# Technological Preparedness of Bangladesh's Pharmaceuticals Industry: A Strategic Evaluation

Presented by

**Syed Yusuf Saadat**

Research Fellow

CENTRE FOR POLICY DIALOGUE

Dhaka: 16 October 2024

# Acknowledgements


- The Centre for Policy Dialogue (CPD), Dhaka, conducted this research as part of its "Technological Preparedness of Bangladesh's Pharmaceuticals Industry: A Strategic Evaluation" study, with support from Friedrich Ebert Stiftung, Bangladesh.
- The Research Ream consisted of *Dr Fahmida Khatun*, Executive Director, CPD; *Mr Syed Yusuf Saadat*, Research Fellow, CPD; *Ms Anika Ferdous Richi*, Former Programme Associate (Research Division), CPD; and *Ms Anisha Ushrat Aurchi*, Programme Associate (Research Division), CPD.
- The Research Team gratefully acknowledges the valuable support received from the Dialogue and Communications Division and the Administration and Finance Division in conducting this study.
- Concerned officials belonging to several organisations have extended their valuable support to the Research Team members, and the Team would like to express its sincere thanks.

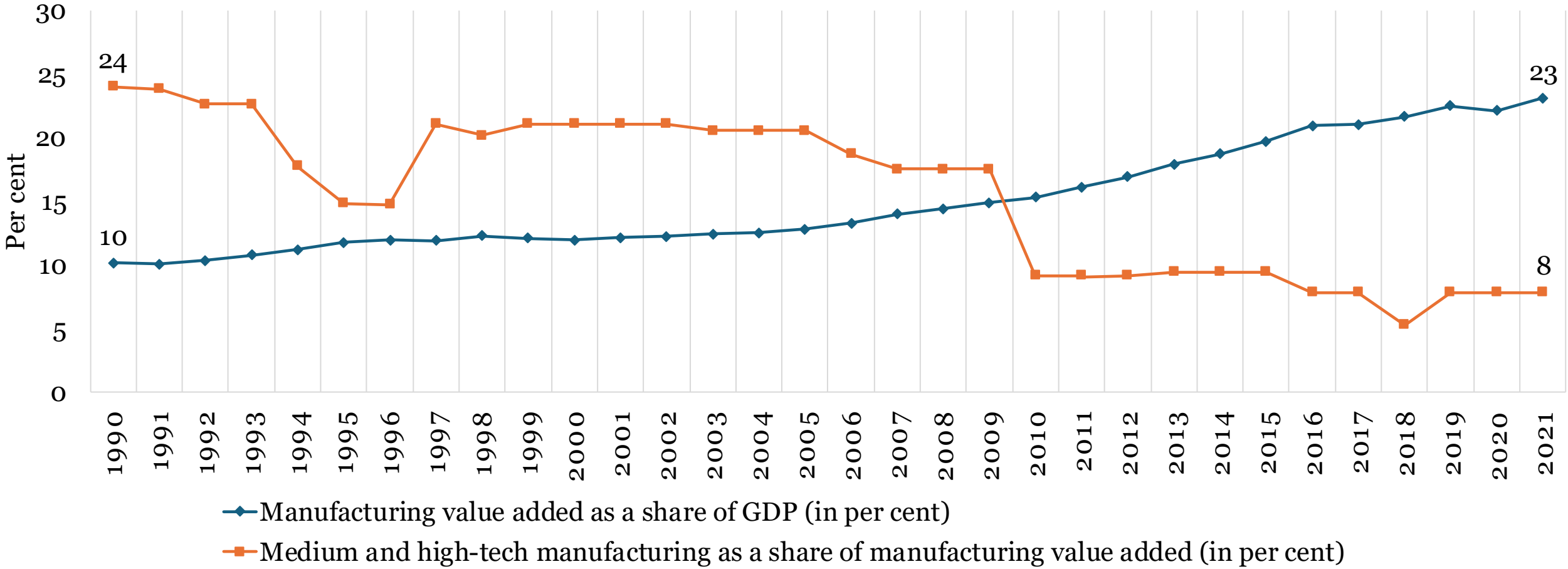
# Outline

1. Introduction
2. Innovation in the Pharmaceutical Industry
3. The TRIPS Pharma Waiver
4. Research Questions
5. Overview of the Pharmaceutical Industry in Bangladesh
6. Findings
7. Conclusions and Policy Recommendations

# 1. INTRODUCTION

# 1.1 Decline in medium & high-tech industry

**Figure: Manufacturing value added as a share of GDP and medium and high-tech manufacturing as a share of manufacturing value added in Bangladesh (in %)**




Source: United Nations Industrial Development Organisation (UNIDO)

# 1.2 Bangladesh's pharmaceutical industry

- One of the most technologically advanced industries in the country
- Crucial provider of affordable medications, both domestically and to other LDCs
- Significant contributor to global public health and national economic growth

# 1.3 Some successes and challenges

## Successes

- The pharmaceutical industry is the only major medium and high-tech industry in Bangladesh
- Bangladesh is the LDC that made the most of its ability to produce patented medicines under the TRIPS waiver for LDCs
- The pharmaceutical industry in Bangladesh shapes the global public health landscape by supplying affordable medicines

## Challenges

- Potential loss of TRIPS waiver leading to increased costs and patent compliance
- Potential impact on the affordability of medicines for low-income populations
- Risk of reduced export competitiveness
- High dependence on imported active pharmaceutical ingredients (API)

# 1.4 Technological readiness and innovation

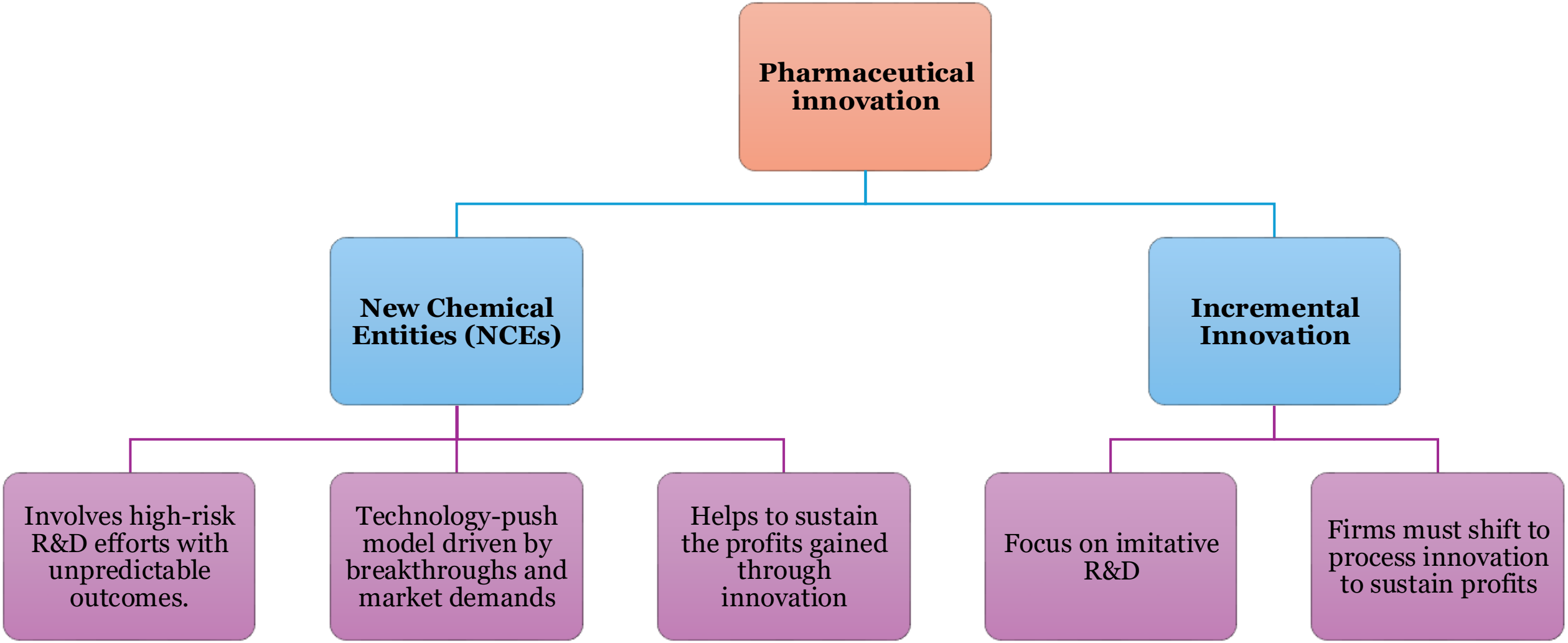


- Evaluate current technological capacity
- Address innovation gaps to enhance competitiveness

- Ensure a smooth transition and sustained growth post-LDC graduation
- Support public health initiatives in Bangladesh and other LDCs

# 2. Innovation in the Pharmaceutical Industry

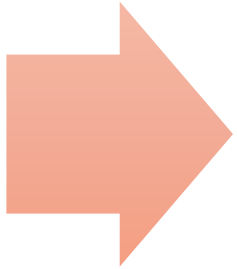
# 2.1 Pharmaceutical innovation



# 2.2 Manufacture of non-patented drugs

- Active Pharmaceutical Ingredients (APIs) are critical to drug effectiveness
- Manufacturing includes two steps: API production and final formulation

The **production of APIs,** requiring chemical synthesis abilities



The **final formulation**, by mixing API with other non-active ingredients to manufacture pharmaceutical products such as pills, tablets, etc.

## API production challenges

- Over 90% of raw materials are imported, mainly from India and China
- Lack of technological and manufacturing capacity to produce APIs domestically

# 2.3 Limitations to innovation

Factors that limit the industry's innovative and technological capacity:

| MICRO | MESO | MACRO |
| --- | --- | --- |
| • **Intellectual isolation of researchers** and a **lack of incentive or motivation** for joint or individual research | • **Lack of access to information and technology inputs**, lack of scientific support infrastructure for universities, public research organisations, and businesses, insufficient human capital generation, and institutional instability | • The disjunction between the demand for health research and the current output, **bureaucratic rigidity** and **corruption**, as well as a **weakened public support system** |

# 3. THE TRIPS PHARMA WAIVER

# 3.1 Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)

- Intellectual property rights are the rights given to persons over the **creations of their minds**.
  - They usually give the creator an **exclusive right** over the use of his/her creation for a **certain period of time**.
- The World Trade Organisation's (WTO) Agreement on **Trade-Related Aspects of Intellectual Property Rights (TRIPS)**, negotiated during the 1986-94 Uruguay Round, introduced intellectual property rules into the multilateral trading system for the first time.
- The TRIPS Agreement is Annex 1C of the Marrakesh Agreement establishing the World Trade Organization, signed in Marrakesh, Morocco on **15 April 1994**.

# 3.2 Overview of the TRIPS agreement

**General provisions and basic principles** of the multilateral trading system (such as Most Favoured Nation Principle and National Treatment Principle) apply to international intellectual property

**Minimum standards** of protection for intellectual property rights

Procedures members should provide for the **enforcement** of those rights in their own territories

How to **settle disputes** on intellectual property between members of the WTO

**Special transitional arrangements** for the implementation of TRIPS provisions (especially for LDCs)

# 3.3 LDCs in the TRIPS agreement

## Preamble

- "Recognizing also the **special needs of the least-developed country Members** in respect of **maximum flexibility** in the domestic implementation of laws and regulations in order to enable them to create a **sound and viable technological base**."

## Transitional Arrangements

***Article 66.1:*** "In view of the **special needs and requirements** of least-developed country Members, their **economic, financial and administrative constraints**, and their **need for flexibility to create a viable technological base**, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years....."

"The Council for TRIPS shall, **upon duly motivated request** by a least-developed country Member, **accord extensions of this period**."

# 3.4 TRIPS pharma waiver for LDCs

| Transition Period | Length of Transition Period | End of Transition Period | Documents |
|---|---|---|---|
| In Built Transition Period | 10 years | 1 January 2006 | Article 66.1 |
| First Extension (2002) | 10 years | 1 January 2016 | Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2)<br><br>Decision of the Council for TRIPS of 27 June 2002 (IP/C/25) |
| Second Extension (2015) | 17 years | 1 January 2033 | Decision of the Council for TRIPS of 6 November 2015 (IP/C/73) |
| **Total Length of Transition Period** | **37 years** | | |

# 3.5 Bangladesh and TRIPS

- As per the **transitional arrangements** for LDCs under **Article 66.1 of TRIPS**, Bangladesh's pharmaceutical industry enjoys **patent waiver benefits**, which allow it to thrive by producing affordable generic versions of patented medicines.
- The TRIPS waiver and extended transition period allow Bangladeshi pharmaceutical manufacturers to **produce patented drugs**, enabling **imitation**, follow-on **innovation**, and the accumulation of **reverse engineering experience**.
- Bangladesh's pharmaceutical industry can export to other LDCs and non-WTO member countries without patent protection.
- **As Bangladesh prepares to graduate from the LDC status in 2026, this waiver will be withdrawn.**
- This transition presents challenges and opportunities for the country's pharmaceutical sector.

# 3.6 Impact of TRIPS pharma waiver withdrawal

- New intellectual property laws and higher patent compliance **costs** may make the medication **less affordable** and accessible for low-income people in Bangladesh and other LDCs.
- Bangladesh's domestic pharmaceutical industry will face **renewed global competition**, highlighting the need for strategic planning and policy adjustments.
- Assessing **Bangladesh's technological readiness** and innovation is necessary to prepare its pharmaceutical industry for growth and competitiveness after LDC graduation and support public health in Bangladesh and other LDCs.
- LDC graduation risks slowing down the **technological learning process** that has fuelled development in Bangladesh's pharmaceutical industry by driving up costs, preventing imitation, hindering innovation, and limiting access to essential R&D resources.
- The **demand for patented drugs is expected to rise** with changing disease patterns, increasing costs post-LDC graduation due to royalty payments.
- Due to the **rise of non-communicable diseases**, withdrawing the TRIPS waiver will hinder **SDG 3.8**, which seeks universal access to safe, effective, quality, and affordable essential medicines and vaccines.

# 4. Research Questions

# 4.1 Research questions

To what extent does the pharmaceutical industry depend on the TRIPS waiver to generate its sales revenue and profits?

What strategies are pharmaceutical manufacturers taking to prepare for the post-LDC withdrawal of the TRIPS waiver?

Apart from TRIPs, what other barriers are pharmaceutical manufacturers in Bangladesh facing regarding technology adoption?

# 5. Overview of the Bangladesh Pharmaceutical Industry

# 5.1 Overview of the pharmaceutical industry

USD 3.2 billion market size in 2021

98% of local demand met by domestic production

0.24 million people employed in 2022

Largest private sector white-collar employer

Highest R&D expenditure per worker in 2019

USD 134 million export in 2023

150 export destinations, including 31 LDCs

Medicine price currently among the lowest in the world

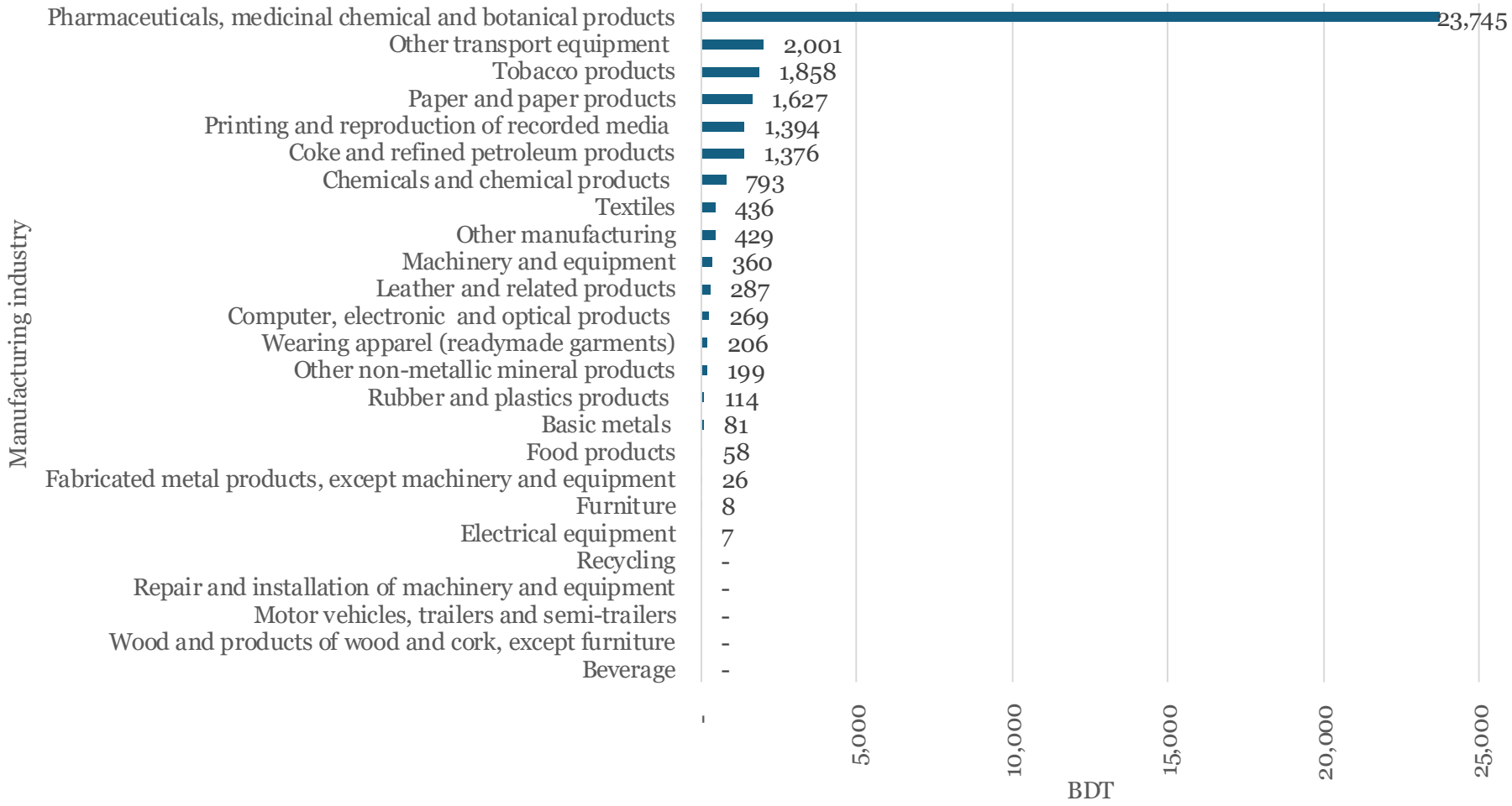
Sources:


1. https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/CDP-review-2020-1.pdf
2. http://www.bapi-bd.com/bangladesh-pharma-industry/overview.html
3. https://www.trademap.org/Country_SelProductCountry.aspx?nvpm=1%7c050%7c%7c%7c%7c30%7c%7c%7c2%7c1%7c2%7c2%7c1%7c1%7c2%7c1%7c1%7c1
4. https://bbs.portal.gov.bd/sites/default/files/files/bbs.portal.gov.bd/page/b343a8b4_956b_45ca_872f_4cf9b2f1a6e0/2023-10-25-07-38-4304abd7a3f3d8799fbcb59ff91007b1.pdf
5. https://bbs.portal.gov.bd/sites/default/files/files/bbs.portal.gov.bd/page/b343a8b4_956b_45ca_872f_4cf9b2f1a6e0/2022-02-24-04-32-b25cbe0e82109a3b6eb0b4c76553d206.pdf

# 5.2 R&D expenditure

- The pharmaceuticals, medicinal chemicals, and botanical products industry spends the most on R&D per worker.
- We can also observe that most industries spend less than BDT 500 in R&D expenditure per worker per year, which is an alarmingly low amount.

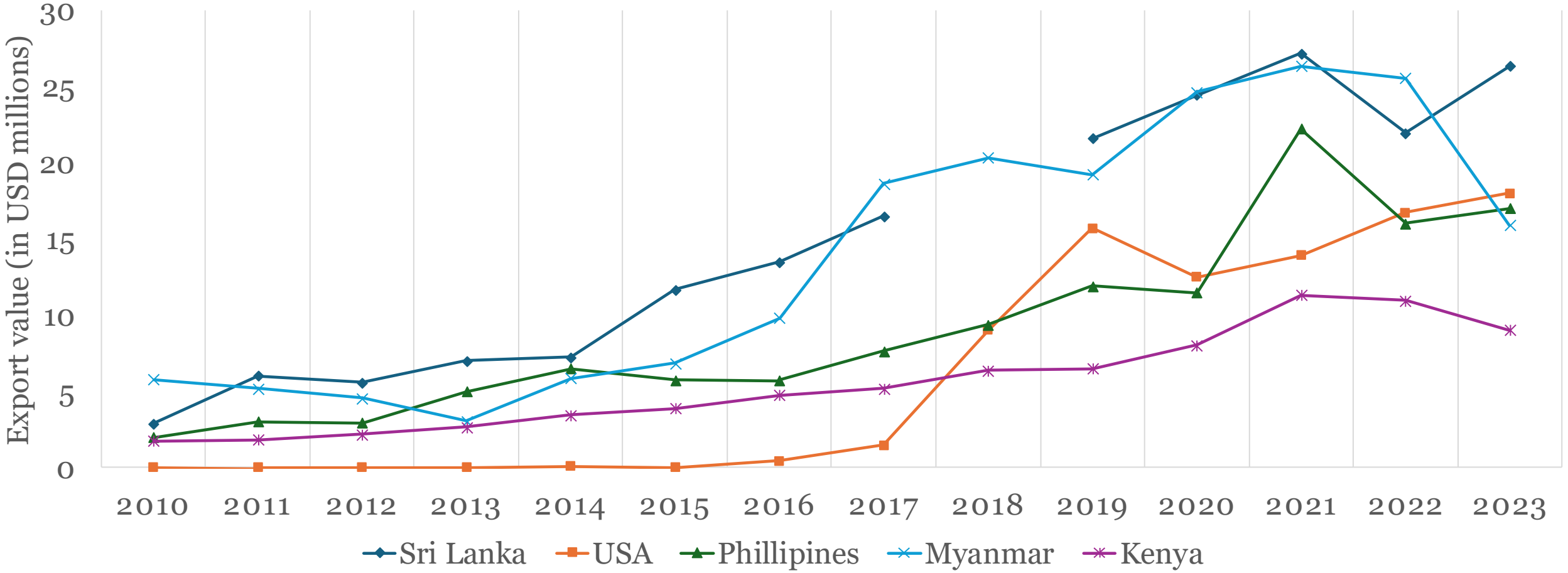
**Figure: R&D expenditure per worker across different industries (in BDT)**




Source: Bangladesh Survey of Manufacturing Industries 2019, BBS

# 5.3 Major export destinations

Figure: Bangladesh's Top 5 Export Destinations




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

# 5.4 Extent of the TRIPS dependence

- In terms of production volume, **20% of pharmaceutical products manufactured in Bangladesh are patented**, and 80% are non-patented.
- As an LDC, Bangladesh can **import patented products and re-export them** to other developed countries at far lower prices than many other countries.
- Bangladesh utilises TRIPS flexibilities to restrict pharmaceutical product and process patenting until the transitional period or LDC graduation, restrict certain medicines, restrict imports, require foreign manufacturers to be licensed, and define "invention" to include an improvement of an invention to allow for reverse engineering patents.

# 5.5 Non-IPR barriers to technology adoption

- **Weak Human Capital:** Low quality of primary, secondary, and tertiary education limits the availability of a skilled workforce.
- **Limited Labour Mobility:** Insufficient movement of experienced professionals from multinational firms to local industries hampers skill and knowledge transfer.
- **Lack of Workforce Training:** A significant gap in training for pharmaceutical industry workers reduces capacity for adopting new technologies.
- **Financial Constraints:** Limited access to financing, particularly for capital-intensive technology investments, makes it challenging for the sector to upgrade its technological capabilities.
- **Inadequate Investment in R&D:** Insufficient focus on research and development limits the ability to innovate and adopt advanced technologies.

# 5.6 Strategies for the post-LDC period

**Measures taken by the Government of Bangladesh**

**API Production Incentives:** 100% tax waivers for producers of 5 API molecules, and 75% for 3 API molecules. Tax exemptions extend to API producers and laboratory reagent manufacturers until 2032 (BIDA, 2023).

**API Industrial Park:** 200-acre park in Munshiganj for API manufacturing, aiming to reduce API import dependency and increase job creation (BAPI, 2024).

**Export Subsidies:** 20% subsidy for API exports, 7% for pharmaceuticals, boosting export competitiveness (BIDA, 2023).

**Measures taken by pharmaceutical companies**

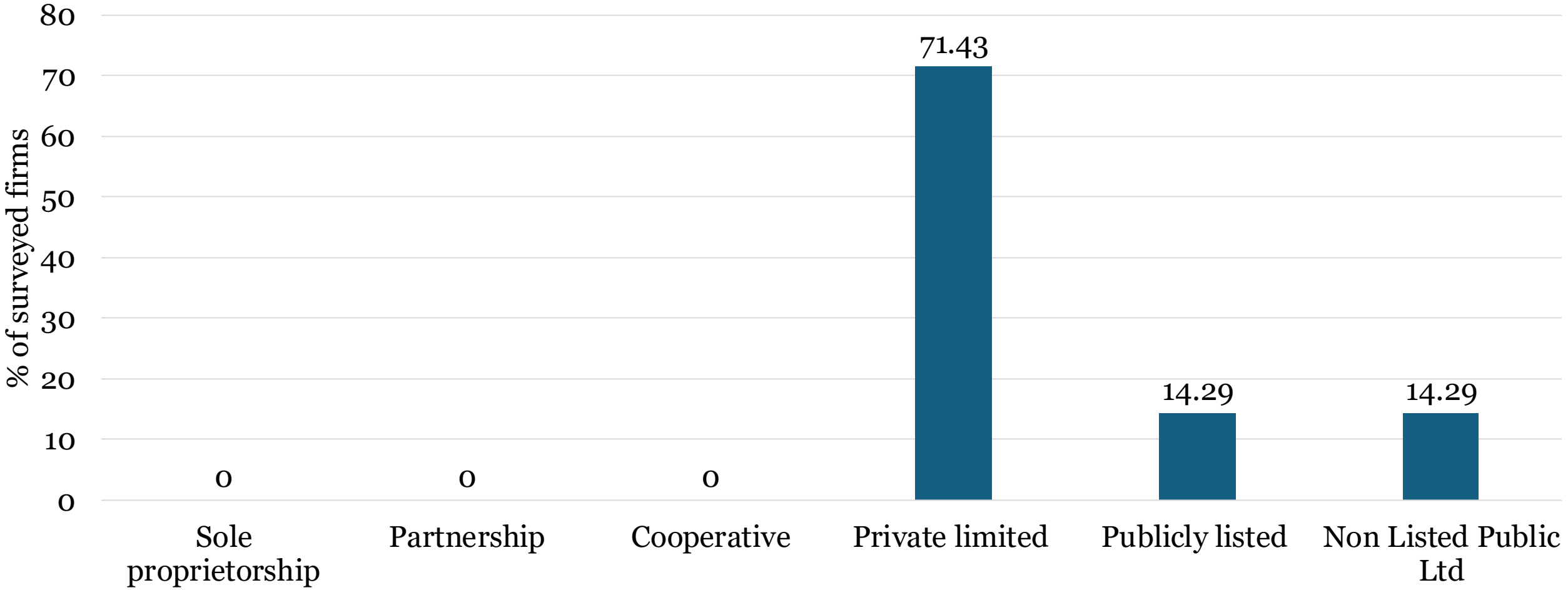
**Targeting Regulated Markets:** Expanding into highly regulated markets like the EU, USA, UK, and Australia with accreditations like Food and Drug Administration (FDA) and Good Manufacturing Practice (GMP) (BAPI, 2024).

**R&D Investments:** Companies are developing advanced pharmaceutical products like insulin analogues, monoclonal antibodies, and complex formulations to prepare for post-LDC competition (Mitsumori & Kubo, 2022).

# 6. Survey Findings

# 6.1 Legal status

**Figure: Current legal status of the pharmaceutical firms**




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

# 6.2 General information about the firms

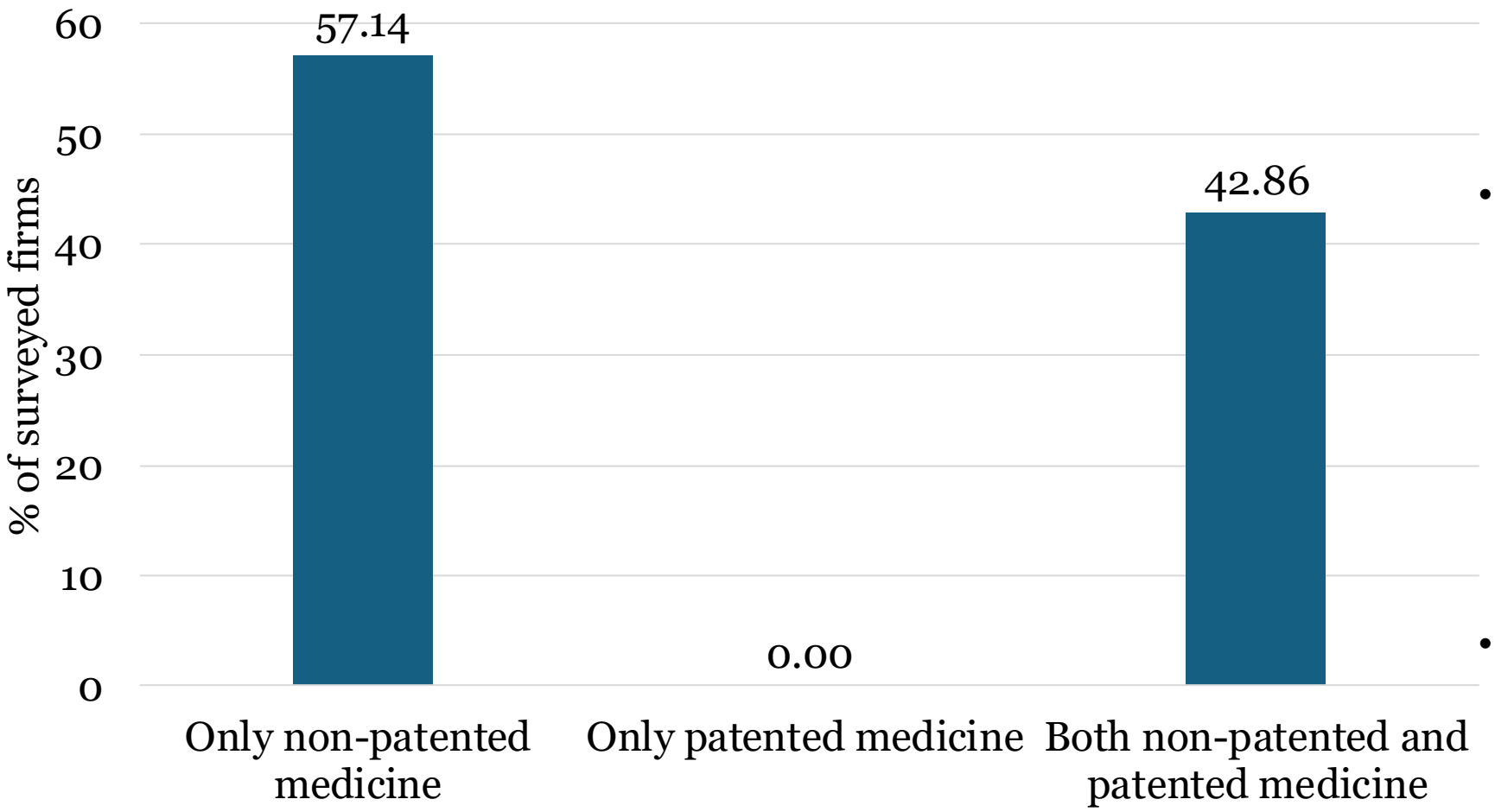
- In our survey, **71.43% of the pharmaceutical firms** mentioned that their **largest owner is also the top manager of their company**.
- The top managers, on average, had **30.3 years of experience** in the pharmaceutical sector, manifesting their expertise in this sector.
- **None of the surveyed firms'** owners, CEOs, top managers, or board members were elected or appointed to a **political position in Bangladesh**.
- Our survey found that all the firms have **at least one female owner** in their establishment, demonstrating that gender plays a vital role in this sector.

# 6.3 Establishments' information

- According to our survey, the establishments began operating from as early as 1958 to as recently as 2015.
- Being in the pharmaceutical industry for so long, **71% of the establishments obtained internationally recognised quality certifications.**
- According to our survey, 86% of **pharmaceutical establishments export their products**, of which 37.3% are exported to other LDCs.
- Our study reflects low local production of API and other inputs, as only **28.3% of the establishments' purchases of material inputs or supplies were of domestic origin.**

# 6.4 Type of medicine manufactured

**Figure: Type of medicine manufacturing taking place in the firms**



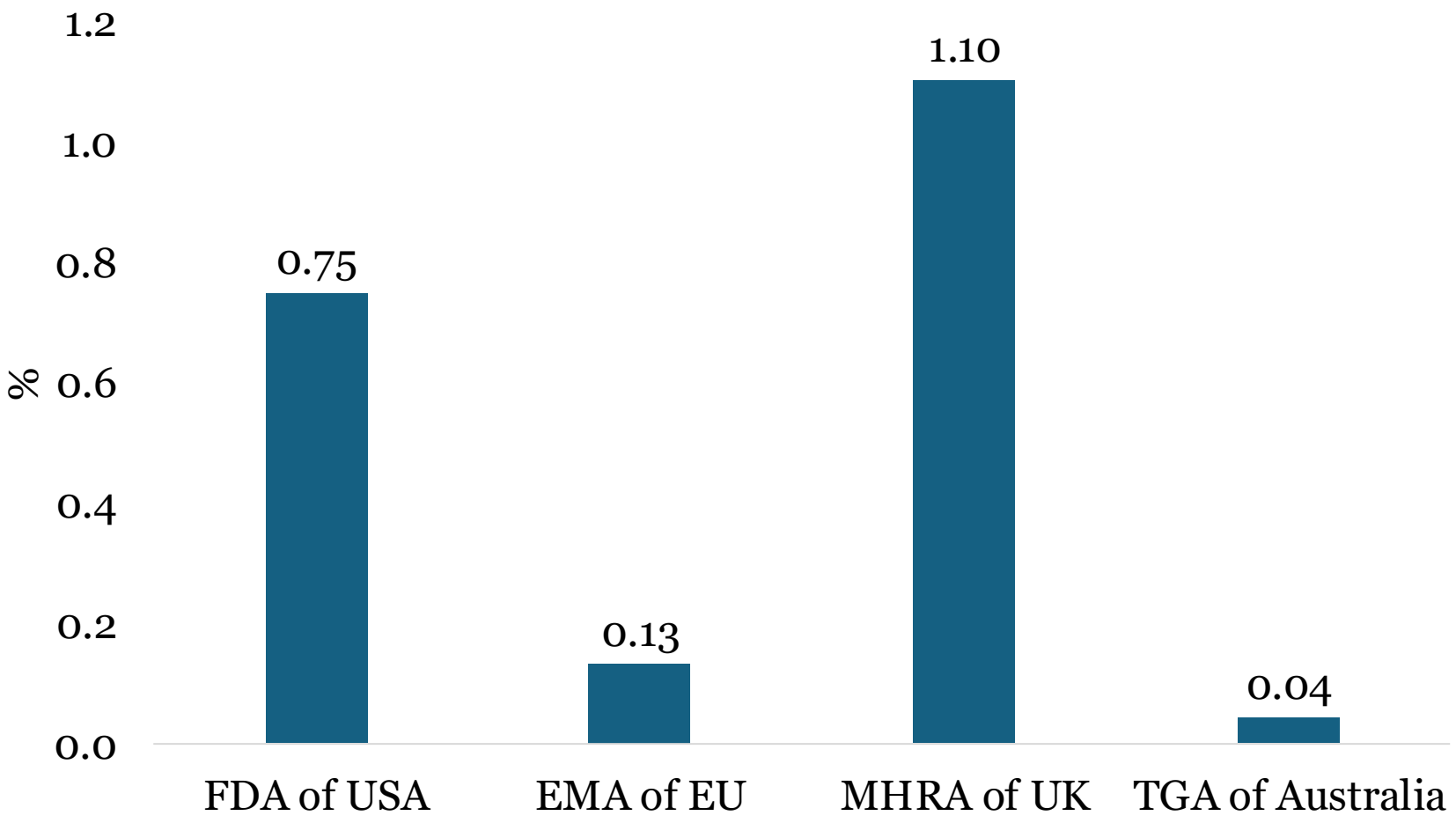

Source: Authors' illustrations based on the data from the survey conducted as part of this study.

- The surveyed firms manufacture different types of products, ranging from **40 products to a maximum of 879 products.**
- Initially, local firms in Bangladesh were known for producing simple generic drugs. As the industry grew, **the abolition of product patent protection allowed local companies to diversify into more complex patented products.**
- Now, on average, **12% of patented medicines are manufactured by firms** that produce patented and non-patented medicines.

# 6.5 Internationally approved products

- One of the primary goals of the National Drug Policy 2005 is to manufacture high-quality pharmaceuticals domestically and adhere to the **good manufacturing practice (GMP) rules established by WHO**.
- Bangladeshi pharmaceutical firms received the highest number of approvals from the Medicines and Healthcare Products Regulatory Agency (MHRA) of the UK and the Food and Drug Administration (FDA) of the USA.

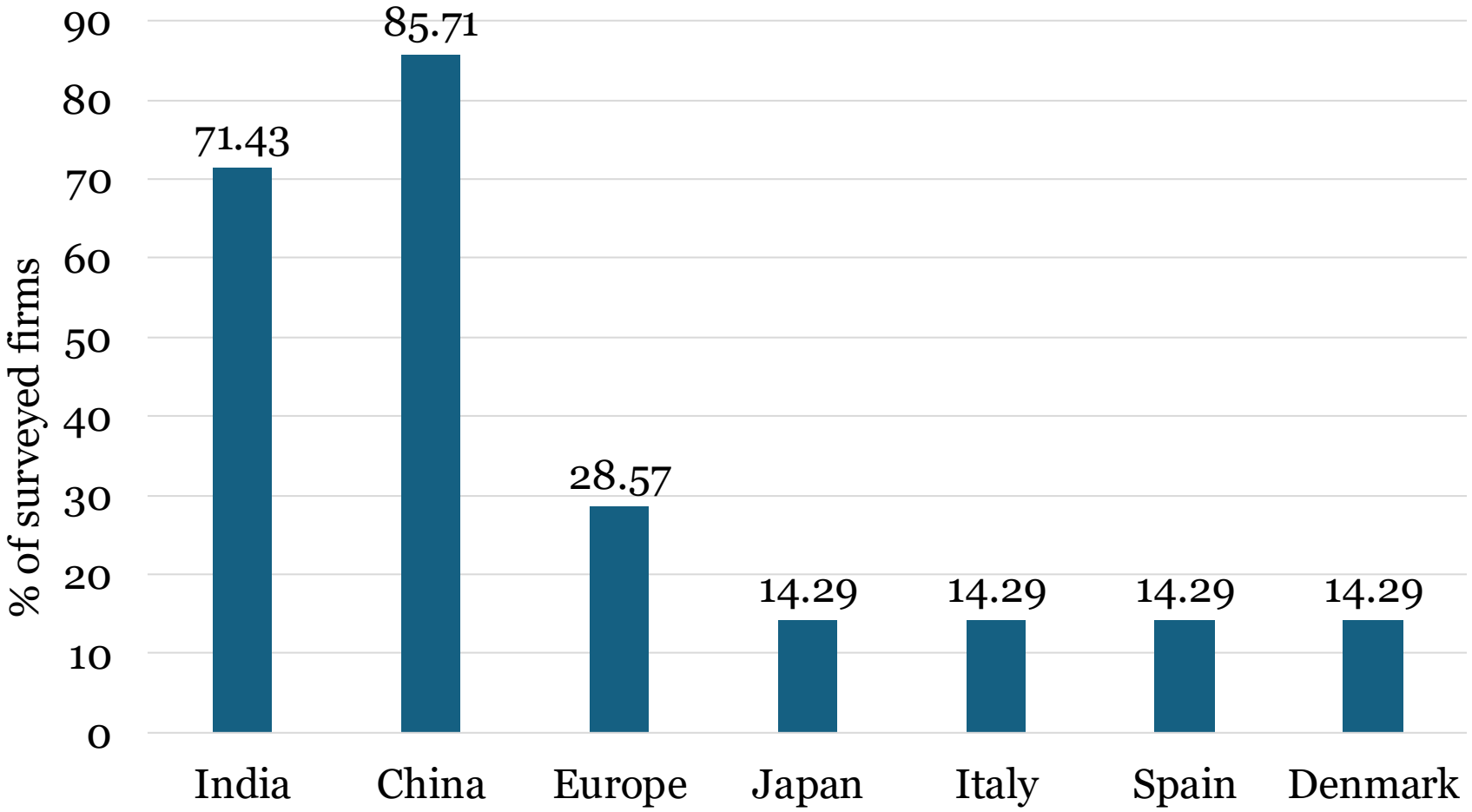
**Figure: Approved pharmaceutical products (in %)**




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

# 6.6 Active pharmaceutical ingredient import

**Figure : API import sources**



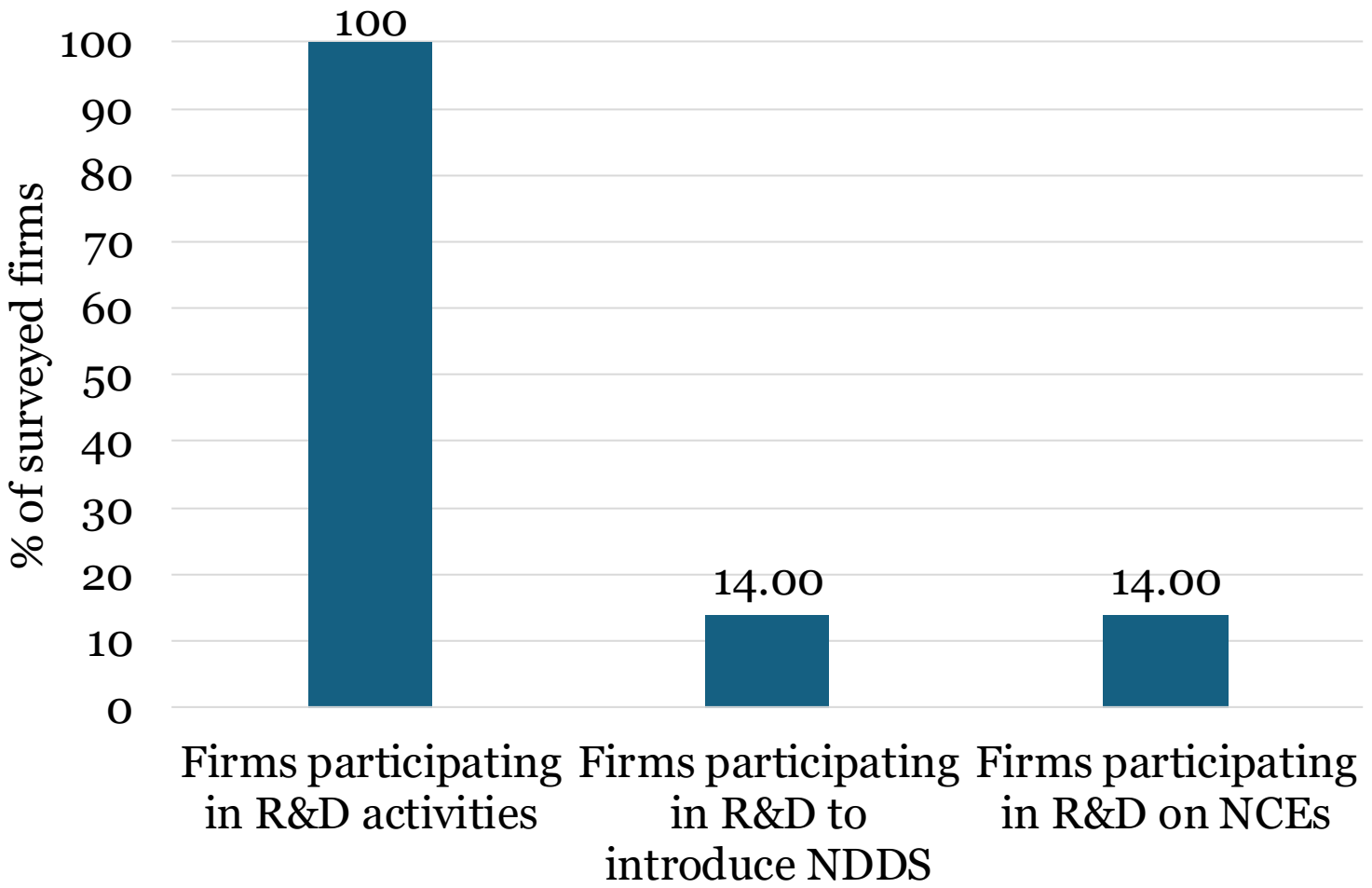

- Only **28.3% of the establishments' purchases of material inputs or supplies were of domestic origin.**
- Our survey showed that **94.6% of the APIs were imported** in 2024
- Our surveyed pharmaceutical firms **import most APIs from China and India.**
- Currently, **29% of the firms take part in the production of APIs.**
- On average, the surveyed firms produced **5% of the APIs** in the last fiscal year and are also **taking part in reverse engineering APIs.**

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

# 6.7 Participation in R&D

- Currently, **all establishments participate in R&D activities, spending an average of 3.4% of their total annual expenditure on R&D**.
- Only **14%** of the firms participate in **R&D activities to introduce new drug delivery systems (NDDS).**
- Among the rest who do not participate, only 50% of them plan to participate in R&D activities to introduce NDDS or invent new molecules.
- Half of the firms plan to participate in research on NCEs in the future

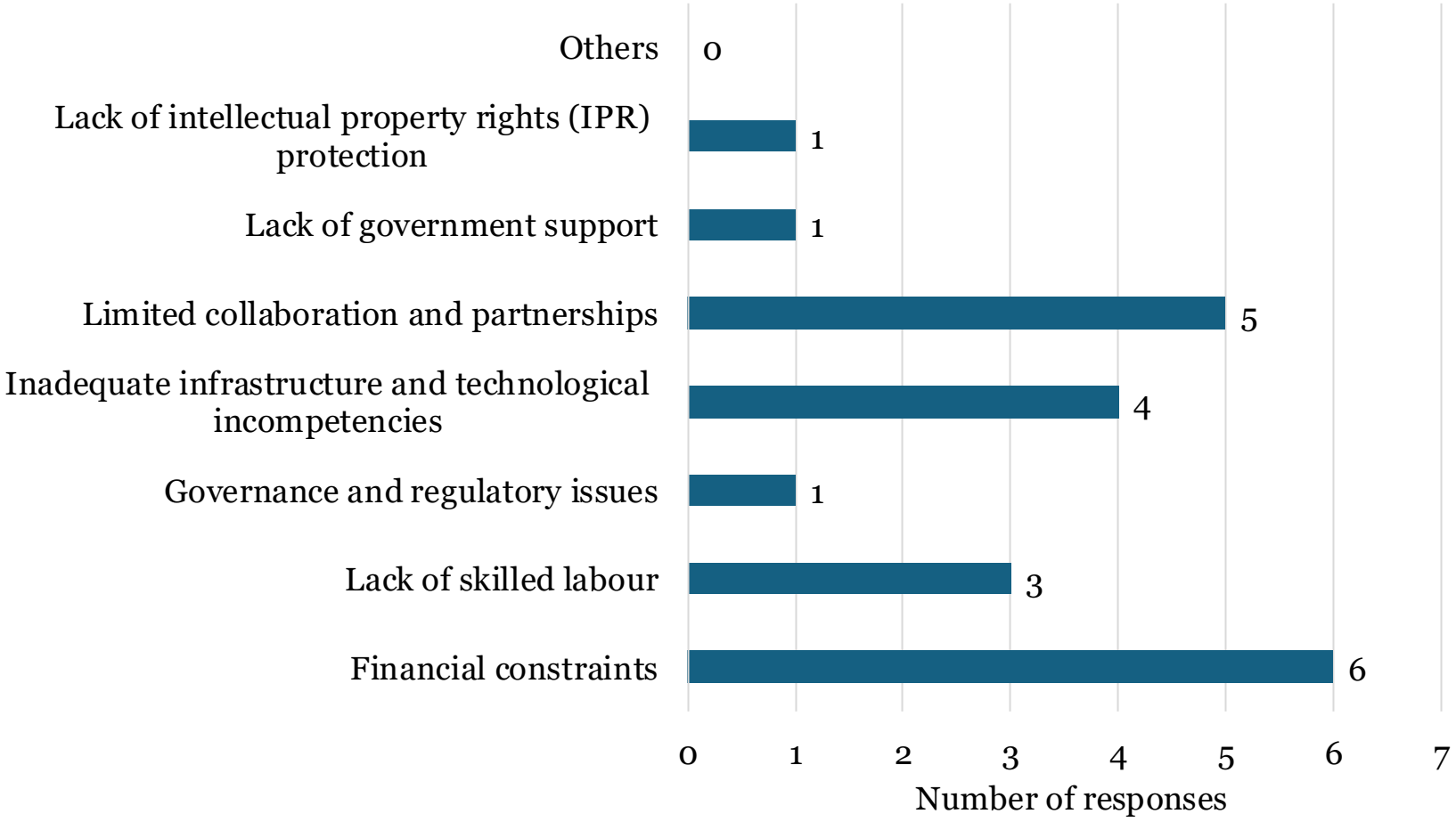
**Figure: Firms' participation in R&D**




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

# 6.8 Obstacles to engage in R&D

**Figure: Biggest obstacles to engage in R&D activities**



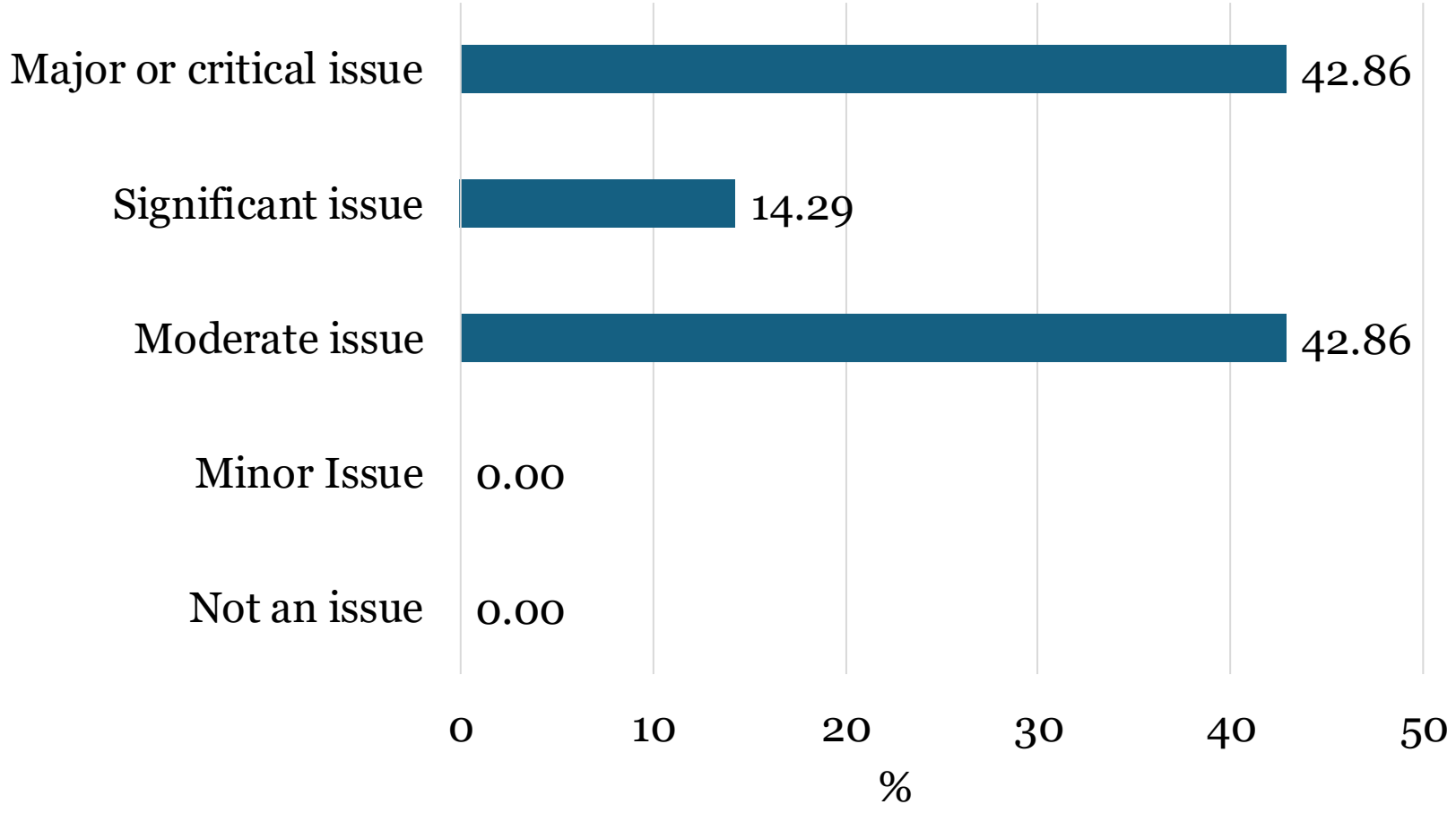

- Among the top 3 factors representing the firm's most significant obstacles to engaging in R&D activities, **financial constraints** are their most significant hurdle.
- Other major challenges to conducting R&D include inadequate infrastructure, technological incompetencies, limited collaboration and partnerships between industries, research organisations, and academia, and lack of skilled labour.

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

# 6.9 Workforce skills gaps

- The availability of skilled labour is a crucial factor supporting innovation in the pharmaceutical industry.
- From our survey, we found that **42.86%** of firms think that the **lack of relevant skills in the workforce is a major or critical issue** when engaging in R&D activities.

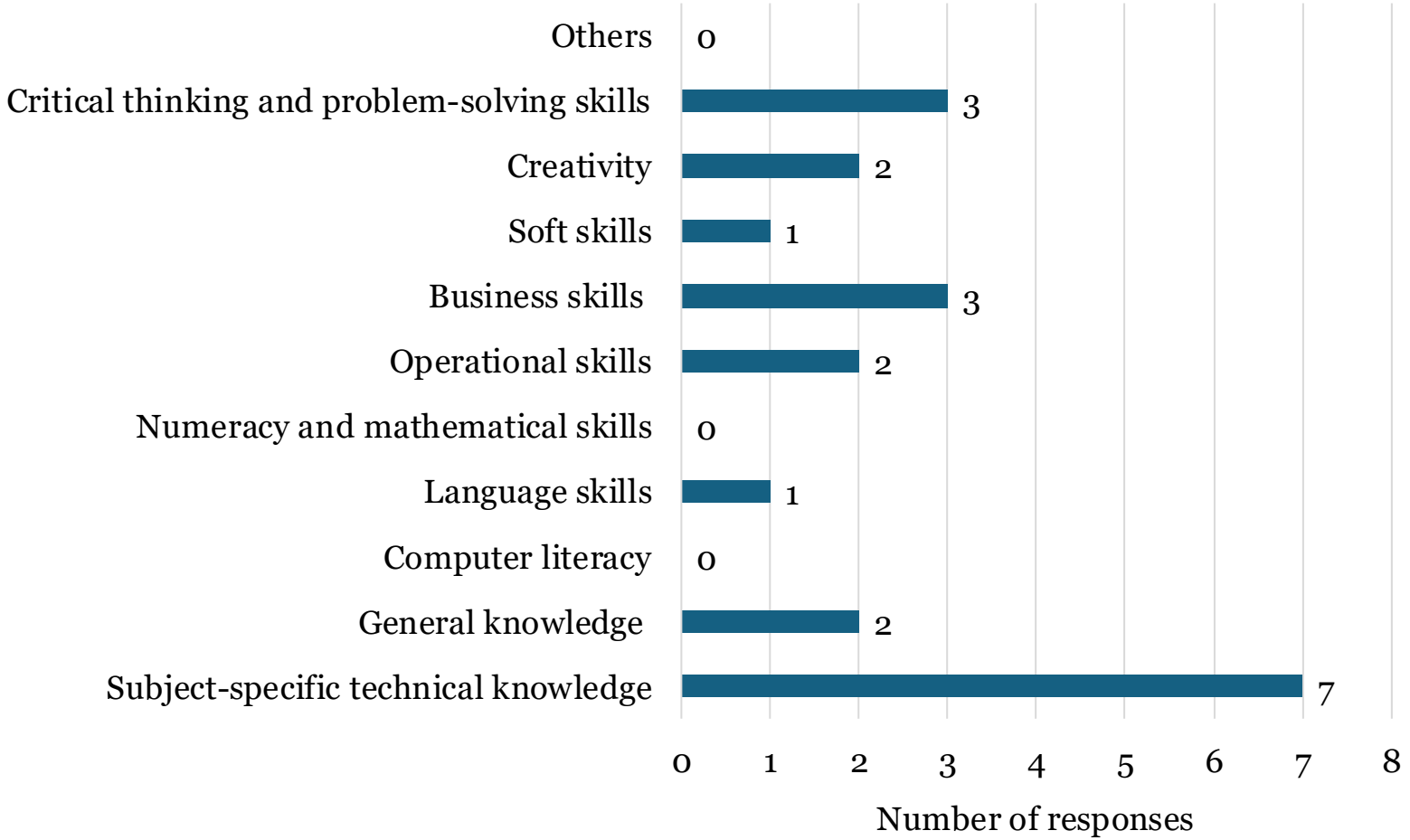
**Figure: The extent to which workforce skill gaps hinder R&D activities**




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

# 6.10 Skills that employers seek

**Figure 12: : The skills that employers seek in the current workforce lack**




- The surveyed pharmaceutical firms mentioned that subject-specific **technical knowledge** is the most required skill they seek, which current job seekers often lack.
- Employers also look for critical thinking, creativity, operational skills, and business skills.

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

# 6.11 Barriers to R&D

- Only **14.3%** of the firms agree that the **curriculum** for pharmaceutical sciences in Bangladesh's universities is **adequately designed** to reflect the needs of the industry requirements.
- All the firms offer internships for university students seeking more hands-on industry-based training, of which **57% offer paid internships** for university students.
- Only **14.3%** of the establishments are **collaborating with local universities** or research organisations, whereas **28.3%** are **collaborating with foreign universities** or research organisations to conduct their research.
- Moreover, **71.4%** of the establishments partner or **collaborate with foreign pharmaceutical companies** to produce their products at lower prices.

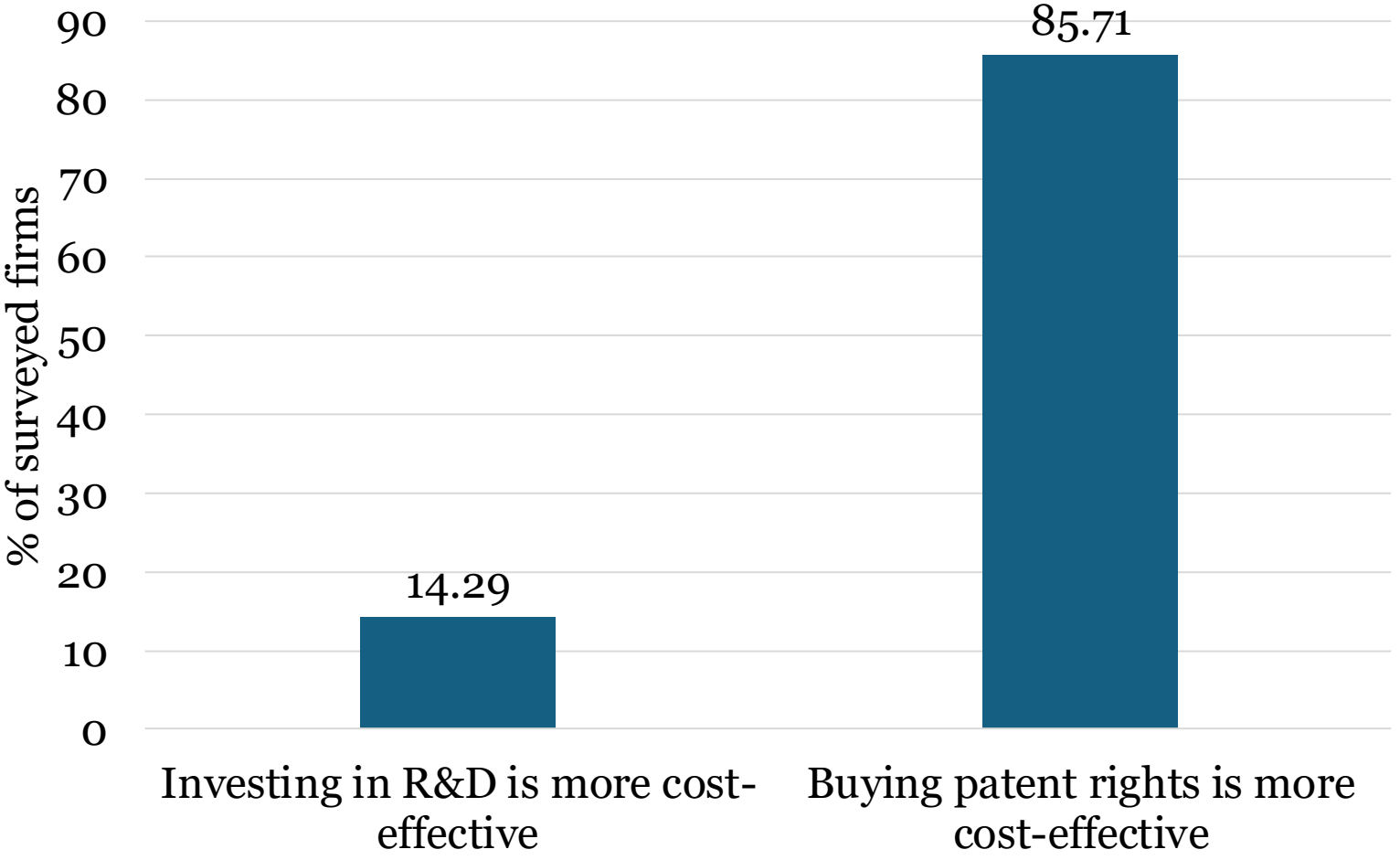
# 6.12 Innovation and R&D

- The survey findings show that **85.7%** of the firms **invested in the API park** built by the government.
- **43%** of the establishments **invested time** in decoding formulation parameters of any patented pharmaceutical product to enhance its **reverse engineering** skills.
- Furthermore, **14.3%** of the firms **disagree that adequate government support schemes are in place** to support the pharmaceutical industry as Bangladesh graduates from the LDC status.
- We also found that **43%** of the firms agree that **lowering the costs of APIs** by producing them locally could **compensate for rising costs post-LDC graduation**.

# 6.13 Cost-effectiveness of R&D

- **85.71%** of the firms think that **buying patent rights** to produce the patented drugs post-LDC graduation is **more cost-effective** for the company to keep earning profits from patented medicines rather than investing in R&D to innovate new drug formulations to replace the patented ones

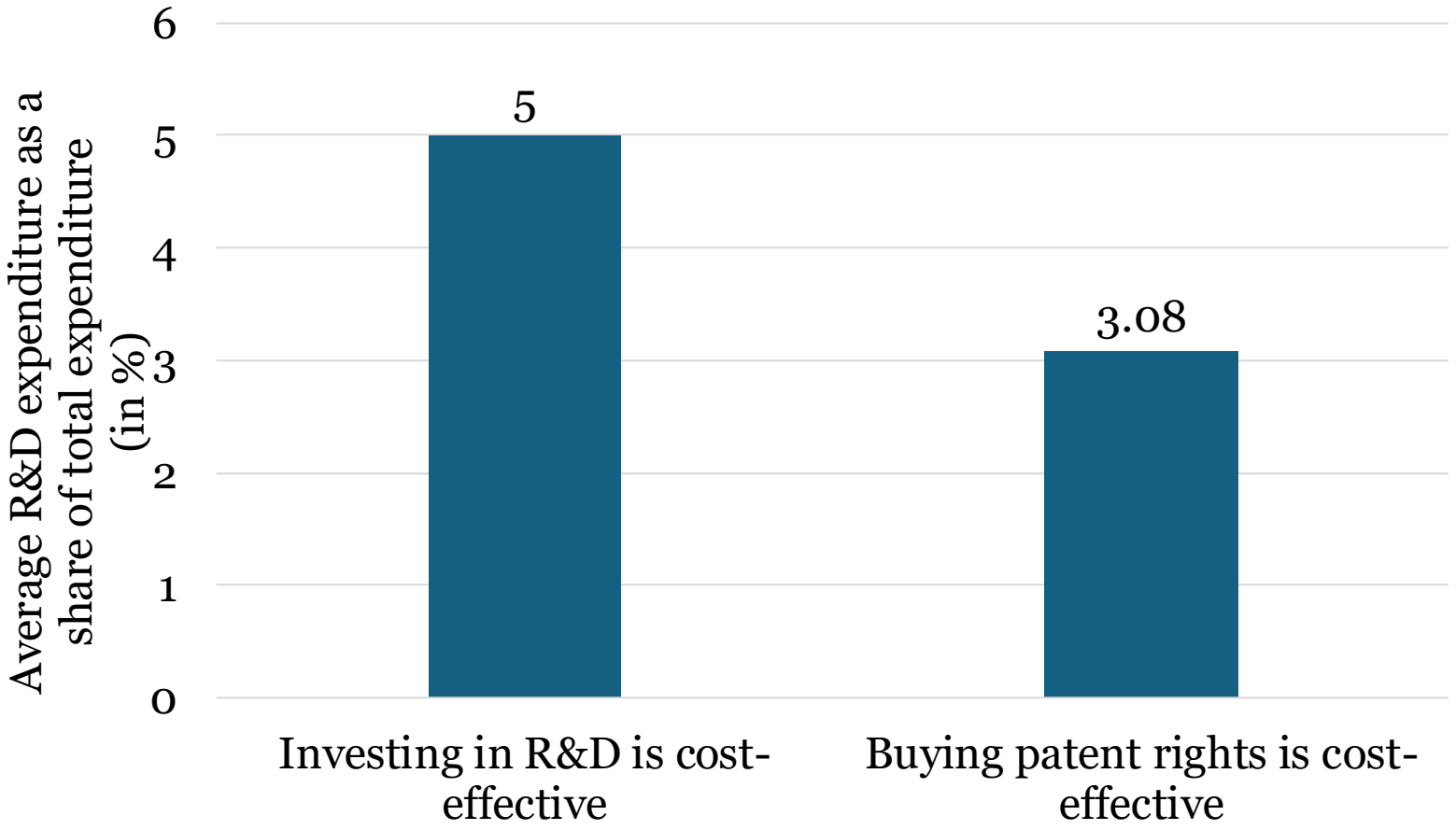
**Figure: Cost-effectiveness of investing in R&D or buying patent rights**




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

# 6.14 Views about R&D

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




- Firms that spend **5%** of their total expenditure **on R&D activities**, on average, agree that **investing in R&D is more cost-effective** than buying patent rights.

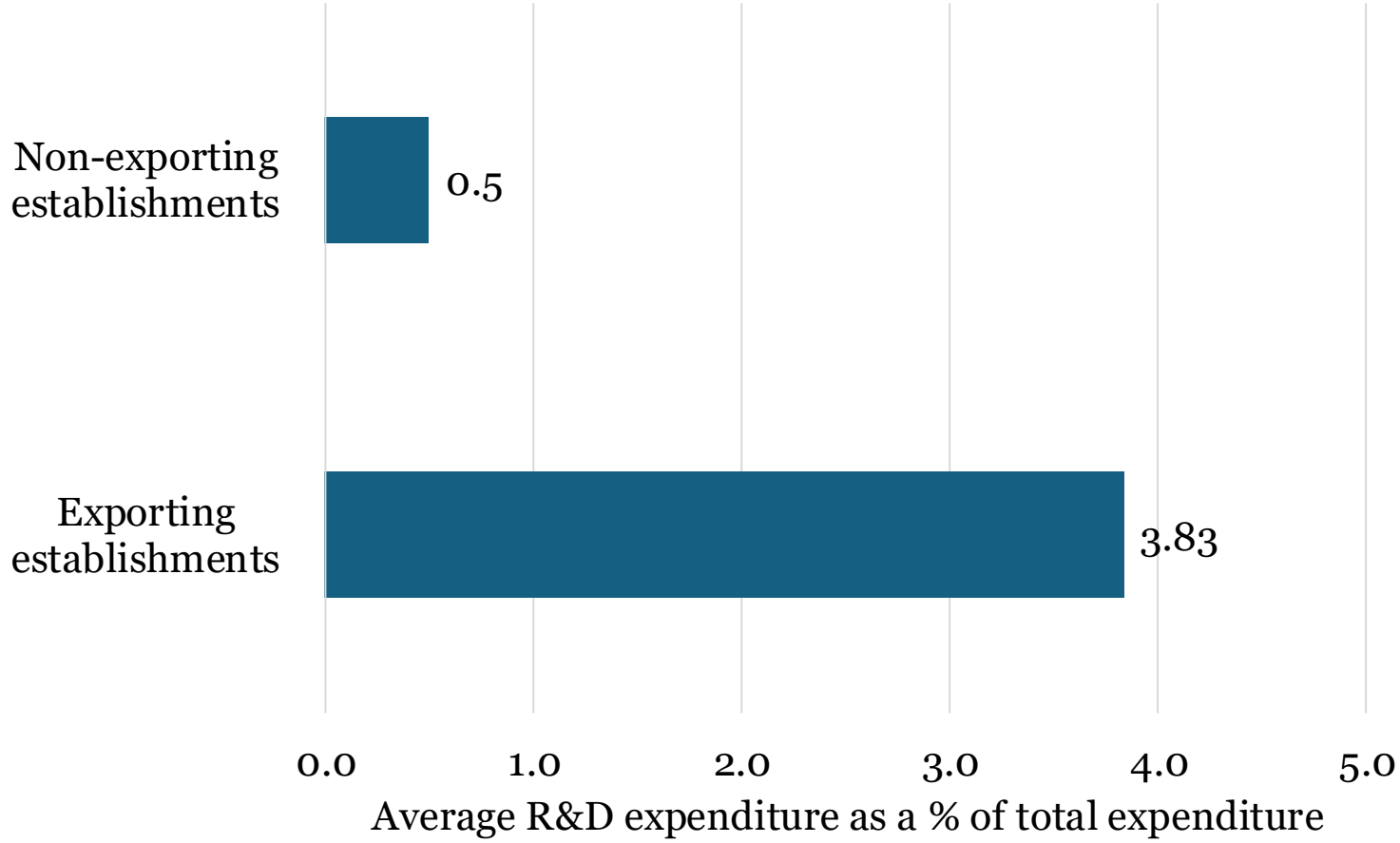
- On average, the establishments that think **buying patent rights is more cost-effective** invest **3.08%** of their total **expenditure on R&D**

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

# 6.15 Export and R&D expenditure

- Pharmaceutical establishments that export their products **spend 3.83% on R&D.**
- Exporting establishments are exposed to global competition, which drives them to invest more in R&D to develop new products and augment their competitiveness.
- In our survey, **non-exporting firms spent only 0.5% of their expenditure on R&D**.

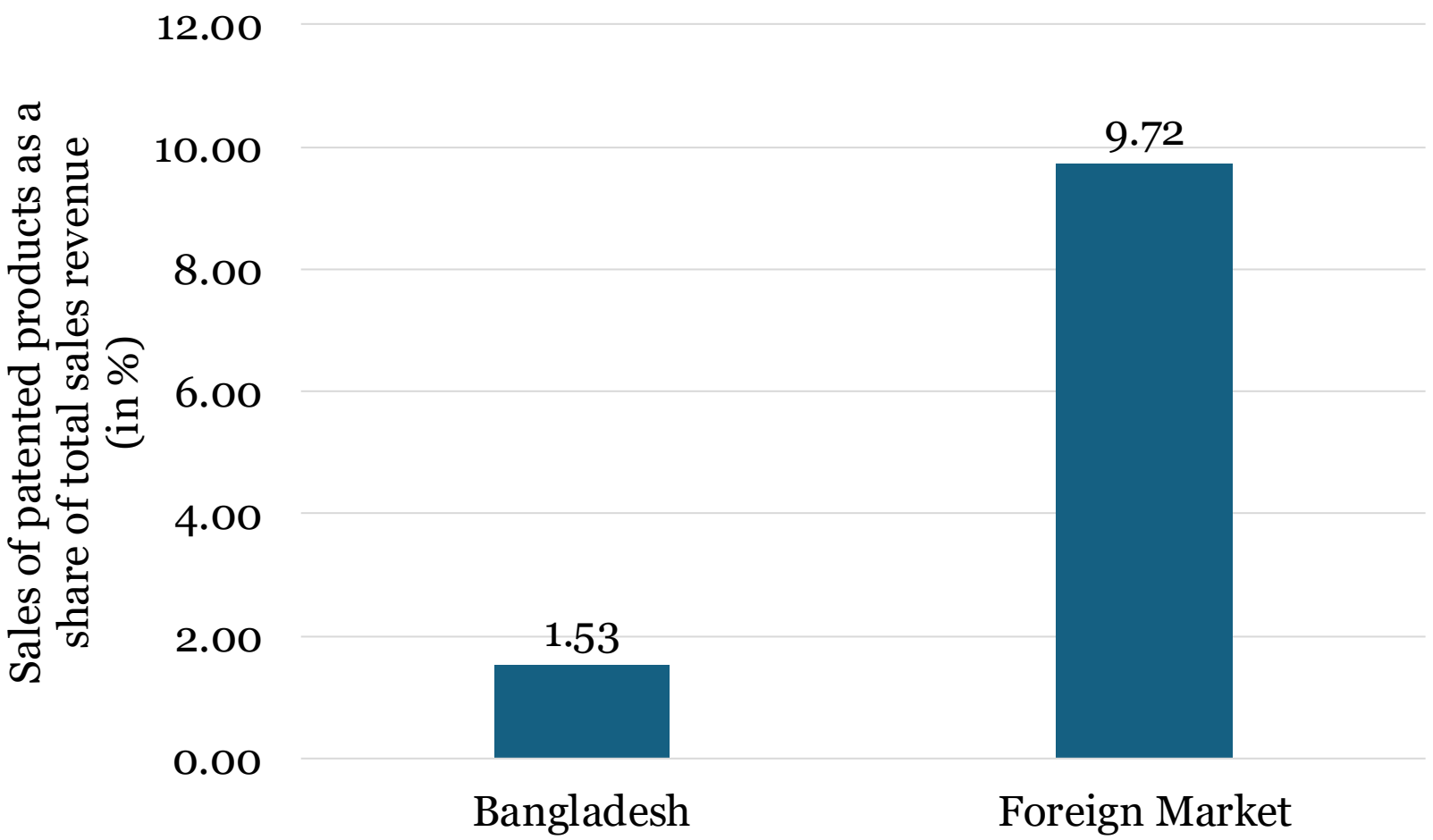
**Figure: Relationship between firms who export and their average R&D expenditure**




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

# 6.16 Sales of patented products

**Figure: Sales of patented products as a share of total sales revenue (in %)**




- In **Bangladesh**, the proportion of **patented product sales** to the total sales revenue of the surveyed firms is **1.53%**.
- Conversely, **9.72%** of the company's total sales revenue from **overseas markets** comes from the **sale of patented products**.

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

# 7. Conclusions and Recommendations

# 7.1 Conclusions

**Shift from generics to patented medicines:** Initially focused on generic drugs, Bangladesh now produces complex and patented formulations. The survey shows that 12% of medicines manufactured are patented.

**TRIPS waiver impact:** The TRIPS waiver allowed local firms to produce patented drugs at lower costs, increasing local access and export opportunities. The survey shows that patented products contribute 9.72% of export revenue.

**Imported API dependence:** The survey shows that 94.6% of APIs are imported, mainly from India and China, raising concerns about costs post-LDC graduation. The API Park aims to reduce import dependence and boost local API production.

**R&D and technology barriers:** Despite R&D participation, financial constraints, a lack of partnerships, and workforce skill gaps limit innovation. The survey shows that on average only 3.4% of annual expenditures are spent on R&D.

**3i strategy for the future:** *Increasing R&D, intensifying reverse engineering, and improving human resource capacity will be crucial to success in the post-LDC graduation period.*

# 7.2 Recommendations

- **Developing R&D** to establish the ability to create as many patented APIs as possible before Bangladesh graduates from the LDC status and loses the TRIPs pharmaceutical waiver.
- **Introducing as many patented goods locally** as possible before the TRIPs waiver expiration to help pharmaceutical companies **reduce their reliance on API imports** and address future challenges.
- **Securing registration for new drugs within the next two years** to ensure local companies can maintain access to these drugs, as post-transition patent protections by multinational companies could limit their ability to register and produce these medicines.
- **Enriching backward integration** to emphasise and **boost reverse engineering skills.**

# 7.2 Recommendations

- **Investing in regulatory approvals** for manufacturing facilities will boost exports of off-patent drugs and **enable the production of patented drugs under license agreements**, helping mitigate potential losses once copy versions of patented drugs are restricted.
- **Building the workforce's capacity** by providing an adequate curriculum for pharmaceutical sciences in Bangladesh's universities, designed to reflect the needs of the industry requirements.
- **Upscaling collaboration between firms and public sector institutions** involved in research and development, teaching, and health services.
- **Increasing industry collaboration with local and foreign universities or research organisations** to conduct their research.
- **Investing in digital tools like artificial intelligence (AI), data analytics, and machine learning** to augment the medication development process to enable companies to **accelerate drug development**.

# THANK YOU

https://cpd.org.bd

cpd.org.bd

CPDBangladesh

cpd_bangladesh

Centre for Policy Dialogue (CPD)