Terms of Reference (ToR)

Research initiative by Bangladesh Investment Development Authority (BIDA) on "Identification of key challenges and opportunities for Pharmaceuticals sector of Bangladesh in the Post-TRIP era."

BACKGROUND

Bangladesh is a country of over 170 million people that has significant potential for economic growth, driven by a young and rapidly expanding talented, skilled, semi-skilled and industrious workforce. Strategic geographic location of Bangladesh between South and Southeast Asia with strong internal and regional connectivity is an extra advantage that could establish a bridge between the east and west. The country's thriving pharmaceutical industry is one of the fastest growing sectors, contributing significantly to its economy and healthcare system. However, it faces challenges such as regulatory compliance, dependency on imported raw materials, and competitive global markets. Simultaneously, opportunities exist in areas like API production, exports, and generic drug manufacturing. The present interim government has set time befitting development plans aimed at transforming the country into a high-income, prosperous and New Bangladesh keeping pace with aspirations of the youth-folks and new generations focusing on inclusive economic growth, human capital development, and technological innovation. For investments in various sectors particularly by the foreign investors, Bangladesh has been advancing towards the global markets with its quality and high standard pharmaceutical products, while demand of its pharmaceutical products is growing worldwide.

The pharmaceutical sector of Bangladesh has emerged as one of the country's most promising industries, contributing significantly to the economy through local market dominance and increasing export potentials in recent years. This industry is one of the most developed hi-tech and thrust sector within the country's economy. Now Bangladesh is a leader in the pharmaceutical industry, meeting nearly 98% of the domestic demand for pharmaceutical products. Besides, Bangladesh is exporting pharmaceutical products to more than 100 countries around the world, including the US, the EU, Africa and Latin America. The country's ability to leverage the provisions of the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, particularly the transition period granted to least-developed countries (LDCs), has allowed domestic pharmaceutical companies to flourish by producing generic versions of patented drugs without the constraints of intellectual property protections. However, as Bangladesh approaches its graduation from the LDC status in November 2026, the post-TRIPS era presents a critical juncture for the pharmaceutical industry as the local producers may face obstacles in manufacturing generic drugs and medical products. However, it is also true that may pharmaceutical industries in Bangladesh have gained strengths in research and developments as well as world class drug manufacturing facilities. The potentials of the under construction API zone in Bangladesh needs also to be assessed.

Following those challenges and opportunities, this research will focus on identifying key challenges and opportunities for Bangladesh's pharmaceutical sector in the context of the post-TRIPS era. The challenges are multifaceted, including compliance with global intellectual property regulations, maintaining competitiveness in the international market, and addressing technological and infrastructural gaps. At the same time, significant opportunities also exist, such as the potential for innovation, entry into high-value pharmaceutical segments, and the expansion of export markets.

In this context, this research aims to provide a comprehensive understanding of how the pharmaceutical sector can navigate these challenges while capitalizing on emerging opportunities to sustain its growth trajectory. By doing so, it seeks to offer actionable insights for policymakers, industry stakeholders, and international partners to ensure a smooth transition and bolster the sector's resilience and global competitiveness.

The Pharmaceutical industry is witnessing a remarkable development driven by innovation, sustainability, and market demand both at home and abroad. By addressing challenges and leveraging opportunities, stakeholders can ensure the continued growth and profitability of pharmaceutical products in both domestic and international markets. This research has the potential to contribute to the development of actionable recommendations for sustaining and expanding the growth of Bangladesh's pharmaceutical sector in a globalized, TRIPS-compliant environment.

Considering all these aspects and features, BIDA has conceptualized a research initiative on the captioned subject above with the following objective and scope.

2. RESEARCH OBJECTIVE

This research work will be carried out with the objective of:

a. identifying the key challenges faced by the pharmaceutical sector of Bangladesh which are hindering growth, innovation, and market expansion in the post-TRIPS era

b. analyzing the potential opportunities available to the sector such as innovation, research and development (R&D), export potential, market expansion, and high-value pharmaceutical production and technological expansion.

c. assessing strength and readiness of Bangladesh's pharmaceutical companies to transition to a TRIPS-compliant regime evaluating technological capacity, human resources, and investment in R&D.

d. exploring strategies for mitigating challenges in the post-TRIPS era with a focus on policy support, international collaborations, and capacity building.

e. Providing recommendations for policymakers, stakeholders, industry leaders, and international partners for sustainable growth and global competitiveness to ensure sustainable growth and competitiveness of the pharmaceutical sector.

3. SCOPE OF WORK

3.1 Literature Review

Review of existing studies, reports, regulatory frameworks and policies related to pharmaceutical industry

3.2 Temporal Scope

Analyze the pre-TRIPS compliance period to understand the advantages leveraged by Bangladesh under TRIPS flexibilities and examine the post-TRIPS compliance era (post-2026) to assess anticipated challenges and opportunities for the sector.

3.3 Thematic Scope

Challenges on Intellectual Property (IP) compliance and its impact on generic drug production, Regulatory and legal adjustments required for TRIPS compliance, Market competitiveness amidst rising costs of production and licensing fees, Dependence on imported Active Pharmaceutical Ingredients (APIs), and R&D capabilities and technological readiness for innovation.

Opportunities in expansion into high-value pharmaceutical products (e.g., biosimilars, vaccines), on growth in export markets, leveraging quality production standards

3.4 Key Stakeholder Perspectives

The consulting firm should engage with key stakeholders, including Pharmaceutical manufacturers and industry associations (e.g., Bangladesh Association of Pharmaceutical Industries - BAPI), government agencies, legal experts, researchers and academic institutions on the Act's effectiveness and challenges focused on pharmaceutical innovation as well as international organizations (e.g., WTO, WHO) and foreign investors; Collect insights from investors, government agencies, collaborate on data collection, and ensure alignment with the interests of the Government of Bangladesh; Engagement with key stakeholders, including:, Government bodies and regulators (e.g., Directorate General of Drug Administration - DGDA),

Examine investor confidence and perceptions related to Bangladesh's investment climate.

3.5 Data Collection and Analysis

Conduct surveys, interviews, and focus group discussion with industry stakeholders

Analyze primary and secondary data to identify trends, challenges and opportunities

3.6 Market Assessment

Evaluate domestic and international markets, focusing on export potential and competition

3.7 Regulatory and Policy Analysis

Assess the impact of existing regulations and policies on the pharmaceutical industry

3.8 SWOT Analysis

Identify the strengths, weaknesses, opportunities, and threats to the pharmaceutical sector

3.9 Report Preparedness

Develop a comprehensive report with findings. Based on the research findings, propose a set of actionable policy recommendations to relevant government authorities. These recommendations should focus on mitigating challenges, providing incentives, and creating an enabling regulatory environment to create opportunities for further expansion and promotion of sector growth and innovation.

3.10 Deliverables

Sl.	Timeline	Deliverables
1.	Within 2 weeks of agreement signing	Submit an Inception Paper detailing the research perspectives, literature review, research procedure, questionnaire to be used and deliverables.
2.	Within 4 weeks	Organize a stakeholder consultation (local workshop) with relevant players of the sector
3.	Within 8 weeks	Submit the draft report
4.	9th week	Organize a national workshop to discuss on the draft report
5.	11th week	Submit the final report

4. METHODOLOGY

A systematic approach is essential for identifying the key challenges and opportunities in the pharmaceutical sector in Bangladesh. Below is a proposed methodology:

1. Research Design

Adopt a mixed-methods approach that combines qualitative and quantitative research to gain comprehensive insights to outline the current state of the pharmaceutical sector and identify challenges and opportunities through stakeholder engagement.

2. Data Collection Methods

Primary Data Collection

a. Through surveys and questionnaires:

Target respondents: pharmaceutical executives, policymakers, healthcare professionals, and academicians.

Focus areas: Challenges in manufacturing, R&D, and regulations.

Opportunities in exports, technology, and market expansion.

b. In-depth Interviews: Conduct semi-structured interviews with key stakeholders like Industry leaders, government officials, and regulators, representatives from trade bodies (e.g., Bangladesh Association of Pharmaceutical Industries).

c. Focus Group Discussions (FGDs): Small group discussions to explore collective insights on sectoral dynamics.

Secondary Data

Literature Review:

a. Analyze existing studies, reports, and policy documents related to the pharmaceutical industry in Bangladesh.

b. Industry Reports and Statistics: World Health Organization (WHO), Bangladesh Bureau of Statistics (BBS), and international trade organizations. Collect export/import data and market trends.

c. Regulatory Documents: Examine laws, policies, and guidelines like the National Drug Policy and API and Laboratory Reagents Production and Export Policy.

d. Competitor Analysis: Study global pharmaceutical markets to benchmark challenges and opportunities.

3. Sampling Strategy

a. Sampling Technique: Purposive Sampling: Select industry experts, policymakers, and academics based on their relevance to the research.
Stratified Random Sampling: For broader data from pharmaceutical employees and customers.
b. Sample Size: Standard sample size for surveys, interviews and focus group discussions

4. Data Analysis

a. Quantitative Analysis: Use statistical tools (e.g., SPSS, Excel) to analyze survey results. Identify trends, correlations, and patterns in challenges and opportunities.
b. Qualitative Analysis: Apply thematic analysis to categorize insights from interviews and FGDs. Use tools like NVivo for coding qualitative data.

5. SWOT Analysis:

Perform a SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis of the sector.

6. Reporting and Recommendations:

1. Report Structure:

a) Executive Summary
b) Introduction
c) Methodology
d) Findings: Key Challenges and Opportunities
e) Conclusion and Recommendations

2. Policy Recommendations:

Provide actionable insights for policymakers, industry leaders, and stakeholders.

7. DELIVERABLES

I. Inception Report on the agreed methodology detailing plan and disposition of the research plan;

II. 1st Draft Report in accordance with the Scope of Work and a Presentation on the highlights of the Draft Report;

III. 2nd Draft Final Report and Presentation of findings/analysis/draft report to BIDA and relevant stakeholders in dissemination workshop;

IV. Final Report incorporating all feedbacks from the dissemination workshop.

**For each deliverable, soft and hard copy must be submitted*

8. TERMS & CONDITIONS

I. On-time execution of responsibilities and delivery of deliverables without failure;

II. Performance of contracted jobs and responsibilities within agreed budget and plans;

III. Presentation of research methodology/inception report in front of expert panel; and

IV. Time to Time monitoring by the Marketing and Communication wing

8. REQUIREMENTS:

A. Requirement of the firm:

a. Legal documents of the firm (including but not limited to Registration of Firm, TIN, VATs, trade license, etc.).

b. The firm should have experience of at least 10(Ten) years in research studies on regulatory and policy or social studies.

c. Availability of key personnel (see Part B) in regular payroll for conducting research or social studies of the assignments.

d. Experience of the firm in similar task/assignments (example of past experience of similar nature and for complexity including cost and duration of the assignment).

e. Support Services of the firm (including but not limited to office space, support staff, equipment).

f. Financial Statement supported by audit report for the last 3 (three) years.

B. Requirement of Individual and Experts

The Consulting Firm should have human resources/ experts with following qualifications:

Position	Qualification	Experience
Team leader	Team Leader should have excellent academic background with Master's degree in any subject related to Economics/ Development Studies/ Pharmacy/ Biochemistry/Applied Chemistry/ Microbiology from any reputed University in Bangladesh.	Team Leader should have minimum 10 (Ten) years' experience in research study/consulting with adequate experiences on market research/ economic analysis of industries or sectors including the pharmaceutical industry is a prerequisite. The consultant must be aware of government laws, rules and policies.
Deputy Team Leader	Deputy Team Leader should have excellent academic background with Master's degree in any subject related to Economics/ Development Studies/ Pharmacy/ Biochemistry/Applied Chemistry/ Microbiology from any reputed University in Bangladesh.	Deputy Team Leader should have 8(eight) years' of experience in research study/consulting with adequate experiences on market research/ economic analysis of industries or sectors including the pharmaceutical industry is a prerequisite. The consultant must be aware of government laws, rules and policies.
Pharmacist	Pharmacist should have Master's degree in Pharmacy from any reputed University of Bangladesh.	Pharmacist should have 7(seven) years' experience in any reputed University of Bangladesh along with strong communication and liaison with the relevant line ministries and executing agencies.
Data Analyst	Master's degree in Statistics/ Economics or Social Sciences with data analysis skills using computer aided analytical tools.	Data Analyst should have 5(five) years' experience and excellent quantitative and qualitative data analysis expertise, presentation, communication and report writing skills.

8. TIMEFRAME

The contract shall remain valid for **120 (One Hundred Twenty) days** from the date of signing of contract. All the deliverables must be submitted by the given timeline. The working plan and timeline will be developed upon discussion with the procurement office.

9. COORDINATION AND LOGISTICS

The experts of the firm may be based in any part of Bangladesh; however, there might be requirements for visiting outside Dhaka City (all over Bangladesh or necessary economic hubs in northern part of Bangladesh). The firm will be responsible for logistics, including office equipment, computer, software and transportation required for the research. Number of associates and a detailed plan of field visits must be mentioned in the financial proposal, which can be finalized during the inception phase of the assignment.

10. **PROCUREMENT METHOD:** The procurement will be a Fixed Budget Selection Method.

11. **PAYMENT MODE:**

Payment mode: 30% of the bill will be disbursed after successful submission and approval of Inception report, 30% of the bill will be disbursed after successful submission and approval of Draft report and 40% bill will be disbursed after successful submission and approval of the final report.

VAT and Tax will be curtailed from the bill according to the govt. policy

12. For any query or other details, please contact:

Md Sirajul Islam Khan
Director (Deputy Secretary)
Investment Research and Economic Observatory
Bangladesh Investment Development Authority
Address: Plot: E-6/B, Agargaon,
Sher-E-Banglanagar, Dhaka-1207.
Phone No: 02-44826776
Cell: +8801711952685
e-mail: khanmilad@yahoo.com
research@bida.gov.bd

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Md. Sirajul Islam Khan
Director (Deputy Secretary)
Bangladesh Investment Development Authority
Chief Adviser's Office