta_i'z}}$ and the additional adding-up condition: $\sum_{i=1}^{3}\eta_i=0$. The uncompensated price elasticity of demand for good *i* with respect to the price of good *j* (ϵ_{ij}) is derived from Poi (2012) and given as follows:

$$\epsilon_{ij}^h=\frac{d\ln q_i}{d\ln p_j}=-\delta_{ij}+\frac{1}{\omega_i}\left(\gamma_{ij}-\left[\beta_i+\eta_i'\boldsymbol{Z}+\frac{2\lambda_i}{b(\boldsymbol{p})c(\boldsymbol{p},\boldsymbol{Z})}\ln\left\{\frac{m}{\bar{m}_0(\boldsymbol{Z})a(\boldsymbol{p})}\right\}\right]\times\left(\alpha_j+\sum_k\gamma_{ik}\ln p_k\right)-\frac{\left(\beta_j+\eta_j'\boldsymbol{Z}\right)\lambda_i}{b(\boldsymbol{p})c(\boldsymbol{p},\boldsymbol{Z})}\left[\ln\left\{\frac{m}{\bar{m}_0(\boldsymbol{Z})a(\boldsymbol{p})}\right\}\right]^2\right) \quad (5)$$

where $\delta_{ij}=1$ if *i = j* and 0 otherwise, and h is the index for households. The expenditure or income elasticity for good *i* (μ_i) is derived as follows:

$$\mu_i^h=\frac{d\ln q_i}{d\ln m}=1+\frac{1}{\omega_i}\left[\beta_i+\eta_i'\boldsymbol{Z}+\frac{2\lambda_i}{b(\boldsymbol{p})c(\boldsymbol{p},\boldsymbol{Z})}\ln\left\{\frac{m}{\bar{m}_0(\boldsymbol{Z})a(\boldsymbol{p})}\right\}\right] \quad (6)$$

The formula for price elasticities here is at the household level. The price elasticities at the market level are then the average of the household-level price elasticities. We estimate these elasticities for major medicine groups treating some particular conditions. Since data on marginal costs of medicines are generally not available and, even if available, would likely be incorrect, we estimate the marginal costs of the medicines using following formula:

$$\frac{P-c}{p}=-\frac{1}{n}\frac{Q}{P}\frac{dP}{dQ}=-\frac{1}{nE_D} \quad (7)$$

Where p is the current market price, n is the number of producers, E_D is the estimated elasticities, and c is the marginal cost to be estimated. Here p, n, and E_D are observable, so we can estimate the current marginal cost of medicine. After the LDC graduation, the marginal costs of on-patent and off-patent medicines will be affected differently. For off-patent medicines, the cost of importing active pharmaceutical ingredients (APIs) will likely be the same; hence, the marginal costs may not change for these drugs. For on-patent medicines, pharmaceutical

firms may need to pay some patent fees or royalties to patent holders for these APIs' imports. we can simulate the marginal costs of on-patent medicines in the post-LDC period in Bangladesh under several counterfactual scenarios. Using the estimated marginal costs of medicines in the post-LDC period, we can compute the prices of medicines in Bangladesh, as shown in (7).

Annex A3: Off-patented drug price comparison between Bangladesh and India

Generic	Disease	Description	Bangladesh's price (BDT)	India's price (BDT)	Difference (%)
Acetylsalicylic acid	Pain	75mg tablet	0.5	3.71	643%
Adapalene	Skin	0.1% Gel 10gm	60.18	245.42	308%
Alfuzosin	Urinary	10mg tablet unit	10.07	29.05	189%
Apixaban	Cardiovascular	2.5mg tablet	15	17.51	17%
Atenolol	Cardiovascular	50mg tablet	0.77	3.24	320%
Atomoxetine	Neurological	10 mg capsule	8	10.88	36%
Azithromycin	Infections	500mg tablet	30	35.02	17%
Baclofen	Neurological	10mg tablets	8	16.58	107%
Bismuth	Gastrointestinal	87.5mg/5ml oral solution, 200ml	95	179.09	89%
Bisoprolol	Cardiovascular	5mg tablet unit	10	14.90	49%
Bromhexine	Respiratory	4mg 100ml syrup bottle	40	87.56	119%
Calcium	Vitamins	250mg tablet	3.01	5.81	93%
Calcium dobesilate	Gastrointestinal	500mg capsule	20	29.72	49%
Carbonyl iron	Hematologic disorders	50mg capsule	3.01	6.63	120%
Carvedilol	Cardiovascular	25mg tablets	8	22.42	180%
Cefazolin	Antibiotic	1gm injection vial	200	237.46	19%
Cefradine	Antibiotic	500mg capsule	10	16.05	61%
Cefuroxime axetil	Antibiotic	250mg tablet	25	39.47	58%
Celecoxib	Pain	200mg capsules	8	26.53	232%
Cetirizine	Allergy	10mg tablet	2.5	2.79	12%
Chlorhexidine	Antiseptic	2% mouthwash, 100ml bottle	68	114.09	68%
Chlorine	Neurological	250mg capsules	3	10.21	240%
Chondroitinsulfuric acid	Osteoarthritis	200mg tablet	8.07	16.58	105%
Chromium	Vitamins	200mg capsule	35	43.78	25%
Cilnidipine	Cardiovascular	5mg tablet	6	10.25	71%

Ciprofloxacin	Infections	.3% eyedrop 5ml	40	95.75	139%
Citicoline	Cardiovascular	500mg tablet	50	91.54	83%
Citric acid	Respiratory	125mg/5ml syrup, 100ml	45	103.47	130%
Clobetasol	Skin	0.05% ointment, 15mg tube	70	92.86	33%
Clotrimazole	Infections	1% cream 20gm tube	60	99.50	66%
Cod liver oil	Vitamins	600 IU capsule	3	4.44	48%
Colecalciferol	Osteoarthritis	20000IU capsule	2.5	5.81	132%
Crotamiton	Infections	10% cream, 60ml	150	190.53	27%
Cyanocobalamin	Vitamins	1000mcg 1ml injection vial	6	46.43	674%
Dapoxetine	Sex	30mg tablet	30	72.96	143%
Desloratadine	Allergy	5mg tablet unit	2.5	12.60	404%
Dexamethasone	Pain	.1% 5ml eye drop	120	148.58	24%
Dextromethorphan	Respiratory	10mg/5ml 100ml syrup	24.37	70.28	188%
Diosmin	Cardiovascular	450mg tablet	11	33.60	205%
Docusate	Gastrointestinal	120mg tablet	1.8	15.92	784%
Dutasteride	Neurological	.5mg capsule	20	41.12	106%
Empagliflozin	Diabetic	10mg tablet	23	34.36	49%
Eplerenone	Cardiovascular	25mg tablets	30	38.90	30%
Erythromycin	Antibiotic	250mg tablets	4.5	6.50	44%
Esomeprazole	Gastrointestinal	20mg tablet	10	10.75	7%
Ezetimibe	Cardiovascular	10mg tablet	14	25.07	79%
Febuxostat	Metabolic Disorders	40mg tablet	12.03	18.44	53%
Fenofibrate	Cardiovascular	200mg capsules	7	17.91	156%
Flunarizine	Pain	10mg tablet	5	7.16	43%
Fexofenadin	Allergy	120mg tablet	7.5	14.45	93%
Fluocinolone acetonide	Pain	0.025% ointment, 5gm	38	104.20	174%
Folic acid	Hematologic disorders	5mg tablet	0.35	2.26	544%
Furosemide	Metabolic Disorders	40mg tablet	1	1.63	63%
Gabapentin	Pain	300mg tablet/capsule	16	35.15	120%

Gatifloxacin	Antibiotic	.3% 5ml eye drop	100	111.63	12%
Glimepiride	Diabetic	1mg tablet	9	19.63	118%
Glucosamine	Osteoarthritis	250mg tablet	8.07	17.25	114%
Guaifenesin	Respiratory	200mg syrup, 100ml	85	198.99	134%
Hesperidin	Pain	50mg tablet	8	12.60	58%
Hydrochlorothiazide	Cardiovascular	12.5mg tablet	12.5	21.86	75%
Irbesartan	Cardiovascular	150mg tablet	10	24.28	143%
Iron metal	Hematologic disorders	100mg/5ml ampule 5ml	335	426.42	27%
Isosorbide mononitrate	Cardiovascular	20mg tablet	1.42	5.40	280%
Ketoconazole	Infections	2% cream 15gm tube	50	144.27	189%
Ketotifen	Respiratory	1mg tablet	2.5	5.24	110%
Lansoprazole	Gastrointestinal	30mg capsule (large variation in price)	4	13.13	228%
Levodopa	Neurological	50mg tablet	8	14.59	82%
Levofloxacin	Infections	.5%, 5ml solution eye drop	87	273.28	214%
Lidocaine	Anaesthetic	30mg cream, 30gm	100	318.38	218%
Lomefloxacin	Antibiotic	.3%. 5ml eye drop	70.32	131.33	87%
Loratadine	Allergy	10mg tablet	3	13.27	342%
Losartan	Cardiovascular	25mg tablet	4.05	7.30	80%
Magnesium	Metabolic Disorders	400mg tablet	8	13.93	74%
Melitracen	Neurological	10mg tablet (large variation	5.02	9.29	85%
Metolazone	Kidney	5mg tablet	25	37.81	51%
Metoprolol	Cardiovascular	50mg tablet	1.15	6.54	469%
Miconazole	Skin	2%cream, 20gm tube	50	131.33	163%
Montelukast	Respiratory	4mg tablet	7	10.61	52%
Naproxen	Osteoarthritis	500mg tablet	7	13.80	97%
Nebivolol	Cardiovascular	5mg tablet unit	8.05	18.71	132%
Neomycin	Antibiotic	5mg ointment, 15g tube	32	116.74	265%
Nicorandil	Cardiovascular	10mg tablet	3.5	22.68	548%
Nitrofurantoin	Antibiotic	100mg tablet	20	23.30	16%
Olmesartan medoxomil	Cardiovascular	20mg tablet	11	17.91	63%

Omeprazole	Gastrointestinal	20mg capsule	4	4.26	6%
Orlistat	Metabolic Disorders	120mg capsule	40	100.42	151%
Ornidazole	Antibiotic	500mg tablet	7.02	17.25	146%
Pantoprazole	Gastrointestinal	20mg tablet	3	10.08	236%
Paracetamol	Pain	500mg tablet	1.3	1.33	2%
Permethrin	Skin	5% w/w cream, 30gm tube	60	76.94	28%
Pioglitazone	Diabetic	15mg tablet	10	10.10	1%
Povidone-iodine	Miscellaneous	5%, 20gm ointment	40	78.59	96%
Prasugrel	Cardiovascular	10mg tablet	20	34.23	71%
Prazosin	Cardiovascular	5mg tablet	15	15.92	6%
Pregabalin	Neurological	50mg capsule	13	16.98	31%
Prilocaine	Anaesthetic	2.5% w/w, 30gm cream	400	1003.57	151%
Propafenone	Cardiovascular	150mg tablet	15	19.77	32%
Pseudoephedrine	Allergy	30mg syrup, 100ml	100	151.70	52%
Pyridostigmine	Miscellaneous	60mg tablet	25	25.47	2%
Pyridoxine	Neurological	10mg tablet	5	8.34	67%
Quetiapine	Neurological	50mg tablet	8	10.61	33%
Rabeprazole	Gastrointestinal	20mg tablet	10	12.07	21%
Ramipril	Hypertension	5mg tablet	8.03	12.15	51%
Riboflavin	Vitamins	5mg tablet	0.3	1.72	475%
Risedronic acid	Osteoarthritis	50mg tablet	120.37	406.74	238%
Risperidone	Neurological	2mg tablet	5	6.37	27%
Rivastigmine	Neurological	3mg tablet	30	30.25	1%
Roflumilast	Respiratory	500mcg tablet	15	18.24	22%
Salbutamol	Respiratory	50mcg/puff, inhaler	250	340.74	36%
Salicylic acid	Skin	3% cream, 10gm (additional molecules not found)	70	79.60	14%
Salmeterol	Respiratory	50mcg, inhaler	520	625.93	20%
Sevelamer	Kidney	400mg tablet	30	30.51	2%
Sildenafil	Sex	100mg tablet	50.15	63.68	27%
Silodosin	Urinary	8mg tablet	25	34.11	36%
Sodium (valporate)	Neurological	300mg tablet/capsule	9	9.29	3%
Solifenacin	Urinary	5mg tablet	15	56.78	279%

Sotalol	Cardiovascular	80mg tablet	10	15.45	55%
Sparfloxacin	Antibiotic	200mg tablet	16	23.22	45%
Sulfasalazine	Miscellaneous	500mg tablet	5.22	7.00	34%
Tamsulosin	Urinary	.4mg tablet	10	16.58	66%
TETRACYCLINE (hcl)	Antibiotic	250mg capsule	1	2.79	179%
THIAMINE (hcl)	Vitamins	100mg tablets	0.86	3.05	255%
Tolfenamic acid	Pain	200mg	10	26.53	165%
Tolterodine	Urinary	2mg tablet	3	23.75	692%
Topiramate	Neurological	5mg tablet	5	21.09	322%
Torasemide	Cardiovascular	20mg tablet	8	17.11	114%
Tranexamic acid	Miscellaneous	500mg/5ml, 5ml ampule	80	95.48	19%
Ursodeoxycholic acid	Miscellaneous	150mg tablet	15	24.01	60%
Valaciclovir	Miscellaneous	500mg tablet	40	89.89	125%
Warfarin	Cardiovascular	5mg tablet	3	3.56	19%

Annex A4: Annual Out of Pocket Expenditure on Medicines for Chronic Diseases (BDT)

Chronic Disease	National	Rural	Urban	Female Household Head	Male Household Head
Chronic Fever	10,380.59	9,649.38	11,601.39	7,800.00	10,712.65
Injuries	12,351.39	11,779.29	13,093.99	16,635.79	11,968.01
Chronic Heart Disease	21,839.76	19,264.92	24,217.07	25,274.15	21,516.30
Respiratory	12,905.89	12,243.16	13,634.10	16,585.77	12,520.58
Diarrhoea	6,739.36	7,138.87	6,210.00	4,466.67	6,982.86
Ulcer	7,909.77	7,928.27	7,886.73	8,743.30	7,826.59
Blood pressure	12,235.42	10,763.61	13,349.06	13,871.21	12,055.26
Arthritis	10,014.04	9,770.67	10,400.40	11,826.30	9,830.97
Skin problem	8,073.33	7,886.27	8,278.46	8,557.71	8,030.84
Diabetes	21,834.02	19,009.71	23,316.52	25,065.47	21,470.46
Cancer	46,717.04	41,589.71	51,024.00	6,900.00	48,526.91
Kidney Diseases	24,164.73	23,162.75	25,088.44	29,331.43	23,682.51
Liver Diseases	19,162.77	15,712.17	22,664.12	16,132.50	19,563.47
Mental Health	14,074.52	11,492.00	16,941.73	17,988.95	13,427.79
Paralysis	21,279.02	21,240.00	21,320.51	25,432.50	20,826.94
ENT problem	8,998.58	7,256.82	10,933.87	14,754.15	8,302.48
Eye problem	9,516.06	9,649.27	9,345.00	10,311.60	9,428.16
Other	13,664.17	13,219.63	14,121.06	13,216.85	13,709.48

Source: Authors' illustration using HIES 2022.

Annex A5: Moments of monthly costs on medicines associated with treatment of chronic illness

Chronic disease	Average	Median	Standard Deviation	Minimum	Maximum
Chronic Fever	752.59	450	812.20	30	5000
Heart Disease	1445.94	1000	1559.30	12	12000
Respiratory Disease	983.72	500	2158.92	10	50000
Diarrhoea/Dysentery	608.60	350	818.80	20	4000
Gastric/ ulcer	414.19	210	723.57	2	15000
Blood pressure	647.51	445	770.19	10	7000
Arthritis/ Rheumatism	779.81	500	928.49	6	8250
Skin problem	707.57	350	1061.45	10	9000
Diabetes	1316.77	900	1369.26	6	12000
Cancer	3366.46	1500	4401.76	30	18000
Kidney Diseases	1680.85	1200	1712.55	20	10000
Liver Diseases	1438.73	1000	1615.84	40	8000
Mental Health	1282.14	750	1412.84	10	10000
Paralysis	1719.20	1200	1847.59	20	11500
Ear/ENT problem	756.14	450	932.23	10	8000
Eye problem	872.99	450	1561.11	7	15000
Other (specify)	1234.27	600	2088.34	5	30000

Source: Authors' computation using HIES 2022

Annex A6: Impact of LDC graduation on poverty rate because of changes in medicine prices

	Current poverty rate	Case 2: Monopoly pricing	Case 3: Increase in Marginal Costs		Case 4: Royalty payment		Case 5: Per cent fall in HHI		
			10%	20%	4%	10%	10%	20%	30%
Chronic disease	Upper poverty line								
Chronic fever	23.49	42.72	24.74	25.31	23.9	23.9	22.54	22.54	20.6
Injuries	17.98	17.98	17.98	17.98	17.98	17.98	17.98	17.98	17.98
Heart disease	12.8	31.68	13.09	13.37	12.8	12.8	12.65	12.65	12.61
Respiratory	17.61	34.14	17.96	17.96	17.79	17.79	17.16	15.59	15.35
Diarrhoea	8.57	22.91	12.11	12.11	8.57	12.11	8.57	8.57	8.57
Ulcer	18.28	40.53	18.55	18.55	18.34	18.44	17.67	17.12	16.34
Blood pressure	12.63	36.64	12.99	13.25	12.67	12.92	12.53	11.6	11.41
Arthritis	17.07	37.42	17.51	17.57	17.39	17.46	16.81	16.73	16.5
Skin disease	15.31	45.48	15.56	15.73	15.31	15.31	15.07	14.88	14.88
Diabetes	8.65	27.86	9.14	9.14	8.95	8.95	8.31	8.21	7.64
Cancer	7.15	21.8	7.15	7.15	7.15	7.15	7.15	7.15	7.15
Kidney disease	8.47	33.09	8.47	8.47	8.47	8.47	8.47	8.1	8.1
Liver disease	17.86	46.98	17.86	17.86	17.86	17.86	17.86	16.84	15.32
Mental health	22.07	42.72	22.07	22.07	22.07	22.07	22.07	19.62	18.06

Paralysis	18.3	43.14	18.3	18.3	18.3	18.3	18.3	18.3	18.3
ENT	10.5	27.92	10.5	10.5	10.5	10.5	9.7	9.7	9.37
Eye problem	14.67	37.75	15.06	15.06	15.06	15.06	14.67	14.67	14.67
Other	16.5	33.65	16.94	17.3	16.63	16.63	15.55	14.88	14.33
Total	15.98	36.22	16.32	16.43	16.1	16.18	15.56	15.03	14.59
Chronic disease	**Lower poverty line**								
Chronic fever	5.19	22.25	5.33	5.33	5.19	5.19	5.19	4.38	4.38
Injuries	3.77	3.77	3.77	3.77	3.77	3.77	3.77	3.77	3.77
Heart disease	4.09	22.39	4.53	4.6	4.24	4.31	3.3	3.15	2.74
Respiratory	6.01	22.33	6.35	6.65	6.35	6.35	5.49	5.31	4.93
Diarrhoea	2.83	14.17	2.83	2.83	2.83	2.83	2.83	2.83	2.83
Ulcer	5.37	24.84	5.37	5.56	5.37	5.37	5.18	4.91	4.8
Blood pressure	3.33	26.63	3.6	3.6	3.58	3.58	3.33	3.17	2.93
Arthritis	5.34	21.95	5.44	5.51	5.4	5.41	5.26	4.91	4.73
Skin disease	5	32.8	5.41	5.41	5.41	5.41	4.71	4.56	3.89
Diabetes	2.5	13.87	2.5	2.5	2.5	2.5	2.5	2.31	1.9
Cancer	0	8.09	0	0	0	0	0	0	0
Kidney disease	1.4	16.29	1.4	1.4	1.4	1.4	1.4	1.4	1.4
Liver disease	5.79	27.46	5.79	5.79	5.79	5.79	5.79	5.79	5.79
Mental health	4.04	26.47	4.04	4.32	4.04	4.04	4.04	4.04	3.27
Paralysis	5.04	26.99	10.04	10.69	5.04	10.04	3.74	3.74	3.74
ENT	3.13	13.53	3.13	3.13	3.13	3.13	3.13	3.13	3.13
Eye problem	2.61	24.16	2.61	2.61	2.61	2.61	2.21	2.21	2.21
Other	5.54	19.94	5.54	5.57	5.54	5.54	5.19	5.19	5.15
Total	4.71	22.36	4.88	4.97	4.8	4.85	4.49	4.3	4.08

Source: Authors' estimation using HIES 2022.

Annex A7: GTAP regional aggregation

Model aggregation	GTAP region
Bangladesh	Bangladesh (BGD)
Canada	Canada (CAN)
China	China (CHN)
India	India (IND)
Japan	Japan (JPN)
South Korea	South Korea (KOR)
United Kingdom	United Kingdom (UK)
United States of America	United States of America (USA)
European Union 27	Austria (AUT), Belgium (BEL), Bulgaria (BGR), Croatia (HRV), Cyprus (CYP), Czech Republic (CZE), Denmark (DNK), Estonia (EST), Finland (FIN), France (FRA), Germany (DEU), Greece (GRC), Hungary (HUN), Ireland (IRL), Italy

	(ITA), Latvia (LVA), Lithuania (LTU), Luxembourg LUX), Malta (MLT), Netherlands (NLD), Poland (POL), Portugal (PRT), Romania (ROU), Slovakia (SVK), Slovenia (SVN), Spain (ESP), Sweden (SWE)
Rest of World	Argentina (ARG), Bolivia (BOL), Chile (CHL), Colombia (COL), Ecuador (ECU), Paraguay (PRY), Peru (PER), Uruguay (URY), Venezuela (VEN), Rest of South America (XSM), Costa Rica (CRI), Guatemala (GTM), Honduras (HND), Nicaragua (NIC), Panama (PAN), El Salvador (SLV), Rest of Central America (XCA), Dominican Republic (DOM), Jamaica (JAM), Puerto Rico (PRI), Trinidad and Tobago (TTO), Caribbean (XCB), Bahrain (BHR), Islamic Republic of Iran (IRN), Israel (ISR), Jordan (JOR), Kuwait (KWT), Oman (OMN), Qatar (QAT), Saudi Arabia (SAU), United Arab Emirates (ARE), Rest of Western Asia (XWS), Egypt (EGY), Morocco (MAR), Tunisia (TUN), Rest of North Africa (XNF), Benin (BEN), Burkina Faso, (BFA), Cameroon (CMR), Côte d'Ivoire (CIV), Ghana (GHA), Guinea (GIN), Nigeria (NGA), Senegal (SEN), Togo (TGO), Rest of Western Africa (XWF), Central Africa (XCF), South Central Africa (SAC), Ethiopia (ETH), Kenya (KEN), Madagascar (MDG), Malawi (MWI), Mauritius (MUS), Mozambique (MOZ), Rwanda (RWA), Tanzania (TZA), Uganda (UGA), Zambia (ZMB), Zimbabwe (ZWE), Rest of Eastern Africa (XEC), Botswana (BWA), Namibia (NAM), South Africa (ZAF), Rest of South African Customs (XSC), Mongolia (MNG), Taiwan (TWN), Rest of East Asia (XEA), Brunei Darussalam (BRN), Lao People's Democratic Republic (LAO), Rest of Southeast Asia (XSE), Nepal (NPL), Sri Lanka (LKA), Rest of South Asia (XSA), Australia (AUS), Brazil (BRA), Cambodia (CAM), Hong Kong (HKG), Indonesia (IDN), Malaysia (MAL), Pakistan (PAK), Philippines (PHL), Russia (RUS), Singapore (SGP), New Zealand (NZL), Thailand (THA), Turkey (TUR), Vietnam (VNM), Rest of Oceania (XOC), Mexico (MEX), Rest of North America (XNA), Switzerland (CHE), Norway (NOR), Rest of EFTA (XEF), Albania (ALB), Belarus (BLR), Ukraine (UKR), Rest of Eastern Europe (XEE), Rest of Europe (XER), Kazakhstan (KAZ), Kyrgyzstan (KGZ), Tajikistan (TJK), Rest of Former Soviet Union (XSU), Armenia (ARM), Azerbaijan (AZE), Georgia (GEO), Rest of the World (XTW)

Annex A8: GTAP commodity classification

#	Sector Name	#	Sector Name
1	Paddy rice	**34**	Basic pharmaceutical products
2	Wheat	**35**	Rubber and plastic products
3	Cereal grains nec	**36**	Mineral products nec
4	Vegetables, fruit, nuts	**37**	Ferrous metals
5	Oil seeds	**38**	Metals nec

6	Sugar cane, sugar beet	**39**	Metal products
7	Plant-based fibres	**40**	Computer, electronic and optic
8	Crops nec	**41**	Electrical equipment
9	Bovine cattle, sheep and goats	**42**	Machinery and equipment nec
10	Animal products nec	**43**	Motor vehicles and parts
11	Raw milk	**44**	Transport equipment nec
12	Wool, silk-worm cocoons	**45**	Manufactures nec
13	Forestry	**46**	Electricity
14	Fishing	**47**	Gas manufacture, distribution
15	Coal	**48**	Water
16	Oil	**49**	Construction
17	Gas	**50**	Trade
18	Minerals nec	**51**	Accommodation, Food and service
19	Bovine meat products	**52**	Transport nec
20	Meat products nec	**53**	Water transport
21	Vegetable oils and fats	**54**	Air transport
22	Dairy products	**55**	Warehousing and support activities
23	Processed rice	**56**	Communication
24	Sugar	**57**	Financial services nec
25	Food products nec	**58**	Insurance
26	Beverages and tobacco products	**59**	Real estate activities
27	Textiles	**60**	Business services nec
28	Wearing apparel	**61**	Recreational and other service
29	Leather products	**62**	Public Administration and defence
30	Wood products	**63**	Education
31	Paper products, publishing	**64**	Human health and social work
32	Petroleum, coal products	**65**	Dwellings
33	Chemical products		

Annex A9: Firm-wise market share, generic and growth information

Firm	Market share	No of generics	Growth
Square Pharmaceuticals PLC	17.6%	616	8.4%
Incepta Pharmaceuticals Ltd.	11.9%	762	19.7%
Beximco Pharmaceuticals Ltd.	9.5%	395	17.8%
Healthcare Pharmaceuticals Ltd.	7.2%	329	17.8%
Renata Limited	4.9%	309	9.5%
Opsonin Pharma Ltd.	4.5%	499	10.0%
Aristopharma Ltd.	4.1%	332	20.1%

Radiant Pharmaceuticals Ltd.	3.9%	122	25.1%
Eskayef Pharmaceuticals Ltd.	3.8%	420	4.1%
ACI Limited	3.8%	390	25.1%
ACME Laboratories Ltd.	3.7%	496	18.4%
Drug International Ltd.	3.3%	453	17.1%
Popular Pharmaceuticals Ltd.	3.1%	349	31.1%
UniMed UniHealth Pharmaceuticals Ltd.	2.4%	324	11.2%
Novo Nordisk Pharma (Pvt.) Ltd	1.6%	12	13.9%
General Pharmaceuticals Ltd.	1.5%	281	18.4%
Beacon Pharmaceuticals PLC	1.3%	281	13.0%
Ibn Sina Pharmaceuticals Ltd.	1.1%	347	20.2%
Ziska Pharmaceuticals Ltd.	1.1%	187	16.4%
NIPRO JMI Pharma Ltd.	1.1%	115	20.2%
Synovia Pharma PLC.	0.9%	102	25.6%
Sun Pharmaceutical (Bangladesh) Ltd.	0.9%	66	7.5%
Novartis (Bangladesh) Ltd.	0.9%	37	13.5%
Navana Pharmaceuticals Ltd.	0.8%	195	37.8%
Nuvista Pharma Ltd.	0.8%	89	10.5%
Roche Bangladesh Ltd.	0.8%	17	3.0%
Orion Pharma Ltd.	0.7%	147	8.1%
Servier Bangladesh Operation	0.5%	8	17.5%
Biopharma Limited	0.3%	189	2.8%
Labaid Pharma Ltd.	0.3%	60	-1.5%
Delta Pharma Ltd.	0.3%	100	10.9%
Globe Pharmaceuticals Ltd.	0.2%	176	-37.5%
Pharmasia Limited	0.1%	111	14.2%
Pacific Pharmaceuticals Ltd.		165	
Kemiko Pharmaceuticals Ltd.		133	
OSL Pharma Limited		126	
Jayson Pharmaceuticals Ltd.		123	
Techno Drugs Ltd.		118	
Albion Laboratories Limited		115	
Chemist Laboratories Ltd.		111	
Edruc Limited		111	
Alco Pharma Ltd.		110	
Euro Pharma Ltd.		107	
Gonoshasthaya Pharma Ltd.		103	
Zenith Pharmaceuticals Ltd.		103	
Asiatic Laboratories Ltd.		95	
Everest Pharmaceuticals Ltd.		95	
Rephco Pharmaceuticals Ltd.		94	
Pharmadesh Laboratories Ltd.		93	
Sharif Pharmaceuticals Ltd.		93	
The White Horse Pharmaceuticals Ltd.		92	

Amico Laboratories Ltd.		88	
Benham Pharmaceuticals Ltd.		88	
Jenphar Bangladesh Ltd.		88	
Apex Pharmaceuticals Ltd.		86	
Kumudini Pharma Ltd.		85	
Desh Pharmaceuticals Ltd.		84	
Concord Pharmaceuticals Ltd.		82	
Medicon Pharmaceuticals Ltd.		82	
Team Pharmaceuticals Ltd.		81	
Silva Pharmaceuticals Ltd.		79	
Somatec Pharmaceuticals Ltd.		79	
Nipa Pharmaceuticals Ltd.		74	
Rangs Pharmaceuticals Ltd.		74	
Ambee Pharmaceuticals Ltd		73	
Medimet Pharmaceuticals Ltd.		73	
Novatek Pharmaceuticals Ltd.		73	
Ad-din Pharmaceuticals Ltd		72	
Monicopharma Ltd.		70	
Doctor's Chemical Works Ltd.		69	
Reman Drug Laboratories Ltd.		68	
Gaco Pharmaceuticals Ltd.		67	
Silco Pharmaceutical Ltd.		67	
SANDOZ (A Novartis Division)		66	
Ethical Drugs Limited		65	
Hudson Pharmaceuticals Ltd.		65	
Novo Healthcare and Pharma Ltd.		65	
Veritas Pharmaceuticals Ltd.		65	
ZAS Corporation		64	
Leon Pharmaceuticals Ltd.		62	
One Pharma Ltd.		62	
Bristol Pharmaceuticals Ltd.		61	
Astra Biopharmaceuticals Ltd.		57	
Cosmic Pharma Ltd.		57	
Supreme Pharmaceutical Ltd.		55	
Doctor TIMS Pharmaceuticals Ltd.		54	
Biogen Pharmaceuticals Ltd.		52	
Al-Madina Pharmaceuticals Ltd		51	
Virgo Pharmaceuticals Ltd.		48	
Seema Pharmaceuticals Ltd.		47	
Millat Pharmaceuticals Ltd.		46	
Central Pharmaceuticals Ltd.		45	
Union Pharmaceuticals Ltd		45	
Goodman Pharmaceuticals Ltd.		44	
Hallmark Pharmaceuticals Ltd.		43	

Modern Pharmaceuticals Ltd.		43	
Sunman-Birdem Pharma Ltd.		41	
United Pharmaceuticals Ltd.		39	
Apollo Pharmaceutical Ltd.		37	
Naafco Pharma Ltd.		37	
Amulet Pharmaceuticals Ltd.		35	
DBL Pharmaceuticals Ltd.		35	
Aexim Pharmaceuticals Ltd		34	
Pristine Pharmaceuticals Ltd		34	
Premier Pharmaceuticals Ltd.		33	
Reliance Pharmaceuticals Ltd.		33	
Cosmo Pharma Laboratories Ltd.		31	
Globex Pharmaceuticals Ltd.		31	
Novelta Bestway Pharma Ltd.		30	
Orbit Pharmaceuticals Ltd.		30	
Indo Bangla Pharmaceutical		29	
Marker Pharma Ltd.		29	
MST Pharma		29	
APC Pharma Ltd.		28	
Mystic Pharmaceuticals Ltd.		28	
Janata Traders		27	
City Overseas Ltd.		26	
Jayson Natural Products Ltd.		26	
Decent Pharma Laboratories Ltd.		25	
Genvio Pharma Ltd.		25	
Radiant Nutraceuticals Ltd.		25	
Total Herbal & Nutraceuticals		25	
Guardian Healthcare Ltd.		24	
Peoples Pharma Ltd.		24	
Salton Pharmaceuticals Ltd.		23	
Novus Pharmaceuticals Ltd.		21	
Sonear Laboratories Ltd.		21	
Maks Drug Limited		20	
Belsen Pharmaceuticals Ltd.		19	
Marksman Pharmaceuticals Ltd.		19	
Purnava Limited		19	
Arges Life Science Limited		18	
Centeon Pharma Ltd.		18	
Mundipharma (BD) Pvt. Ltd.		18	
S.N. Pharmaceutical Ltd.		17	
Bengal drugs Ltd.		16	
Orion Infusion Ltd.		16	
Credence Pharmaceuticals Ltd.		15	
Alkad Laboratories		14	

Aztec Pharmaceuticals Ltd.		14	
MedRx Life Science Ltd.		14	
Pharmik Laboratories Ltd.		14	
Prime Pharmaceuticals Ltd.		14	
Syntho Laboratories Ltd.		14	
Bexter (Ay) Laboratories		13	
Skylab Pharmaceuticals Ltd.		13	
BOTS Pvt. Limited		12	
Legends Pharma		12	
Radius Pharmaceuticals Ltd.		12	
Opsonin Herbal & Nutraceuticals Ltd.		11	
Libra Infusions Ltd.		9	
Oyster Pharmaceuticals Ltd.		9	
Total Natural Company (Unani)		9	
RN Pharmaceuticals		8	
Royal Pharmaceutical Ltd.		8	
Allied Pharmaceuticals Ltd.		7	
FnF Pharmaceuticals Ltd.		7	
Get Well Limited		7	
Pharmacil Limited		7	
Institute of Public Health (IPH)		6	
Quality Pharmaceuticals Ltd.		6	
AqVida bangladesh		5	
Bronson Laboratories (BD) Ltd.		5	
International Agencies (Bd.) Limited		5	
Alien Pharma		4	
C2C Pharma Ltd.		4	
Momotaz Pharmaceuticals Ltd.		4	
Reckitt & Benckiser Ltd.		4	
CuRx		3	
Libra Pharmaceuticls Ltd.		3	
MGH Healthcare Limited		3	
EMCS Pharma Limited (An enterprise of ICDDR,B)		2	
Greenland Pharmaceuticals Ltd.		2	
GSK Bangladesh Limited		2	
River Pharma		2	
Ultra Pharma Ltd.		2	
Beauty Formulas		1	
Bright HealthCare		1	
Derma Health Care		1	
Diva's Secret		1	
Dr Rhazes		1	
EMPECS Medical Device Co., Ltd.		1	

Empiric Laboratories Ltd.		1	
JMI Syringes & Medical Devices Ltd.		1	
Kawsar Chemicals		1	
Lexicon Pharma		1	
Marie Stopes Bangladesh		1	
MicroMed		1	
NEMUS Pharmaceutical Pvt. Ltd.		1	
Nutrilife Pharma		1	
Pfizer		1	
Radiant Export Import Enterprise		1	
Shuvro Limited		1	
Unilever Bangladesh Limited		1	
Unique Pharmaceuticals Ltd.		1	
West-Coast pharmaceutical works ltd.		1	
SHINIL Pharma Limited			

Source: Medex