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POLICY BRIEF

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

Abstract: Bangladesh's impending graduation from least developed country (LDC) status in November 2026 will introduce significant changes for its pharmaceutical sector by ending the policy space afforded under the shield of LDC status, which has supported domestic production and medicine accessibility. Drawing on a detailed study using both qualitative and quantitative methods, this policy brief examines the potential impacts of these changes and identifies policy priorities to address emerging challenges. The key findings are:

- Analyses suggest that medicine prices are unlikely to be significantly impacted by LDC graduation, partly due to the proactive measures under the Bangladesh Patent Act (BPA) 2023, which incorporates critical flexibilities aligned with global regimes on intellectual property rights and medicine accessibility. Consequently, the poverty and welfare implications arising from LDC graduation per se for Bangladeshi households, particularly those reliant on essential medicines, are expected to be limited. While the discontinuation of export subsidies could have a moderate negative impact on pharmaceutical exports, the small scale of exports relative to the sector limits broader implications.
- Bangladesh's current capacity to produce patented medicines remains limited, reducing the likelihood of immediate disruptions post-graduation.
- BPA 2023 includes key measures such as compulsory licensing, reasonable royalties, and parallel importation, ensuring continued public health support and protecting against monopolistic pricing.
- Critical Need for Capacity Building: Enhanced institutional, legal, and judicial capacities are essential for managing the anticipated rise in patent filings, addressing infringement disputes, and ensuring compliance with stricter intellectual property regulations in the post-LDC period.

This policy brief underscores the importance of leveraging BPA 2023's provisions, targeted capacity-building efforts, and strategic public policy interventions to support Bangladesh's pharmaceutical sector in navigating the post-LDC graduation landscape while enhancing access to affordable medicines.

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* This policy brief is based on a study conducted by Research and Policy Integration for Development (RAPID). The authors of the study are Mohammad Abdur Razzaque (Team Leader), Md Deen Islam, Jillur Rahman, Towhidul Islam, and Rakin Uz Zaman. The authors would like to acknowledge the advice and guidance received from Sitesh Chandra Bachar and Nakib Muhammad Nasrullah. Research assistance was provided by Sumaeya Akhter, Syeda Fabiha Tasnim, and Md. Salay Mostofa. The study has benefited from extensive consultations with industry stakeholders. The study was supported by South and Southeast Asia Research and Innovation Hub, Foreign, Commonwealth & Development Office (FCDO), Government of UK. However, the views expressed herein do not necessarily reflect the official policies of Government of UK.

I. Background

Bangladesh stands out among least developed countries (LDCs) for its relatively advanced pharmaceutical industry. Over the years, domestic manufacturing capabilities have grown significantly, contributing to the public health objective of enhancing access to affordable medications and reducing reliance on multinational corporations. This transition, driven by targeted policy interventions, has enabled the sector to primarily serve the domestic market while developing limited export capacity. One of the key factors in this progress has been Bangladesh's LDC status, which has allowed regulatory measures such as withholding patents on medicines and restricting imports of drugs that can be produced locally, thereby fostering the growth of the domestic industry.

Bangladesh's impending graduation from LDC status, scheduled for November 2026, will result in the loss of key policy flexibilities, including the ability to maintain a patent-free regime for pharmaceutical inventions, access duty-free markets in key destinations, provide export subsidies, and produce patented drugs without paying royalties to original inventors. These shifts in the policy landscape have raised concerns among various stakeholders, who fear that the loss of such flexibilities could impede access to essential medicines and pose profound challenges for the pharmaceutical industry in adapting to a more stringent regulatory environment.

This policy brief, based on a detailed study of the impacts of Bangladesh's LDC graduation on medicine accessibility and the pharmaceutical sector, summarises the key findings to assess the validity of the relevant concerns. Combining qualitative and quantitative methods, the research underlying this brief incorporates extensive literature reviews and stakeholder consultations on key issues such as the Trade Related Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO), Bangladesh's legal provisions, and their implications for medicine accessibility and affordability. Quantitative analyses include disease profiling from the 2022 HIES data and econometric modelling using the Quadratic Almost Ideal Demand System (QUAIDS) to assess the price sensitivity of medicines and, thus effects of price changes on demand. Additionally, a global computable general equilibrium modelling framework, namely the Global Trade Analysis Project (GTAP)—one of the most popular and widely used tools for analysing trade policy impacts, has been applied to simulate broader economic impacts arising from LDC graduation-related trade policy changes including the discontinuation of export subsidies, and potential increases in Active Pharmaceutical Ingredient (API) procurement costs.

The main finding is that access to most medicines currently in use in Bangladesh is unlikely to be significantly affected by LDC graduation per se. On the other hand, the current level of access to essential drugs can be improved by addressing structural issues such as the high out-of-pocket expenditure on medicines in Bangladesh. Therefore, irrespective of LDC graduation, there remains

substantial scope for public policy to enhance medicine accessibility. Although domestic production of patented drugs may be affected after LDC graduation, the current domestic capacity for such production is quite limited to expect any profound impact.

Furthermore, provisions consistent with the global patent regime and the rules of the World Trade Organization (WTO)—already incorporated in the Bangladesh Patent Act—should enable Bangladesh to authorise local production or import of essential drugs during public health emergencies, ensuring affordability and accessibility, if needed, by compensating patent holders through regulated royalties. However, as Bangladesh transitions to stricter compliance with global patent regimes post-LDC graduation, it will require strengthened regulatory, legal, and judicial capacity to address challenges such as a surge in patent applications, including those not qualifying as novel inventions, patent infringement cases, and disputes with multinational corporations, all of which could potentially affect drug prices and accessibility. Additionally, addressing existing supply-side challenges to boost domestic production capacities for both generic and patented drugs will be critical for safeguarding public health and effectively leveraging TRIPS flexibilities. The findings on the impact of discontinuing export subsidies on the industry's export performance indicate a moderate negative impact. Nevertheless, given the relatively small scale of pharmaceutical exports, the overall implications are expected to remain limited.

II. Bangladesh's Pharmaceuticals Sector

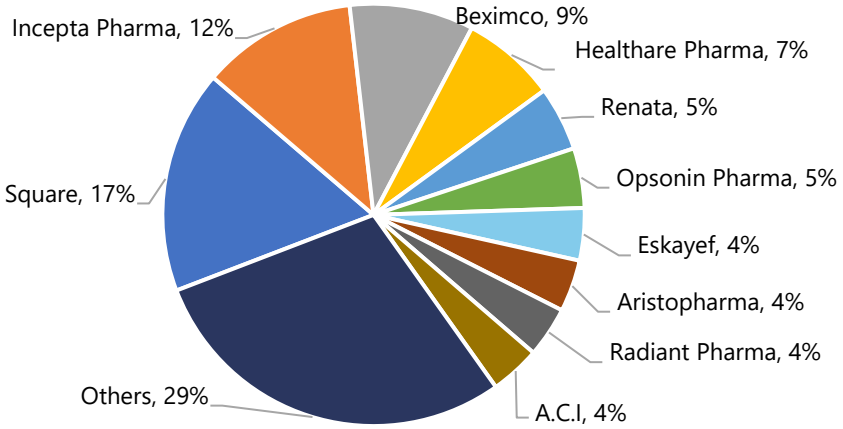
The Survey of Manufacturing Industries (SMI), conducted by the Bangladesh Bureau of Statistics in 2019, estimated the pharmaceutical industry's gross output at approximately BDT 268.6 billion ($3.2 billion) (Bangladesh Bureau of Statistics 2020). Based on growth rates from the National Account Statistics, this figure is projected to have reached around BDT 425 billion ($3.5 billion) in FY24 (Bangladesh Bureau of Statistics 2024).[1] Until the 1980s, multinational companies (MNCs) produced three-quarters of all drugs in Bangladesh. However, domestic firms now reportedly meet approximately 98 per cent of local demand (Commonwealth Secretariat and United Nations 2024). Key policies, including the National Drug Policy (1982), the Drugs (Control) Ordinance (1982), and subsequent drug policies in 2005 and 2016, facilitated this transition by reducing MNC dominance in the domestic market, controlling drug prices, and prohibiting pharmaceutical patents. Currently, 284 pharmaceutical firms are listed in Bangladesh, with the top ten accounting for approximately 71 per cent of the market share (Figure 1).

Bangladesh currently exports pharmaceutical products to approximately 156 countries, with export revenue growing from less than $50 million in FY12 to a peak of $189 million in FY22 before

[1] 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.

declining to $175 million in FY23 (Figure 2a).[2] The top ten export destinations (Figure 2b), including Myanmar, Sri Lanka, and the USA, account for about 70 per cent of its pharmaceutical export earnings.

Figure 1: Market share of leading pharmaceutical manufacturers in Bangladesh, 2023



Source: IQVIA (2023).

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

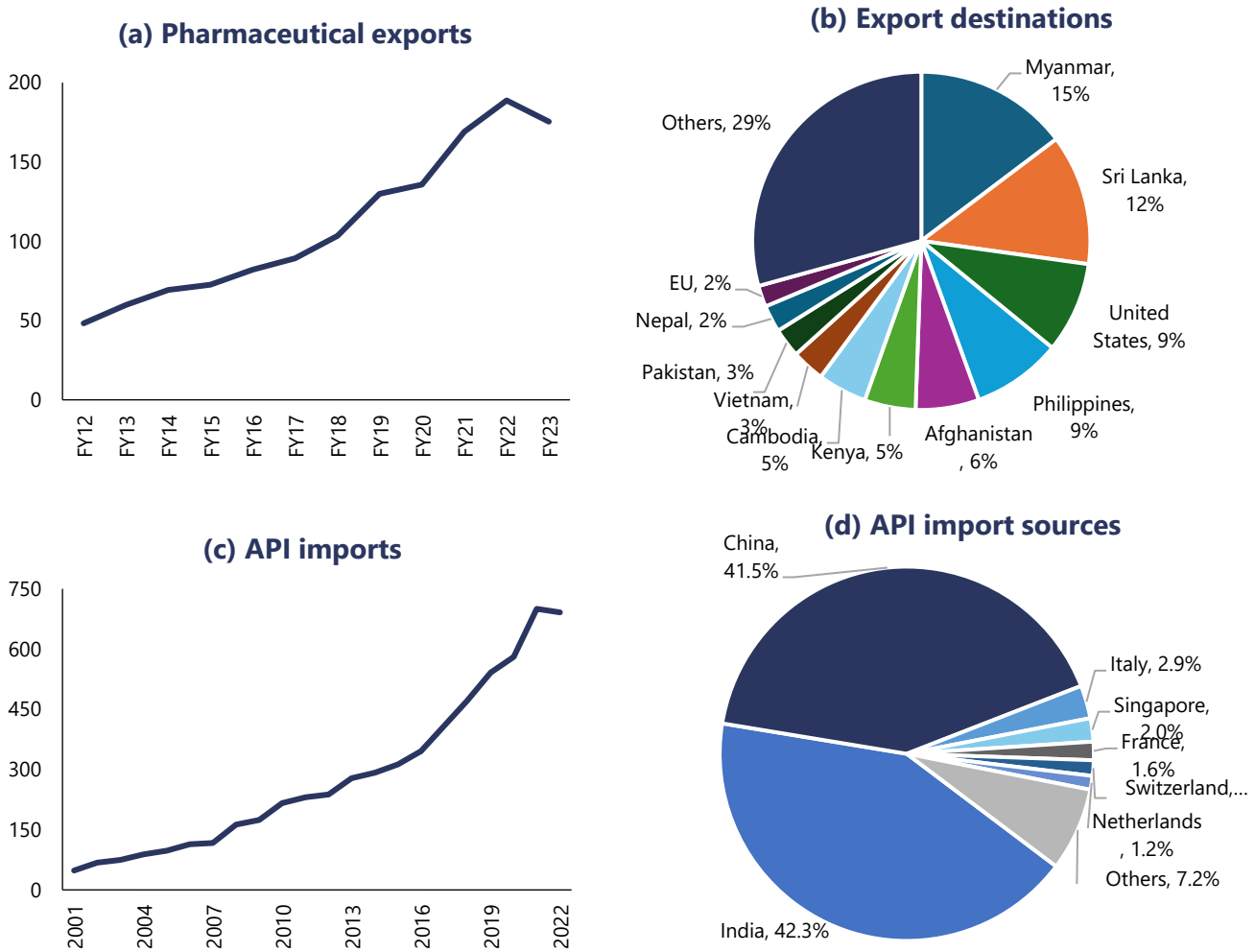
Despite domestic manufacturers meeting nearly all local demand for generic drugs, Bangladesh remains heavily reliant on imported Active Pharmaceutical Ingredients (API), with around 95 per cent of API requirements sourced from abroad. In 2022, API imports totalled approximately $691 million (Figure 2c), with China and India together supplying over 80 per cent of these imports (Figure 2d). Additionally, data from Bangladesh Bank indicates that pharmaceutical products worth approximately $177 million were imported during FY23.

In 2023, the chemical and pharmaceutical sectors attracted foreign direct investment (FDI) of approximately $117 million, marking an all-time high and accounting for about 4 per cent of total net FDI inflows (Bangladesh Bank 2024). This represents a significant increase from $13.17 million and a 1.16 per cent share of total FDI in 2011. Policy initiatives to promote investment include tax holidays, cost-effective import facilities for API producers, and the establishment of an API Industrial Park. Located 37 km from Dhaka, in Gazaria of Munshiganj district, the park aims to reduce Bangladesh's reliance on foreign suppliers and enhance its competitive position in the

[2] Over the same period, India's pharmaceutical exports increased from $9.6 billion to $21.3 billion, while China's exports rose from $5.8 billion to $11.3 billion.
[3] The HS code of top five products are: HS 300490, HS 300320, HS 300439, HS 300410, HS 300390.

global API market. Although still in its early stages, the park is expected to employ 25,000 individuals and reduce the country's vulnerability to external shocks.

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



Source: Export Promotion Bureau (2024) and ITC Trade Map (2024).

III. Pharmaceutical Policies and LDC Graduation Implications

The WTO's TRIPS Agreement provides a global framework for regulating intellectual property (IP) related to medicines, by setting minimum standards for intellectual property rights (IPRs) among member countries. To address the unique developmental challenges faced by LDCs, TRIPS includes special and differential treatment (S&DT) provisions, known as the LDC pharmaceutical waiver. It allows LDCs to delay compliance with most TRIPS obligations, except for principles such as national treatment, most-favoured-nation (MFN) status, and the right of priority in patent applications. The waiver remains in force until 2033 or a country's LDC graduation, whichever comes first.

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 (Anon 2023).

While BPA 2023 provides legal provisions for filling patent applications for innovations and mandates a 20-year patent protection in accordance with the WTO-TRPIs regime, raising the protection period from 16 years provided under the PDA 1911, pharmaceutical and agricultural chemical products remain outside the scope of patent protection as long as the period of exemption from patent protection remains in force given the country's LDC status.

It is technically possible for Bangladesh to extend its patent-free regime for pharmaceuticals by an additional three years after LDC graduation, leveraging the decision made at the WTO's 13th Ministerial Conference (MC13), held in Abu Dhabi in February 2024. The MC13 decision permits graduating LDCs to benefit from the S&DT provision outlined in Article 24 of the Dispute Settlement Understanding (DSU) for three years following graduation (World Trade Organization 2024). Specifically, Article 24.1 urges WTO members to exercise due restraint in initiating disputes or seeking compensation against graduating LDCs, implying that even in the absence of patent protection until November 2029, Bangladesh (set to graduate in November 2026) should not face legal action from WTO members during this period.

The BPA 2023 incorporates critical TRIPS flexibilities to address challenges such as evergreening[4], national emergencies, and high drug prices. Rigorous patentability criteria now define an invention, preventing patents on minor modifications of existing substances. Under this provision, Bangladesh will not grant patents for medicines already patented or invented before its graduation from LDC, as they fail to meet novelty criteria. Compulsory licensing provisions will allow the government to authorise local production or import of patented medicines during emergencies or in response to anti-competitive practices. Before issuing a compulsory license, the TRIPS agreement mandates that an effort must be made to secure a license from the patent owner

[4] Evergreening refers to the practice of extending the commercial lifespan of a patented drug by making minor modifications or incremental changes to the original product. These changes, such as altering dosage forms, formulations, or delivery mechanisms, often lack significant therapeutic advancements but are used to secure new patents, thereby delaying generic competition and maintaining market exclusivity.

on fair commercial terms. The BPA 2023 includes this provision with a royalty capped at 4 per cent of total sales. The inclusion of parallel import flexibility aims to curb patented drug prices, while the experimentation exception facilitates reverse engineering, empowering domestic firms to develop generics as patents expire, ultimately enhancing accessibility and affordability.[5]

Empirical studies on TRIPS implementation indicate that stronger IP protections often lead to higher drug prices, with TRIPS-Plus provisions under bilateral or plurilateral trade agreements exacerbating this trend.[6] However, flexibilities such as compulsory licensing and parallel importation have proven effective in mitigating these impacts. For instance, compulsory licensing has significantly reduced drug prices in various countries, while parallel importation has enhanced bargaining power with patent holders, sometimes lowering prices for branded medicines.

Studies indicate that a stronger IPR regime often benefits large firms, particularly multinational corporations (MNCs), as they possess the resources to invest in research and development. This could lead to increased competition from MNCs, potentially stifling the growth of local firms. Moreover, concerns over evergreening—where minor modifications to existing drugs are patented to extend market exclusivity—highlight the need for robust legal and regulatory capacity to prevent abuse. Without such capacity, curbing evergreening and ensuring equitable access to medicines will remain a significant challenge.

IV. Major Findings

Stakeholder perspectives

Consultations and key informant interviews (KII) with industry stakeholders reveal a general consensus on the critical role of WTO waivers for LDCs in supporting pharmaceutical sector growth. Several stakeholders expressed concerns that enforcing patent protection post-LDC graduation could increase production costs for patented drugs, leading to higher prices and reduced accessibility to essential medicines. However, some industry insiders argued that, given Bangladesh's relatively small volume of API imports and limited production of patented drugs, the immediate impact of LDC graduation on the sector might be minimal.

Beyond the specific context of LDC graduation, stakeholders highlighted the pharmaceutical sector's heavy reliance on imported APIs, which leaves it highly susceptible to supply chain

[5] The parallel importation provision under the TRIPS Agreement allows a country to import a patented product from another country where it is sold at a lower price, without requiring the permission of the patent holder. This provision is particularly relevant in the context of public health, enabling countries to access essential medicines more affordably. Experimentation facilitation refers to legal provisions that allow using patented inventions without the patent holder's permission for research and experimental purposes. This can be used, among others, to enable exploration of reverse engineering to develop generic versions that can enter the market once the patent expires.

[6] Many regional and bilateral trade agreements consider patent obligations more stringent than those under the TRIPS regime.

disruptions. These vulnerabilities, exacerbated by geopolitical tensions and trade conflicts, underscore the urgent need to enhance domestic API production capacity to safeguard the industry's competitiveness in a post-LDC landscape. Concerns were also raised regarding the discontinuation of export incentives, which many believe could undermine the sector's export competitiveness in the long term.

Figure 3: Major issues raised in interviews with industry stakeholders

Source: Based on consultation with industry stakeholders.

Impact of LDC graduation on medicine prices: Key scenarios

The impact of Bangladesh's graduation from LDC status on access to medicines presents a multifaceted landscape with varying scenarios. Based on a review of TRIPS provisions, the Bangladesh Patent Act (BPA) 2023, and empirical research conducted for this study, the key implications can be summarised as follows:

- ***Access to patented medicines***: Accessibility to patented medicines that Bangladesh cannot domestically produce is expected to remain unchanged, as these are primarily sourced through expensive imports. This scenario highlights the persistent challenge of affordability for essential treatments, such as cancer therapies and advanced biological medicines. LDC graduation will have no direct impact on these medicines, as Bangladesh does not currently manufacture them.

- ***Generic medicines under foreign patents***: For generic medicines currently produced in Bangladesh but under foreign patent protection, recent regulatory reforms in Bangladesh are significant. The removal of the mailbox provision and the introduction of stricter novelty criteria under BPA 2023 safeguard against monopolistic pricing, thereby preserving current affordability levels. In the absence of these reforms, patents granted under the previous mailbox provisions

could have led to price surges, with our estimates indicating that prices could have risen threefold for some cancer medications and up to twentyfold for certain skin disease treatments.

- ***Impact of API costs on generic medicine prices***: If concerns about potential increases in production costs for generic medicines due to higher API import prices post-graduation prove to be valid, such cost increases could lead to higher retail prices, particularly impacting low-income groups reliant on affordable treatments.[7] Our econometric analysis indicates a one-to-one relationship between API import costs and the production costs of corresponding medicines. That is, a 10 per cent increase in API costs is estimated to result in a 10 per cent rise in production costs. Given the inelastic nature of demand, manufacturers are likely to pass these additional costs onto consumers.

- ***Future medicines patented after November 2029***: Medicines patented after November 2029, given that Bangladesh graduates as scheduled, will require royalty payments for local production. These royalties will introduce cost implications that could affect affordability. The negotiation of royalty rates will play a crucial role in determining the extent of price increases. Our results indicate that with a 4 per cent royalty fee for producing generic versions, medicine prices would be approximately 2 to 3 per cent higher compared to a regime with no royalty payment.

- ***Relaxation of import restrictions for off-patent generic medicines***: Finally, relaxation of import restrictions on off-patent generic medicines post-graduation presents an opportunity for increased competition and potentially lower prices. Allowing the import of off-patent generic medicines could also expand the range of options available to consumers. This would necessitate stricter quality standards for locally manufactured drugs to ensure their efficacy and reliability. Our analysis estimates that a 10 per cent decrease in market concentration, driven by competition, is associated with price reductions ranging from approximately 2 per cent to 6 per cent.[8]

Expenditure on medicines and poverty impact of LDC graduation

Public spending on health in Bangladesh is among the lowest when compared to global economies. This may partly explain why Bangladesh has one of the highest out-of-pocket health expenditures in the world.[9] According to the World Health Organization (WHO) Global Health Expenditure Database, out-of-pocket spending accounted for 73 per cent of total health expenditure in Bangladesh in 2021 (Figure 4). This is more than four times the global average of 17 per cent and significantly higher than the averages for lower-middle-income countries (49.4%)

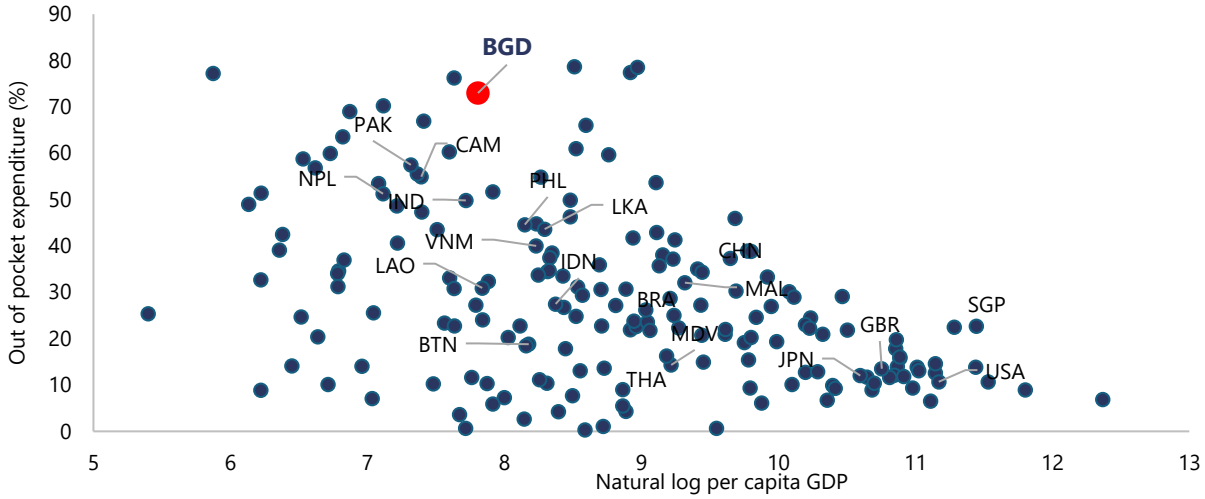
[7] Bangladesh primarily sources APIs from China and India, both of which are major global producers of off-patent generic drugs. These countries may perceive Bangladesh as a competitor in the global generic medicine market, potentially leading to higher API prices for Bangladeshi manufacturers. Furthermore, for on-patent generic medicines currently produced in Bangladesh, sourcing APIs could become more challenging post-LDC graduation, increasing the cost of API imports.

[8] Increased competition from foreign producers and imports would result in decreased market concentration.

[9] Out-of-pocket health expenditure refers to direct payments by individuals for healthcare services and medicines at the time of use, often without insurance or reimbursement, posing financial risks for low-income households.

and upper-middle-income countries (31.4%).

Figure 4: Out-of-pocket expenditure (% of current health expenditure) and per capita GDP



Source: Presentation based on WHO (2021; 2023)and WDI (2023) data.
Note: Countries are indicated as BGD – Bangladesh, BTN – Bhutan, BRA – Brazil, CAM – Cambodia, CHN – China, GBR – United Kingdom, IDN – Indonesia, IND – India, JPN – Japan, LAO – Lao PDR, LKA – Sri Lanka, MAL – Malaysia, MDV – Maldives, NPL- Nepal, PAK – Pakistan, PHL – Philippines, SGP – Singapore, THA – Thailand, USA – United States., and VNM – Vietnam.

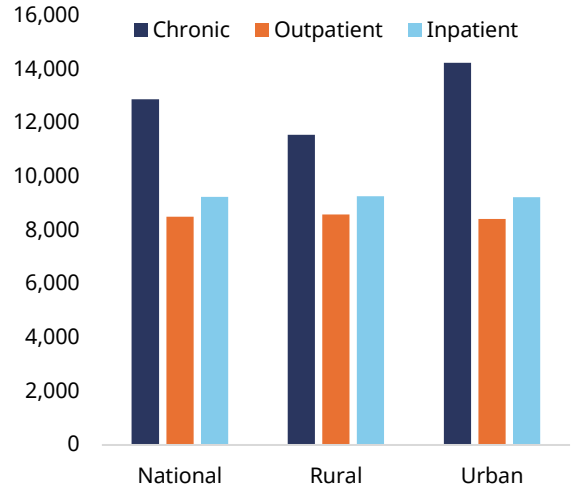
Data from the latest Household Income and Expenditure Survey (HIES) highlights the breakdown of annual per-person out-of-pocket spending on medicines across three main categories: chronic, outpatient, and inpatient medicine expenses (Bangladesh Bureau of Statistics 2023). The largest share is spent on routine medications for chronic diseases, averaging approximately BDT 13,000 per person per year nationally for individuals with chronic conditions (Figure 5). Outpatient medicine costs for non-chronic conditions are also substantial, averaging over BDT 8,500 per person annually nationwide.[10]

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 and 5.3 per cent of per capita GNI in 2022 (Figure 6). For a poor household 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

[10] This expenditure reflects the ongoing need for healthcare services outside of hospital settings, likely encompassing regular consultations and treatments for acute or preventive conditions.Both inpatient and outpatient medicine expenditures are slightly higher in rural areas compared to urban areas. This could be attributed to limited healthcare access in rural areas, resulting in higher costs when treatment is eventually sought or to the use of multiple healthcare sources.

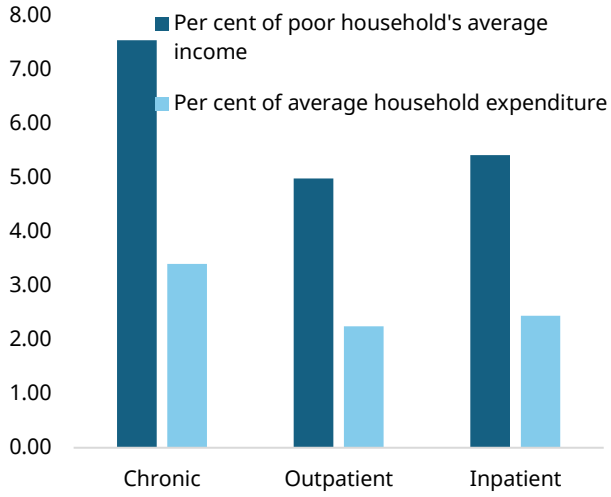
expenditure. For a poor household, the corresponding proportion would be close to 20 per cent.

Figure 5: Annual per person out-of-pocket expenditure on medicines for individuals reporting illness (BDT)



Source: Estimated from using HIES 2022 data.

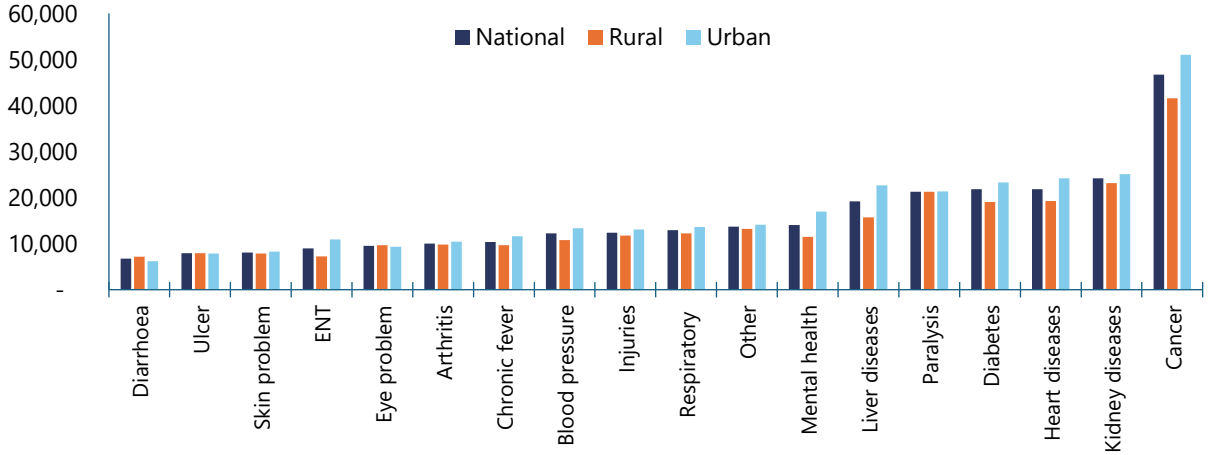
Figure 6: Per person out-of-pocket expenditure on medicines (% of poverty line income and average household expenditure)



Source: Estimated from using HIES 2022 and National Accounts (BBS) data.

The nationwide BBS HIES survey data show for patients with treatment requirements for cancer and kidney diseases, costs are much higher than for other chronic conditions (Figure 7).[11] Understanding how spending varies by disease type allows for a more informed view of medicine needs, which can guide resource allocation for more prevalent and costly chronic conditions.

Figure 7: Average yearly out-of-pocket expenditure on medicines for the person with chronic diseases



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

[11] This is likely due to the high cost of specialised medications, diagnostic tests, and treatments required for these illnesses, which often require long-term and intensive care.

Although health expenditures constitute a significant portion of household income, Bangladesh's graduation from LDC status is unlikely to have a substantial impact on household poverty, particularly for families with members suffering from chronic illnesses, as significant price increases for medications are not anticipated. In scenarios where increased competition leads to price reductions for essential medicines, poverty rates could experience a slight decline.[12] Conversely, under a hypothetical monopoly pricing scenario—which is unlikely due to the removal of mailbox provisions—poverty rates could rise substantially. Scenarios involving increased API import costs or royalty payments for patented medicines post-graduation are projected to result in modest increases in poverty rates.[13] Overall, the effect of LDC graduation per se on household poverty is expected to be negligible, with only minor impacts on households burdened by chronic diseases.

Impact on pharmaceutical exports and the industry

Following LDC graduation, export subsidies will become WTO-incompatible and must, therefore, be discontinued. These subsidies play a crucial role in enhancing the competitiveness of exporters and supporting export earnings. Our econometric regression analysis indicates that a 1 per cent increase in pharmaceutical export unit prices is associated with a 0.5 to 0.8 per cent decline in export revenues. Based on this relationship, the complete removal of export incentives could result in an estimated reduction in export earnings of up to 6.9 per cent, equivalent to $10 to $12 million. The transition to a stricter IPR regime, leading to higher production costs, could further exacerbate this situation. However, given the relatively small scale of pharmaceutical exports, the overall impact is expected to remain limited.

Similar results are also borne out when a computable general equilibrium framework based on the GTAP model has been utilised to analyse the impact of LDC graduation on Bangladesh's pharmaceutical industry. In this model, it is possible to consider several policy changes simultaneously, e.g., Bangladesh facing tariff hikes in major export destinations post-graduation and removal of export subsidies for all products, including pharmaceuticals, and the pharmaceutical sector being compliant with TRIPS regulations. At this, the overall pharmaceutical exports are found to decline by 11.2-14.6 per cent. The simulation of overall LDC graduation

[12] For every 10 per cent reduction in market concentration, medicine prices decrease by 2 to 5 per cent. This leads to a projected reduction in poverty rates of 0.5 percentage points under the upper poverty line and 0.2 percentage points under the lower poverty line. However, households with members suffering from chronic ailments like chronic fever and mental health issues may see larger poverty reductions, up to 4 percentage points under the upper poverty line and 1 percentage point under the lower poverty line.

[13] Under the upper poverty line, a 10 per cent and 20 per cent increase in marginal costs would raise poverty rates by 0.3 and 0.45 percentage points, respectively. Under the lower poverty line, the increases are 0.15 and 0.25 percentage points. Royalty payments for new patented medicines after 2029 would have a smaller impact, with a 4 per cent markup allocation to patent holders increasing poverty rates by about 0.1 percentage point under both poverty lines.

scenario, including tariff rise in destination markets on Bangladesh's all exports, including readymade garments, and discontinuation of all subsidies, produce implications showing a 0–1 per cent reduction in pharmaceutical output in the domestic economy. Conversely, the general equilibrium framework can also capture the hypothetical scenario of rising API import costs for Bangladesh. Along with some adverse consequences, such a scenario can also help raise domestic API production by 12-14.5 per cent (due to potential escalation in API import prices after graduation).

V. Policy Implications

Bangladesh's pharmaceutical sector has thrived under the LDC waiver and supportive domestic policies. While the introduction of patent protection for pharmaceuticals is unlikely to cause significant market disruption, post-LDC production of patented drugs will require patent holder permissions and royalty payments. The Bangladesh Patent Act 2022 incorporates all flexibilities consistent with the WTO-TRIPS framework, providing essential support for the industry while safeguarding public health priorities and facilitating efforts to maintain the availability of affordable medicines. However, the discontinuation of subsidies and increased costs of imported APIs could impact export performance, while import liberalisation may stimulate competition and improve medicine availability. Overall, medicine affordability and supply are expected to remain stable, although heightened competition may challenge the domestic industry, necessitating strategies to enhance market resilience and competitiveness. The following recommendations aim to achieve these objectives and further strengthen the local pharmaceutical sector:

Deepening support for the pharmaceutical industry and leveraging policy space: Bangladesh should fully utilise the transitional policy space available through the extended three-year period post-LDC graduation, as per the WTO MC13 decision, to maintain its current policy regime for the pharmaceutical sector. This includes continuing the production of royalty-free medicines and prioritising capacity-building initiatives to support the development of patented and high-value drugs, particularly biological medicines. Export support measures should be strategically deployed during this period to stabilise export earnings and enhance market competitiveness. Simultaneously, establishing networks with buyers in emerging markets and strengthening regulatory compliance capabilities will position the industry to navigate stricter global trade and intellectual property frameworks effectively. These efforts, coupled with targeted investment in research and development (R&D) and clinical trials, can bolster the industry's resilience and ensure its long-term competitiveness in international markets.

Strengthening supply-side capacities to enhance competitiveness and accessibility: Supply-side improvements are crucial for strengthening Bangladesh's pharmaceutical sector in the post-LDC period. Enhancing competitiveness will not only enable the industry to thrive in increasingly

stringent global markets but also ensure the availability of affordable, high-quality medicines for domestic and international consumers. Addressing cost efficiency, local production capacity, and bioequivalence testing are pivotal to achieving these dual objectives.

To counter the potential rise in production costs after LDC graduation, Bangladesh must fully operationalise the API Industrial Park, ensuring the provision of essential utility services at rationalised costs. Developing a robust petrochemical industry and advancing synthetic chemistry skills will further reduce dependency on imported APIs, improving production capacity and cost efficiency. Establishing a dedicated special economic zone for pharmaceuticals could also attract investment, encourage innovation, and promote export diversification.

In parallel, Bangladesh must fast-track the establishment of bioequivalence testing facilities to ensure that locally produced generic drugs meet the efficacy and safety standards of their branded counterparts. This will reduce reliance on foreign testing facilities, lower production costs, and enhance the credibility of Bangladeshi pharmaceuticals in global markets. Such capabilities are vital for maintaining export competitiveness and reinforcing public confidence in locally manufactured medicines. Together, these supply-side measures will help the industry navigate post-LDC challenges, improve its global competitiveness, and support the broader goal of ensuring affordable access to essential medicines.

Enhancing healthcare affordability and accessibility through specific policy initiatives: While Bangladesh's upcoming graduation from LDC status raises concerns about medicine affordability, addressing structural challenges within the healthcare system remains crucial for ensuring equitable access to essential treatments. High out-of-pocket expenditures, the growing burden of costly non-communicable diseases (NCDs), limited consumer choice due to protectionist policies, and low public healthcare spending exacerbate the affordability issue. Tackling these challenges requires a multifaceted approach.

Expanding health insurance coverage could alleviate the financial burden on households, particularly for low-income populations, by reducing out-of-pocket spending. Targeted initiatives, such as health cards providing free access to essential medicines and healthcare for economically disadvantaged groups, could further mitigate financial barriers to access. Centralised procurement of essential medicines, supported by bulk purchasing strategies, could lower overall costs and improve affordability system-wide. Strengthening procurement mechanisms, including better implementation of the Public Procurement Act of 2006, would also help address supply shortages in public healthcare facilities.

While these measures address broader healthcare affordability challenges, they align with the overarching goal of ensuring sustainable access to medicines and enhancing public health outcomes in the post-LDC graduation era. Integration of these strategies will contribute to the

complementary objectives of building a more resilient healthcare system and supporting the pharmaceutical sector.

Strategic use of import policy to enhance quality, accessibility, and competitiveness: Relaxing import restrictions on APIs and finished medicines offers a strategic option to enhance access to essential drugs. Evidence suggests that domestic manufacturers remain highly competitive in pricing for many essential medicines, indicating minimal risk of market disruption from such liberalisation. Import competition also plays a crucial role in ensuring quality standards, which can further bolster the export prospects of locally manufactured drugs. For consumers, import relaxation can increase the availability and diversity of medicines, potentially reducing prices through greater competition. It can also address supply gaps for drugs not produced locally, while enabling cost-effective API imports to support local production. Carefully implementing this policy with appropriate safeguards can balance consumer benefits with the need to sustain the domestic industry's competitiveness in the post-LDC graduation landscape.

Strengthening legal, judicial, and institutional capacities for post-LDC challenges: Bangladesh's graduation from LDC status will necessitate significant enhancements in legal, judicial, and institutional capacities to address the anticipated rise in patent infringement cases and the complexities of stricter intellectual property regulations. The Department of Patents, Designs, and Trademarks (DPDT), which currently does not handle pharmaceutical patent disputes, must urgently recruit and train specialists in patent law and pharmaceutical patents. This is critical for managing issues such as evergreening, which can limit competition and inflate drug prices.

The newly enacted Bangladesh Patents Act 2023 provides courts with the authority to appoint experts for handling complex patent disputes, a positive step towards managing post-graduation challenges. However, building judicial expertise is equally vital, as effective adjudication of patent infringement cases will require specialised knowledge of pharmaceutical patents and the broader TRIPS framework. Additionally, Bangladesh should explore cost-effective alternatives to the Advisory Centre on WTO Law (ACWL), as its services at discounted rates for LDCs will no longer be available after graduation.

Enhanced capacity at the DPDT and the Directorate General of Drug Administration (DGDA), combined with judicial reforms, will ensure the effective enforcement of IP regulations, counter patent abuses, and support the pharmaceutical sector's integration into competitive global markets while safeguarding access to affordable medicines. These measures are essential for navigating the post-graduation landscape and maintaining the sector's long-term growth and resilience.

Securing an extended Pharmaceutical Waiver from the WTO: To mitigate the potential impact of stricter intellectual property regulations on access to medicines, Bangladesh should prioritise

securing an extended pharmaceutical waiver from the WTO. This waiver would allow the continued production and export of generic medicines without patent restrictions, providing critical support to public health objectives and the pharmaceutical sector during the post-LDC transition period. It would also give Bangladesh additional time to build the necessary capacity to adapt to the changed circumstances of the post-LDC period.

VI. Conclusion

Bangladesh's upcoming graduation from LDC status will create a significantly changed policy environment for its pharmaceutical sector, but the recently enacted Bangladesh Patent Act (BPA) 2023 has introduced key flexibilities to mitigate potential impacts. These provisions are expected to keep medicine prices stable post-graduation, addressing concerns about affordability. Analyses undertaken as part of this policy brief suggest no significant impact on medicine accessibility or affordability arising from LDC graduation alone. Bangladesh can further benefit from an additional three-year transition period after LDC graduation as per a WTO decision, allowing the industry to adapt gradually to new market dynamics.

Globally, access to medicines remains a critical issue. Prof. Yunus' call for less stringent patent protections for medicines for the poor aligns with the growing movement for patent-free medicines as a global public good, supporting the achievement of the Sustainable Development Goals (SDGs) and global health security.

However, significant supply-side challenges persist. Bangladesh's capacity to produce active pharmaceutical ingredients (APIs), patented drugs, and conduct bioequivalence testing remains limited. 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. 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.

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