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Master's Thesis

Internationalization of Least Developed Country Firms: A Case Study on the Bangladeshi Pharmaceutical Industry.

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Abstract

This study examines how pharmaceutical companies from Bangladesh expand into international markets. Bangladesh is a Least Developed Country (LDC), so its firms face different challenges compared to companies from more developed economies. The research is based on in-depth interviews with senior export managers from four leading pharmaceutical companies. It analyzes how these firms enter foreign markets, what factors support them, and what challenges they face during international expansion.

The study uses the Gioia methodology, which follows a step-by-step approach to analyze qualitative data. The findings show that most companies rely on export-based strategies and face long and complex regulatory processes when entering new markets. At the same time, international certifications and strong partnerships play a key role in supporting global expansion.

Several important enablers of internationalization are identified, including the TRIPS waiver, which allows LDC firms to produce generic medicines, WHO prequalification, which builds trust in product quality, and opportunities created by donor procurement agencies. However, firms also face major barriers, such as negative perceptions related to "Made in Bangladesh," weak institutional support at home, and strict regulatory requirements in foreign markets.

Overall, the study shows how pharmaceutical firms from LDCs manage these challenges and develop their own paths to international growth, which differ from firms in more advanced economies. The findings are useful for both companies and policymakers, especially those working to support export-oriented industries. The study also discusses how Bangladesh's graduation from LDC status may affect the future of its pharmaceutical sector.

Keywords:

Internationalization; LDC firms; Pharmaceutical industry; Bangladesh; Gioia methodology; Uppsala model; Institutional theory; Business model adaptation; TRIPS waiver; Regulatory barrier

Table of Contents

1.INTRODUCTION

1.1 Background and Context

The pharmaceutical industry is widely considered one of the most globalised and tightly regulated industries in the world economy. Over the past two decades, the global pharmaceutical market has experienced sustained expansion, with total revenues reaching approximately USD 1.7 trillion in 2024 (Statista, 2024). The market is expected to continue growing, increasing from USD 1,737.97 billion in 2025 to approximately USD 2,776.74 billion by 2033, reflecting a strong compound annual growth trajectory (Grand View Research, 2025). This continuous expansion highlights the strategic importance of the pharmaceutical sector in the global economy.

Within this global context, Bangladesh's pharmaceutical industry has emerged as one of the most dynamic manufacturing sectors among Least Developed Countries (LDCs), a category established by the United Nations in 1975 (UNCTAD, 2023). Over the past four decades, the sector has transformed from being highly dependent on imported medicines to becoming largely self-sufficient in meeting domestic demand. Currently, the industry supplies approximately 97 percent of the country's pharmaceutical needs and exports products to more than 150 countries worldwide (Bangladesh Association of Pharmaceutical Industries [BAPI], 2023).

The domestic pharmaceutical market reached an estimated value of USD 3.1 billion in 2024–2025, while exports amounted to approximately USD 205 million in the fiscal year 2023–2024 (EPB, 2024). This development has been supported by several institutional advantages. The Drug (Control) Ordinance of 1982 created a protective policy environment for domestic manufacturing, while the Trade-Related Aspects of Intellectual Property Rights (TRIPS) waiver granted to LDCs allows Bangladeshi firms to produce patented medicines without full intellectual property restrictions until 1 January 2033.

Despite operating in an environment often characterised by institutional gaps, regulatory inefficiencies, and limited access to advanced technological capabilities (Khanna & Palepu, 2010), the Bangladeshi pharmaceutical industry has made notable progress in international markets. Several leading firms have expanded into markets across Asia, Africa, and Latin America, and have also entered highly regulated markets in Europe and North America

(UNCTAD, 2021). This development demonstrates how firms from resource-constrained environments can overcome institutional limitations through capability development and strategic adaptation.

1.2 Research Problem

The majority of important theories and frameworks are based on the experiences of businesses operating in developed or emerging markets, despite the fact that internationalization has been extensively studied in international business research. Important models such as the Uppsala internationalization model and Dunning's eclectic paradigm typically presuppose stable institutional environments, efficient regulatory frameworks, and easy access to state-of-the-art resources and capabilities. However, such theories usually do not reflect the reality of businesses from Least Developed Countries (LDCs), which typically operate in conditions marked by institutional weaknesses, regulatory delays, and limited company capacities (Johanson & Vahlne, 2009; Khanna & Palepu, 2010).
This brings up a crucial question: **how do pharmaceutical firms from one of the world's least developed economies successfully internationalise in a highly regulated global industry?**

Previous study on Bangladesh's pharmaceutical sector has primarily focused on policy problems, particularly the influence of the TRIPS waiver (UNCTAD, 2011; World Health Organization, 2020). However, there is still a lack of firm-level, theory-driven research that explains how individual LDC pharmaceutical firms select internationalisation methods, change their business models, manage institutional challenges, and gain competitive advantages in foreign markets. Addressing this gap is essential for developing internationalisation theory in LDC contexts and deeper understanding the global strategy of Bangladeshi pharmaceutical industries.

1.3 Research Aim and Objectives

Research Aim

The aim of this study is to explain how Bangladeshi pharmaceutical firms internationalise within the institutional constraints of a Least Developed Country (LDC), by integrating relevant theoretical frameworks with empirical evidence from primary interviews and secondary data.

Research Objectives

- To analyse the internationalisation modes adopted by Bangladeshi pharmaceutical firms.
- To identify the key enablers and barriers influencing their international expansion.
- To examine how firms adapt their business models for foreign markets.
- To assess how existing internationalisation theories explain the behaviour of LDC pharmaceutical firms.
- To evaluate the implications of Bangladesh's LDC graduation for the future competitiveness of the pharmaceutical industry.

1.4 Research Questions

The study is guided by one main research question and two sub-questions.

Main Research Question

- How do pharmaceutical firms from Least Developed Countries internationalise?

This question aims to understand the overall process, patterns, and logic of internationalisation for firms operating in an LDC context, using Bangladesh as a case.

Sub-Questions

1. What internationalisation modes are adopted by Bangladeshi pharmaceutical firms?
2. What enablers and barriers influence their internationalisation?

These questions provide a framework for the empirical investigation and help connect findings to existing internationalisation theories

1.5 Research Gap

Mostly the internationalization of firms from developing countries has gained more academic attention (Cuervo-Cazurra, 2012; Luo & Wang, 2012), companies from Least Developed Countries (LDCs) are still rarely studied. Most international business research focuses on firms from developed economies or large emerging economies such as China, India, and Brazil (Ramamurti, 2012). However, firms from LDCs are different because they face special limitations and challenges, so they require separate analysis. Current literature shows several important gaps. First, there is limited research on how firms from LDCs internationalize compared with firms from emerging economies (Luo & Zhang, 2016). Second, there is not

enough focus on highly regulated industries like pharmaceuticals, where legal and regulatory rules strongly influence international expansion (Orzes et al., 2017). Third, few qualitative and process-based studies explain how LDC firms manage internationalization over time (Welch & Paavilainen-Mäntymäki, 2014). In addition, there is limited understanding of how LDC-specific institutional factors, such as TRIPS waivers and special trade rules, influence firm strategies. Research on Bangladeshi pharmaceutical companies has mainly focused on domestic market issues (Wadud et al., 2020) or policy discussions (Chaudhuri, 2015; Labonté et al., 2021), while firm-level internationalization strategies remain underexplored. This study addresses these gaps by examining the internationalization strategies, enablers, and barriers of Bangladeshi pharmaceutical firms using the Gioia methodology.

2. Literature Review

2.1 LDC Firm Internationalization

2.1.1 The Uppsala Internationalization Model

The Uppsala model, (Johanson and Vahlne 1977) and later revised in 2009, is one of the most widely used theories to explain how firms expand internationally. The model suggests that internationalization is a gradual and step-by-step process, where firms increase their commitment to foreign markets as they gain experience and knowledge. The original model outlines four stages: firms begin with no regular export activities, then export through independent agents, later establish sales subsidiaries, and eventually set up production or manufacturing facilities abroad.

A key concept in the Uppsala model is psychic distance, which refers to differences in language, culture, political systems, education, and economic development that make it difficult for firms to operate in foreign markets (Johanson & Vahlne, 1977). As a result, firms tend to enter psychically close markets first and gradually expand to more distant markets as their knowledge increases. However, in highly regulated industries such as pharmaceuticals, market entry is influenced not only by cultural differences but also by regulatory requirements, suggesting that regulatory distance may play a more critical role than psychic distance.

The revised Uppsala model (Johanson & Vahlne, 2009) introduced the concept of liability of outsidership, which highlights the importance of networks and relationships in internationalization. Firms that are not part of relevant business networks face difficulties in

accessing opportunities and resources in foreign markets. This is particularly relevant in the pharmaceutical industry, where firms depend on distributors, regulatory partners, and international certifications to enter and operate in foreign markets. Therefore, partnerships and strategic alliances become essential mechanisms for overcoming market entry barriers and accelerating international expansion.

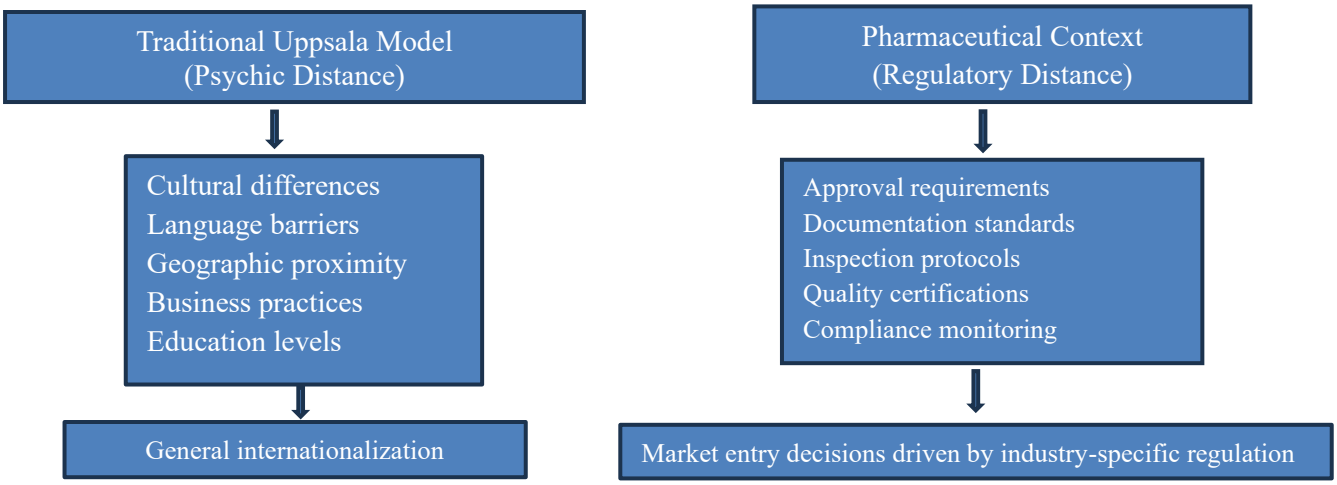
2.1.2 Regulatory Distance in Pharmaceutical Internationalization

While psychic distance focuses on cultural and institutional differences, internationalization in the pharmaceutical industry is strongly influenced by regulatory distance. Regulatory distance means the differences in pharmaceutical rules, approval systems, quality standards, and compliance requirements between countries (Orzes et al., 2017; Castellacci, 2018).

These differences create several challenges for firms. First, documentation requirements vary across countries. Each market may require different types of product dossiers, clinical data, stability studies, and manufacturing information. Second, inspection and certification rules are not the same everywhere. Some countries accept certifications from the home country, while others require their own inspections and approvals. Third, ongoing compliance requirements differ. For example, countries may have different rules for safety monitoring, adverse event reporting, and periodic re-certification. Finally, approval timelines vary widely. In some markets approval may take only a few months, while in others it can take several years. This affects how fast firms can enter new markets and how many resources they must invest.

For pharmaceutical firms from Least Developed Countries (LDCs), regulatory distance becomes even more difficult because of weaknesses in home country institutions. National regulatory authorities in many LDCs are not widely recognized internationally, so approvals from these authorities may not be accepted in other countries. As a result, firms often need to obtain international certifications, such as WHO prequalification, which act as global signals of product quality and reliability (Ahmed & Hossain, 2019).

Figure 1: Regulatory Distance vs. Psychic Distance in Pharmaceutical Internationalization



Traditional internationalization theory, particularly the Uppsala Model, explains market selection through psychic distance, including cultural, linguistic, geographic, and business differences between countries. However In the pharmaceutical industry, regulatory distance—such as differences in approval requirements, documentation standards, inspection protocols, and quality certifications—plays a more decisive role. This industry-specific distance concept better explains the market selection patterns observed in our study.

LDC Firm Specificities

Least Developed Countries (LDCs), defined by the United Nations, have several common characteristics. These include low income levels, weak human development, and high economic vulnerability (UNCTAD, 2021). Low income means that the gross national income per person is below USD 1135 (World Bank, 2024). Weak human development refers to problems in areas such as nutrition, health, education, and literacy. High economic vulnerability means that these countries are more exposed to economic shocks and instability. As of 2024, there are 46 countries classified as LDCs, and Bangladesh is one of the largest among them.

Firms from LDCs face several special challenges when they try to enter international markets. First, many LDCs have institutional weaknesses. This means that regulatory systems may be weak, infrastructure such as transport and logistics may be unreliable, access to finance may be limited, and business support services are often insufficient (Mair et al.,

2012). These conditions make it more difficult for firms to operate efficiently and compete globally.

Second, firms from LDCs often face a liability of origin. This means that the label "Made in an LDC" can create negative perceptions about quality among international buyers. As a result, buyers may be more skeptical about products coming from these countries (Ramachandran & Pant, 2010).

Third, LDC firms usually face resource and capability constraints. Compared with firms from developed or emerging economies, they often have less financial capital, fewer skilled workers, weaker technological capabilities, and limited managerial experience (Gaur et al., 2018). These limitations can slow down international expansion.

Fourth, many LDC firms depend on special trade arrangements, such as tariff exemptions, preferential market access, and international development programs. These benefits help them compete internationally but are often not available to firms from other countries.

Finally, firms from LDCs may experience knowledge gaps. Many companies have limited information about international markets, regulatory requirements, and effective strategies for entering foreign markets.

Because of these challenges, the internationalization process of LDC firms may follow different patterns from those of firms in developed or emerging economies. Ramachandran and Pant (2010) describe this situation as a "double disadvantage," where firms must deal with both limited resources and weak institutional environments. To expand internationally, these firms often need to develop creative and adaptive strategies to overcome these constraints.

2.2 Institutional Factors Affecting Pharmaceutical Internationalization

Institutional Theory and Internationalization

Institutional theory (DiMaggio & Powell, 1983; Scott, 1995) explains how organizations are affected by the rules and systems around them. When firms expand to international markets, they must deal with differences between their home country and the host country. These differences can be understood through three main pillars: regulative, normative, and cognitive (Kostova, 1999). The regulative pillar refers to laws, regulations, and government policies.

The normative pillar includes social values, norms, and expected roles in society. The cognitive pillar refers to common beliefs and shared understandings that people take for granted in a society.

The concept of institutional distance describes how different the institutions of two countries are. When institutional distance is high, firms may face more difficulty when entering foreign markets. Different rules, systems, and expectations can increase the cost of doing business and make it harder for firms to gain trust and legitimacy in the new market (Kostova & Zaheer, 1999). However, firms can gradually learn how to deal with these differences and develop the skills needed to operate in complex institutional environments (Cuervo-Cazurra & Genc, 2008).

For firms from Least Developed Countries (LDCs), these challenges can be even greater. Many LDCs have institutional weaknesses, which create what researchers call institutional voids. This means that important systems, such as strong regulations, reliable intermediaries, and effective contract enforcement, may be missing or weak (Khanna & Palepu, 2010). Because of this, firms often rely more on personal relationships, networks, and informal arrangements to conduct business and manage international activities.

TRIPS Agreement and LDC Pharmaceutical Development

The TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement was created in 1994 under the World Trade Organization (WTO). It set global rules for protecting intellectual property rights. However, the agreement also recognized that Least Developed Countries (LDCs) face special economic and technological challenges. Because of this, LDCs were given extra time and special flexibility. In the pharmaceutical sector, LDCs did not have to follow medicine patent rules until 2016, and this deadline was later extended to 2033 (Labonté et al., 2021).This TRIPS waiver has been very important for the growth of the pharmaceutical industry in Bangladesh and other LDCs. The waiver allows companies to produce generic versions of patented medicines without permission from the patent owner. Firms can also study and reproduce medicines that are patented in other countries. This gives companies cost advantages, because they do not need to pay licensing fees or royalties. It also allows local firms to develop manufacturing skills, improve production, and enter international markets before strict patent rules apply.

Research shows that Bangladesh has used this opportunity effectively. The TRIPS waiver, together with the Drug Control Ordinance of 1982, helped create a supportive environment

for the growth of the local pharmaceutical industry (Chaudhuri, 2015; Rahman & Farin, 2020). However, Bangladesh is expected to graduate from LDC status by 2026, and the TRIPS flexibility will end by 2033. Because of this, pharmaceutical companies must strengthen their international presence and competitiveness before these benefits end (Labonté et al., 2021; Hoque & Chowdhury, 2020).

Regulatory Systems and Quality Certifications

Pharmaceutical regulatory systems are different in every country. Some countries have very strict rules and strong regulatory agencies, while others have weaker systems. The World Health Organization (WHO) classifies national regulatory authorities into different maturity levels. Authorities with Maturity Level 4, such as the US FDA, European Medicines Agency (EMA), MHRA in the UK, and Health Canada, are considered the highest standard (WHO, 2021). Many regulatory authorities in LDCs operate at lower maturity levels, which makes it harder for firms from these countries to gain international trust.

To solve this problem, pharmaceutical companies from LDCs try to obtain international certifications that show their products meet global quality standards. One important certification is WHO Good Manufacturing Practice (WHO-GMP), which sets basic international standards for pharmaceutical production. Another important program is WHO Prequalification, which checks whether medicines meet global standards for quality, safety, and effectiveness. This certification is especially important for supplying medicines to international organizations and donor agencies.

Some companies also try to obtain US FDA approval, which is one of the most respected regulatory approvals in the world. It allows companies to enter the US market and improves their global reputation. Firms may also obtain EU GMP certification and marketing authorization, which allow access to European markets. Another international cooperation system is PIC/S, which supports cooperation and recognition between regulatory authorities.

Getting these certifications requires large investments in factory facilities, quality systems, documentation, and staff training. For companies in LDCs, which often have limited financial resources, choosing which certification to pursue becomes an important strategic decision that influences their international expansion (Ahmed & Hossain, 2019; Mahmud et al., 2022).

Country-of-Origin Effects

Country-of-origin (COO) effects refer to how buyers judge products based on the country where they are produced (Verlegh & Steenkamp, 1999). In the pharmaceutical industry, this effect is very strong because medicines are directly related to human health and safety. Products from countries with strong pharmaceutical reputations, such as Switzerland, Germany, and the United States, usually receive positive perceptions. In contrast, products from Least Developed Countries may face more doubt from buyers (Gaur et al., 2018).

Research shows that the label “Made in Bangladesh” can create challenges for pharmaceutical firms entering international markets. Buyers may question the quality, safety, and reliability of medicines from LDC manufacturers (Mahmud et al., 2022). Because of this, companies need strategies to overcome these negative perceptions.

One strategy is to get international quality certifications, which help show that the product is reliable and of good quality. Another strategy is to work with trusted local distributors, who can help build trust in the market. Companies may also offer lower prices to compete with established firms. Some firms choose to enter markets where concerns about the country of origin are lower. Others build their reputation slowly by consistently providing good-quality products over time.

Role of Donor Procurement Agencies

International health and development organizations play an important role in the pharmaceutical market. Organizations such as UNICEF, UNFPA, UNDP, the Global Fund, USAID, and Gavi (Vaccine Alliance) purchase large quantities of medicines every year for use in developing countries (Sharma et al., 2019). These organizations create opportunities for firms from Least Developed Countries (LDCs) to participate in international markets.Many donor agencies require WHO prequalification for companies that want to participate in procurement tenders. These organizations mainly focus on product quality and safety, rather than the country where the medicine is produced. This helps reduce the negative impact of country-of-origin perceptions for firms from LDCs. In addition, donor agencies often prioritize affordable medicines, which benefits companies from LDCs that usually have lower production costs.

Large procurement contracts from donor agencies can provide high production volumes, although profit margins are generally lower than in commercial markets. At the same time,

supplying medicines through donor programs can help firms build international credibility and reputation, which may support entry into commercial markets later.

For pharmaceutical firms in Bangladesh, donor procurement has become an important pathway for international expansion. It allows companies to enter global supply chains and access international markets while avoiding some traditional entry barriers (Mahmud et al., 2022). However, heavy dependence on donor markets may also create challenges, such as limited pricing power and strong competition, since these markets are highly cost-focused.

2.3 Business Model Adaptation

Business Model Concept

Theory of Business model explains how the business works in a simple way, how a company creates value, delivers it to customers, and earns profit (Osterwalder & Pigneur, 2010; Teece, 2010). Business model has several important parts. These include the value proposition (what the company offers to customers), customer segments (who the customers are), and the revenue model (how the company makes money). It also includes the value chain (how products are made and delivered), the cost structure (where money is spent), and the profit formula (how profit is generated). Another key part is partnerships, which means working with other companies such as suppliers or distributors.

Firms often needs to change its business model while entering International Market. This is because foreign markets are different from the home market. As customer needs, competition, laws, and business systems can be different (Hennart, 2014; Rask, 2014). So, firms must decide which parts of the business model can stay the same and which parts need to be changed to fit the new market.

Partnership Models in International Expansion

For firms with limited resources, partnerships are very important for entering international markets. Partnerships help firms enter new markets with less investment, use local knowledge, and reduce risk (Lu & Beamish, 2006). In the pharmaceutical industry, several types of partnerships are used.

One common model we found is the distributor model, where a local partner buys the product and handles sales, marketing, and regulatory work. This model has low risk and low investment, but also less control. Another model is licensing, where a partner gets the right to

produce or sell the product in a specific country. This can give higher returns but is more complex.

In contract manufacturing, a company produces products for another brand. This increases production volume but gives low profit and low brand visibility. A joint venture means two firms create a new company together. This gives more control but needs more investment. A strategic alliance is a cooperation between firms for a specific purpose without sharing ownership.

Choosing the right partnership depends on control, cost, risk, speed of entry, and expected profit. Firms from Least Developed Countries (LDCs) often choose distributor-based models because they need less money and provide access to local market knowledge (Lu & Beamish, 2006).

Pricing and Revenue Models

Pharmaceutical firms use different ways to set prices and earn revenue in international markets. One common method is transfer pricing, where the manufacturer sells the product to a distributor at a fixed price, and the distributor adds a margin. This is simple but gives less control over final prices.

Another method is profit-sharing, where both parties share profit based on a fixed ratio, such as 60:40. This creates better cooperation but needs more transparency. In the percentage model, the manufacturer receives a part of the final selling price. This links earnings directly to market performance but can be difficult to manage.

In licensing, the partner pays a royalty based on sales. This is common when technology or knowledge is shared. Another method is volume-based pricing, where the price per unit changes depending on how much is ordered. This encourages larger orders.

The choice of pricing model depends on market conditions, partner power, and experience (Hinterhuber, 2017). Firms from LDCs often have weaker bargaining power, so they may accept lower prices to enter international markets.

Value Chain Configuration

The pharmaceutical value chain including R&D, API procurement, manufacturing, quality control, regulatory work, distribution, marketing, and safety monitoring. When businesses expand worldwide, they must decide how to structure their activities across borders.

One option is centralized production, in which things are manufactured in the home country and exported. This helps maintain quality and keep costs down, but it can lead to logistical and transportation issues. Another alternative is distributed production, in which companies produce in or near their target markets. Although this lowers transportation costs, it necessitates greater investment.

Firms must also select how they will manage API sourcing. It can be imported from foreign nations or produced domestically. This decision has consequences for both cost and supply security. They must also choose whether to control distribution themselves or rely on partners, as well as whether to handle regulatory duties locally or centrally.

Centralized production in Bangladesh is popular among pharmaceutical companies in Bangladesh because it uses existing infrastructure and lowers expenses. However, this leads to reliance on imported APIs, primarily from China and India, and necessitates robust export logistics (Hoque & Chowdhury, 2020). Furthermore, Bangladesh's weak air cargo facilities create obstacles, particularly for pharmaceuticals that require cool storage during transportation.

2.4 Theoretical Framework

Integrating Theoretical Perspectives

Instead of relying on a single theory, this study draws on multiple theoretical perspectives to develop a comprehensive understanding of how pharmaceutical firms from Least Developed Countries (LDCs) internationalize. the study takes an integrated approach, as different theories explain different aspects of the internationalization process.

The Uppsala model provides a basic explanation of internationalization as a gradual, learning-based process. However, for LDC pharmaceutical firms, this process is often slower and may not follow the exact stages suggested by the model. This is mainly due to strict regulatory requirements and institutional constraints. In this context, the concept of regulatory distance becomes important, as it explains industry-specific barriers that go beyond traditional psychic distance.

Institutional theory helps explain how LDC firms deal with weak institutional environments in their home countries, as well as differences in rules and expectations in foreign markets. It shows why international certifications become important for gaining trust and legitimacy, and

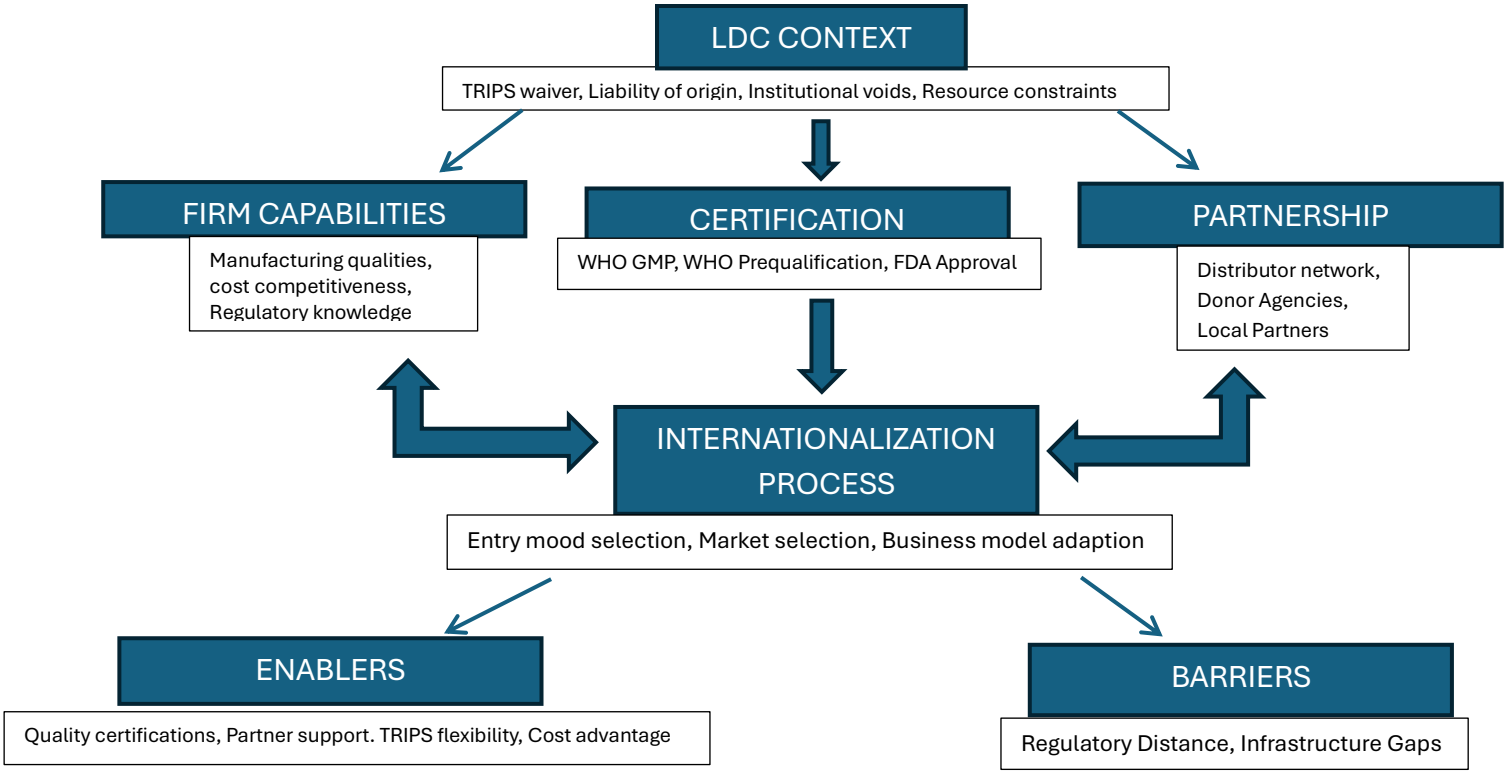
how donor procurement agencies can provide alternative pathways for entering global markets.

Business model adaptation theory focuses on how firms adjust their value creation and value capture strategies when entering international markets. It highlights the importance of partnership models, pricing strategies, and value chain configuration. These decisions are shaped by the firm's resource limitations and the characteristics of the target market.

A Priori Theoretical Framework

Drawing on the literature review, we propose an a priori framework that identifies key theoretical constructs expected to influence LDC pharmaceutical firm internationalization. This framework serves as the starting point for our empirical investigation, to be refined through systematic data analysis using the Gioia methodology.

Figure 2: A Framework for LDC Pharmaceutical Internationalization



This a priori framework proposes that LDC pharmaceutical firm internationalization is shaped by: (1) the distinctive LDC institutional context including both constraints (institutional voids, liability of origin) and opportunities (TRIPS waiver); (2) firm-level capabilities in manufacturing, cost management, and regulatory navigation; (3) strategic

pursuit of international certifications that serve as legitimacy mechanisms; (4) partnership relationships that provide market access and local knowledge; and (5) the interplay of enablers and barriers affecting internationalization success.

Through empirical investigation using the Gioia methodology, we will systematically analyse interview data to refine, extend, or revise this framework, allowing for emergent themes and relationships not anticipated in existing literature.

3. Industry Context

3.1 Historical Development of the Bangladesh Pharmaceutical Sector

Bangladesh's pharmaceutical industry has undergone a remarkable transformation, evolving from a state of import dependence to a robust, domestically driven manufacturing powerhouse. In the wake of its 1971 independence, Bangladesh's pharmaceutical market was predominantly controlled by multinational corporations, leaving local manufacturers to fulfill only a small fraction of the country's medicinal needs (Chowdhury & Alam, 2017). Domestic production capacity was underdeveloped, heavily relying on imported medicines.

The introduction of the Drug (Control) Ordinance of 1982 marked a major turning point, significantly restructuring the pharmaceutical market. The ordinance banned the production of many non-essential drugs and imposed restrictions on the operations of multinational pharmaceutical companies. These measures created opportunities for domestic firms to expand their production and gradually build manufacturing and technological capabilities (Islam et al., 2023).

Throughout the following decades, local pharmaceutical companies strengthened their production capacity, improved quality standards, and expanded their presence in the domestic market. As a result, the industry evolved into a largely self-sufficient sector capable of meeting the majority of the country’s medicinal needs. Today, Bangladesh’s pharmaceutical industry includes around 300 licensed manufacturers, although the market is dominated by a relatively small number of large firms that account for most domestic sales (DGDA, 2024).

Ultimately, the evolution of Bangladesh's pharmaceutical sector is a testament to strategic policy intervention and capability development, illustrating how a nation can cultivate a thriving domestic industry from humble beginnings and paving the way for future innovations.

Table 1: Bangladesh Pharmaceutical Market Evolution (2015-2025)

Year	Market Size (USD)	Growth	Local Share	Companies	Employees
2015	2.0B	15%	97%	230	110000
2017	2.4B	12%	97%	245	125000
2019	3.0B	11%	98%	257	140000
2021	2.8B	-7%	98%	260	145000
2023	3.0B	8%	98%	265	150000
2025*	**3.1B+**	**12%**	**98%**	**270+**	**160000+**

Source: BIDA (2024), BAPI (2023), IDLC (2024). ***Projected.**

Market Structure and Concentration

The Bangladesh pharmaceutical market exhibits significant concentration, with the top 5 companies controlling approximately 52% of market share and the top 10 controlling about 72% (FBCCI, 2023). The market includes over 260 licensed manufacturers, though many smaller firms focus on limited product ranges and domestic distribution.

Table 2: Top 10 Pharmaceutical Companies in Bangladesh by Market Share (2024)

Rank	Company	Market Share	Founded	Export Status
1	Company A*	18.5%	1958	Major exporter
2	Company C*	12.3%	1999	Major exporter
3	Company B*	9.8%	1976	Major exporter
4	Healthcare Pharma	6.2%	1986	Exporter
5	Renata Ltd	5.5%	1972	Exporter
6	Eskayef Pharma	4.8%	1958	Limited export
7	Company D*	4.2%	1956	Exporter
8	Aristopharma	3.9%	1986	Limited export
9	Popular Pharma	3.5%	1983	Limited export
10	ACME Labs	3.2%	1954	Exporter

*Case study companies anonymised. Source: IDLC (2024), company reports.

3.2 Export Performance Analysis

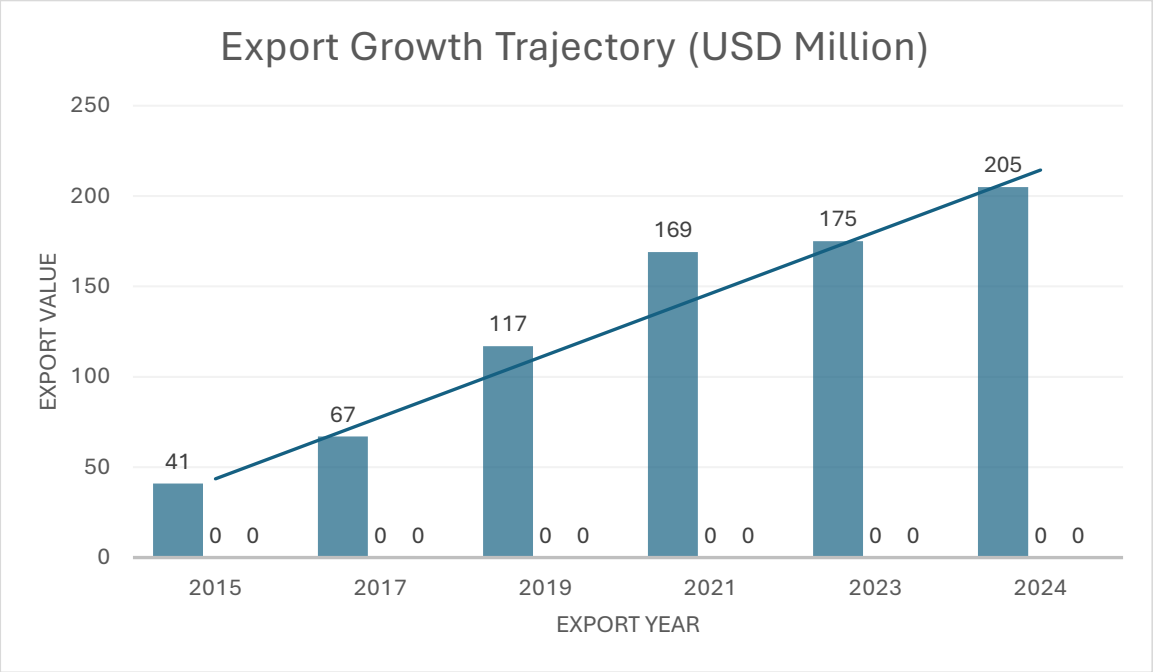
Bangladesh's pharmaceutical exports have grown substantially over the past decade, from approximately USD 41 million in 2015 to USD 205 million in fiscal year 2023-24, representing a compound annual growth rate (CAGR) of approximately 18%. While this growth is impressive, pharmaceutical exports remain modest relative to the domestic market (approximately 6-7% of production) and global pharmaceutical trade. Industry targets aspire to USD 450 million in exports by 2025 and 1% of the global generic market (approximately USD 4-5 billion) in the longer term.

Table 3: Bangladesh Pharmaceutical Export Growth (2015-2025)

Year	**Export Value (USD)**	**Growth**	**Countries**	**Top Region**
2015	41	10	~100	Asia
2016	50	22	~110	Asia
2017	67	34	~120	Asia
2018	89	33	~130	Asia
2019	117	31	~140	Asia
2020	136	16	~145	Asia
2021	169	24	~150	Asia
2022	189	12	~157	Asia
2023	175	-7	~160	Asia
2024	205	17	160+	Asia
2025*	220M+	7+	165+	Asia

Source: EPB (2024), BAPI (2023), OEC (2024). *Projected.

Figure 3: Export Growth Trajectory (USD Million)



3.3 Geographic Distribution of Exports

Market Concentration Patterns

Bangladeshi pharmaceutical exports show high geographic concentration. Myanmar alone accounts for approximately 30-35% of total pharmaceutical exports, followed by the USA (8-10%), Sri Lanka (6-8%), and Kenya (5-7%) (Export Promotion Bureau, 2024). The top 10 destination countries account for approximately 70% of export value, indicating limited geographic diversification.

Table 4: Top Export Destinations for Bangladesh Pharmaceuticals (2023-24)

Rank	Country	Estimated Export Value	Share of Total	Primary Entry Barriers
1	Myanmar	USD 65M	~32%	Political instability, payment risks
2	United States	USD 18M	~9%	FDA approval requirements
3	Sri Lanka	USD 14M	~7%	Economic crisis, forex shortage
4	Kenya	USD 12M	~6%	Regulatory compliance, competition
5	Philippines	USD 10M	~5%	Regulatory requirements
6	Nepal	USD 9M	~4%	Small market size

7	Afghanistan	USD 8M	~4%	Political instability, payment
8	Vietnam	USD 7M	~3%	Regulatory barriers, competition

Export Promotion Bureau (EPB, 2024); ITC Trade Map; Author's compilation.

Market Categorization

Export markets for Bangladeshi pharmaceutical firms can be grouped into different categories based on regulatory strictness and entry difficulty, which has a great impact on strategic decisions and market success.

There are less regulated markets, such as many countries in Sub-Saharan Africa, Myanmar, Nepal, Afghanistan, and some Central Asian regions, where regulatory frameworks are less stringent, allowing for quicker market entry. These markets are easier and faster to enter due to less stringent rules. However, they often present strong competition and lower prices, with occasional concerns about product quality, as evidenced by market reports and industry analyses. Many Bangladeshi firms start their international expansion in these markets.

Semi-regulated markets, including the Philippines, Sri Lanka, Vietnam, and some Latin American countries, have moderate requirements. These markets have moderate requirements. Firms need WHO-GMP certification and product registration, but the process is less onerous than in highly regulated markets. These markets offer a balance between ease of entry and market quality.

Highly regulated markets, such as the United States, European Union countries, Canada, Australia, and Japan, have very strict rules. These markets have very strict rules. Companies must pass facility inspections, submit detailed product documents, and meet high quality standards. The approval process can take 2-5 years and requires significant investment. However, these markets offer higher prices, stronger legal protection, and a better global reputation. Only a few Bangladeshi firms have successfully entered these markets, mainly through FDA approval in the United States.

Another important category is donor procurement markets, which include purchases made by organizations such as UNICEF, UNFPA, the Global Fund, and USAID, playing a crucial role in providing large order volumes and enhancing market credibility for Bangladeshi pharmaceutical firms. To enter these markets, firms usually need WHO prequalification, which requires strict quality checks. These markets offer large order volumes and reduced

country-of-origin concerns, but competition is high and profit margins are low. Most Bangladeshi pharmaceutical firms have entered these markets successfully.

Regional Analysis

Bangladeshi pharmaceutical exports are mainly concentrated in South Asia (35-40%), Sub-Saharan Africa (25-30%), and Southeast Asia (15-20%), with smaller shares going to North America, Latin America, the Middle East, and Europe (Mahmud et al., 2022).

Bangladeshi pharmaceutical exports are mainly concentrated in these regions for several reasons. Nearby countries in South and Southeast Asia are easier and cheaper to access. Many countries in Africa and Asia have similar economic conditions, so their expectations for price and quality are easier to meet. These markets also tend to have less strict regulations, which makes market entry easier compared to developed countries. In addition, donor-funded health programs in Africa and Asia create more opportunities for exporting medicines.

3.4 API Dependency and Supply Chain

Active Pharmaceutical Ingredient Sourcing

Bangladesh's pharmaceutical industry relies heavily on imported active pharmaceutical ingredients (APIs), which are the main raw materials used to produce medicines. Around 85 percent of these APIs are imported, mainly from China and India, and this creates a strong dependence on foreign suppliers (Ahmed et al., 2021; Hoque & Chowdhury, 2020). Because APIs make up a large part of production costs, any change in global prices can directly affect the cost of medicines. At the same time, if there is any disruption in supply from these countries, production in Bangladesh can be seriously affected. This became very clear during the COVID-19 pandemic, when supply chains were interrupted.

Maintaining consistent quality is also a challenge, as firms often source APIs from different international suppliers. In addition, importing APIs requires foreign currency, which exposes firms to exchange rate risks. Since companies depend on external suppliers, they also have limited power when negotiating prices.

Domestic API Manufacturing Initiatives

To reduce this dependence, the government has taken several steps to support local API production. It has introduced incentives such as tax benefits, financial support, and

infrastructure development. Some companies have started producing basic APIs locally, but progress has been slower than expected (Hoque & Chowdhury, 2020).

There are several reasons for this. API production requires large investments in equipment and facilities, as well as advanced technical knowledge and skilled workers. The domestic market is not always large enough to support cost-efficient production for many types of APIs. There are also environmental concerns, as API manufacturing produces chemical waste that needs proper treatment. In addition, producers in countries like China and India have strong advantages because they operate on a large scale and can produce at lower cost.

This dependence on imported APIs has important effects on international expansion. Firms need to consider both cost and supply reliability when setting export prices. Any disruption in supply can affect their ability to meet international demand on time. For some firms, expanding into global markets is also seen as a way to grow and eventually invest in their own API production.

Regulatory Environment

The pharmaceutical sector in Bangladesh is regulated by the Directorate General of Drug Administration (DGDA) under the Ministry of Health and Family Welfare. This authority is responsible for licensing, product registration, quality control, inspections, and monitoring the market, based on national drug laws and policies (DGDA, 2024).

Although the regulatory system has improved over time, it still faces some challenges. These include limited resources, low international recognition, and a shortage of specialized expertise. Because of this, approval from the national authority alone is often not enough for exporting medicines. Companies usually need international certifications or approvals from specific countries, which increases both the cost and the time needed for international expansion (Ahmed & Hossain, 2019).

Table 5: International Quality Certifications of Leading Firms

Certification	A	B	C	D
WHO GMP	Yes	Yes	Yes	Yes
WHO Prequalification	Products	Products	Products	In progress
US FDA	Yes	Yes	Yes	No
UK MHRA	Yes	Yes	Yes	No
EU (EMA)	Yes	Yes	Yes	No
TGA (Australia)	Yes	Yes	Yes	No
Health Canada	Yes	Yes	Yes	No

Company websites and annual reports of Firms A–D (2023–24)

Infrastructure Challenges

Infrastructure limitations create important barriers to pharmaceutical internationalization from Bangladesh. Limited air cargo capacity at airports makes it difficult to export products, especially those that require fast delivery. In addition, there is a lack of proper cold chain facilities, such as storage and transport at 2–8°C, which makes it hard to export temperature-sensitive medicines. Interview respondents also mentioned that airports do not have adequate cold storage for pharmaceutical products.

There are also delays at seaports for both importing raw materials and exporting finished products. These delays increase costs and create uncertainty in the supply chain. Another challenge is the limited availability of advanced pharmaceutical testing laboratories, especially for specialized tests like stability studies, bioequivalence testing, and method validation. At the same time, digital infrastructure is not well developed compared to international standards, which makes regulatory submission and tracking more difficult and time-consuming.

These infrastructure gaps can be seen as institutional voids. To deal with these challenges, firms often need to find alternative solutions, make additional investments, or focus on products that are less affected by these limitations (Khanna & Palepu, 2010; Mair et al., 2012)

4. Methodology

4.1 Philosophy of Science

Interpretivist Paradigm

This research adheres to the interpretivist paradigm, which means that reality is not fixed but is shaped by people's thoughts, experiences, and interactions (Schwandt, 1994). In simple terms, what we understand as "reality" depends on how people perceive and explain their situation. This is different from positivist research, which aims to find general rules using numbers and measurable data. Interpretivism focuses on understanding people's views, meanings, and experiences to explain complex situations (Gephart, 2004).

This approach is suitable for this study because internationalization is not just a technical process; it depends on human decisions, judgments, and relationships. Managers decide where to enter and how to operate based on their understanding of markets. Furthermore, the internationalization of firms from Least Developed Countries (LDCs) is not well studied, so existing theories may not fully explain it. That is why it is essential to learn from real experiences. In addition, context matters a significant role, as each country has different rules, cultures, and business environments. This study primarily aims to understand "how" and "why" things happen, instead of focusing on numbers.

Ontological and Epistemological Foundations

From an ontological point of view, this study employs a constructionist approach. This means that ideas such as internationalization, barriers, and business models are not fixed or objective facts. Instead, they are created through people's actions, decisions, and discussions within organizations (Berger & Luckmann, 1966). Different individuals within the same company may understand these ideas in different ways, depending on their role and experience.

From an epistemological viewpoint, the study takes an interpretivist position. This means that knowledge is gained by understanding how people explain and interpret their experiences (Burrell & Morgan, 1979). The researcher is not merely observing from a distance but is actively trying to understand and interpret what participants say.

This approach differs from positivist research, which tests fixed ideas using large amounts of data. Instead, this study utilizes a qualitative and inductive approach, where understanding is built step by step from detailed real-world data.

Abductive Research Logic

This study uses abductive logic, which involves moving back and forth between theory and data. In this approach, theory helps explain the data, and at the same time, new findings from the data help refine and improve the theory (Alvesson & Kärreman, 2007; Dubois & Gadde, 2002). Abduction is different from both deductive and inductive approaches. Deduction starts with theory and tests it by using data. Induction starts with data and builds theory from observed patterns. In contrast, abduction connects both, allowing continuous interaction between theory and data.

In this study, abductive logic is applied through several steps. First, an initial theoretical framework is developed based on the literature review. Second, detailed qualitative data is collected through interviews. Third, the data is analyzed using the Gioia methodology, where first-order concepts, second-order themes, and aggregate dimensions are identified. After that, the findings are compared with existing theories, and the theoretical understanding is refined based on the results. Finally, a new framework is developed that combines existing theory with new empirical insights.

This approach is especially suitable for studying the internationalization of pharmaceutical firms from Least Developed Countries (LDCs). While existing theories provide a useful starting point, they may not fully explain this context. Therefore, they need to be adjusted or extended based on real-world evidence.

4.2 Research Design

Qualitative Multiple Case Study Design

This study uses a qualitative multiple case study design (Yin, 2018; Eisenhardt, 1989). This method is suitable when the research focuses on “how” and “why” questions. It is also appropriate when the phenomenon cannot be separated from its real-life context, when the researcher has little control over events, and when the topic is contemporary (Yin, 2018). All of these conditions apply to the internationalization of pharmaceutical firms from Least Developed Countries (LDCs).

Using a multiple case design has several advantages compared to a single case study. It strengthens the findings because patterns can be observed across different cases rather than relying on only one case. It also allows for comparison between cases, where similar results can confirm patterns and different results can help explain important variations. This

approach supports theory building by identifying common trends and relationships across cases (Eisenhardt, 1989). In addition, findings from multiple cases are usually more reliable and convincing than those from a single case.

In this study, four companies were selected. This number is considered sufficient to identify patterns while still allowing for detailed and in-depth analysis (Eisenhardt, 1989 suggests using 4–10 cases). The cases are not meant to represent the entire industry statistically. Instead, they are chosen to provide meaningful insights and a deeper understanding of how pharmaceutical firms from LDCs expand into international markets.

Unit of Analysis

The unit of analysis is the internationalization process of individual pharmaceutical firms. While data is collected through interviews with individuals, the analysis focuses on firm-level internationalization strategies, experiences, enablers, and barriers. The study examines how firms as organizational entities engage with international markets, make strategic choices, develop capabilities, and navigate institutional environments.

4.3 Case Company Selection and Profile

Sampling Strategy and Selection Criteria

The case companies in this study were selected using purposive sampling based on clear and practical criteria (Patton, 2015). The main idea was to choose companies that could provide real and useful insights into internationalization. First, the companies needed to be active exporters with at least 10 years of experience, so they had enough knowledge to share. They also needed to operate in many international markets (around 15–20 countries), which helps show different types of experiences.

It was also important to include companies using different ways to enter foreign markets, such as working with distributors, having their own subsidiaries, or supplying through donor procurement. This makes it easier to compare different strategies. In addition, companies with different levels of international certification, such as WHO prequalification or FDA approval, were selected to understand how certification affects international growth. Most of the selected firms are among the leading pharmaceutical exporters in Bangladesh, which means they have strong experience and capabilities. At the same time, only companies that were willing to participate and could give access to senior managers were included.

These criteria helped ensure that the selected companies could provide detailed and meaningful information. They also share some common features, as all of them are pharmaceutical exporters from an LDC, but they are different in terms of size, experience, certifications, and markets. This balance helps to get deeper insights.

To find suitable participants, I tried to contact around 14 companies through LinkedIn and email. However, getting responses was not easy, and in the end, only four companies agreed to take part in the study. These four companies were then selected for detailed analysis.

Case Company Profiles

To maintain confidentiality as agreed with participants, companies are identified as Company A, B, C, and D. Brief profiles are provided:

Company A:

Established in 1958, Company A is Bangladesh's largest pharmaceutical manufacturer with annual revenue exceeding USD 500 million. The company-initiated exports in 1987 and currently exports to 42+ countries across Asia, Africa, Latin America, and North America. Company A holds US FDA approval for seven products, WHO prequalification for multiple products, and operates overseas offices in Kenya, USA, and Philippines. The company has approximately 25 staff dedicated to international business.

Company B:

Founded in 1976, Company B is among Bangladesh's top five pharmaceutical companies. International operations began around 1993, with current exports to markets across Latin America, Southeast Asia, and Africa through regional teams. The company has been working toward US FDA approval and recently entered donor procurement markets. Company B employs distributor-based models predominantly, with limited own international offices.

Company C:

Company C began operations in 1999, positioning as an export-focused manufacturer from inception. Exports started in 2006 and the company now reaches 60+ countries with substantial focus on donor procurement through UNICEF, UNFPA, and USAID. Company C holds WHO prequalification, US FDA approval, and multiple international certifications. The export department comprises 14 members handling institutional procurement and commercial

markets. The company operates own setup in some markets and distributor arrangements in others.

Company D:

Company D has been in pharmaceutical operations since 1960 with international marketing beginning in the 2000s. The company exports to approximately 50 countries, primarily in Asia and Africa, through distributor relationships. Company D holds various international certifications though not US FDA approval. The respondent has 10+ years of experience in export operations, regulatory documentation, and partner management.

Table 6: Case Company Comparison Matrix

Characteristic	Company A	Company B	Company C	Company D
Establishment Year	1958	1976	1999	1960
Export Start Year	1987	~1993	2006	2000s
Export Duration	37+ years	30+ years	18 years	15-20 years
Markets Served	42+ countries	LatAm/SEA/Africa	60+ countries	~50 countries
Own Foreign Offices	Yes (3 locations)	Limited	Yes (selective)	No
Primary Mode	Mixed	Distributor	Mixed	Distributor
Donor Procurement	Significant	Recent entry	Major focus	Limited

This case selection provides variation in firm age, internationalization experience, market coverage, certification levels, and strategic orientations while maintaining common characteristics (all are successful LDC pharmaceutical exporters). This combination enables both within-case depth and cross-case comparison.

4.4 Data Collection

Interview Method

Primary data was collected through semi-structured interviews with senior export managers from the four case companies. Semi-structured interviews are particularly appropriate for exploratory qualitative research as they combine structure (ensuring key topics are covered) with flexibility (allowing unexpected themes to emerge and be explored) (Brinkmann & Kvale, 2015).

Interviews lasted 60-90 minutes each through Zoom Call and were conducted in person at company premises. All interviews were audio recorded with participant consent and subsequently transcribed verbatim for analysis. The use of semi-structured format allowed for natural conversation flow while ensuring that all relevant topics were addressed across all cases, facilitating systematic cross-case comparison.

Interview Guide Development

An interview guide was developed based on the literature review and research questions. The guide covered the following main areas:

• Internationalization background: When and why the company decided to internationalize, initial target markets, evolution of international strategy

• Entry modes and processes: How the company enters different markets, partner selection criteria, contractual arrangements, business model variations across markets

• Decision-making factors: What factors influence market selection, entry mode choices, and resource allocation for international operations

• Enablers and facilitating factors: What factors, resources, capabilities, or conditions enable international expansion and success

• Barriers and challenges: What obstacles, constraints, or difficulties the company faces in international markets, both at entry and in ongoing operations

• Regulatory and certification: The company's experience with regulatory requirements, quality certifications, and compliance management across markets

• Future outlook: Perceptions of LDC graduation implications, future internationalization plans, strategic priorities

While the interview guide provided structure, interviewers used probing questions to explore interesting themes in depth, allowing participants' own frameworks and priorities to emerge (Gioia et al., 2013). This balance between structure and flexibility is essential for rigorous qualitative research.

Respondent Profiles

Interviews were conducted with senior managers responsible for international business operations. Respondent selection criteria included: (1) direct responsibility for international operations; (2) minimum 10 years of experience in pharmaceutical export; (3) involvement in strategic decision-making regarding internationalization; and (4) comprehensive knowledge of company's internationalization history and current operation,

Table 7: Interview Respondent Details

Company	Respondent Position	Years of Experience	Key Responsibilities	Interview Duration
A	Head of International Business	17+ years	Global export strategy, 25-member team	75 minutes
B	Manager, International Business Marketing	17+ years	Regional markets, partnerships	80 minutes
C	Export Manager	12 years	Export operations, 14-member team, donor procurement	85 minutes
D	Export Operations Manager	10+ years	Export coordination, regulatory documentation	70 minutes

All respondents possess deep knowledge of their companies' internationalization experiences, strategic thinking, and operational realities, making them highly credible informants. Their long tenure (10-17+ years) ensures they can provide both historical perspective on internationalization evolution and current operational insights.

Ethical Considerations and Confidentiality

The research adhered to ethical principles for qualitative business research:

• Informed consent: All participants were briefed on research purpose, data use, and their rights, and provided explicit consent to participate and be recorded

• Confidentiality: Company identities are anonymized using letter codes (A, B, C, D). Commercially sensitive information disclosed by participants is either aggregated or excluded from reporting

• Voluntary participation: Participants were informed they could decline to answer any question or withdraw from the study at any time

• Data security: Interview recordings and transcripts are stored securely with access restricted to the research team

• Accurate representation: Analysis strives to represent participants' views faithfully, avoiding misrepresentation or selective reporting that distorts meaning.

4.5 Data Analysis

Gioia Methodology

This study uses the Gioia methodology as a systematic approach to analyze qualitative data and develop theory (Gioia et al., 2013). The main idea of this method is to move step by step from raw interview data to higher-level theoretical insights. It helps the researcher organize large amounts of qualitative data in a clear and structured way while still staying close to what participants actually said. This method is especially useful for studies that aim to build new theoretical understanding from real-world experiences.

First-Order Analysis

In the first stage, the interview transcripts were carefully read and analyzed in detail. The focus at this stage was to stay close to the participants’ own words and expressions. Instead of using technical language, the researcher tried to capture how participants described their own

experiences. This involved reading each interview line by line and identifying meaningful ideas or statements. These ideas were then coded using simple labels that reflect the participants' language. The aim was to understand how participants themselves see and explain their internationalization experiences. This process resulted in a large number of first-order concepts, showing the richness and diversity of the data.

Second-Order Analysis

In the second stage, the researcher moved from participant language to a more analytical level. The first-order concepts were compared with each other to find similarities and differences. Based on this comparison, related concepts were grouped together into broader categories called second-order themes. At this stage, the researcher started to interpret the data and connect it with theoretical ideas. These themes represent patterns that go beyond individual statements and help explain the data in a more structured way. Although the analysis becomes more abstract, it is still grounded in the original data.

Aggregate Dimensions

In the final stage, the second-order themes were further combined into larger theoretical categories known as aggregate dimensions. These dimensions represent the main insights of the study and form the core of the theoretical contribution. The researcher examined how different themes are related and identified broader patterns that explain the internationalization process. This step helps move from detailed observations to a more general understanding of the phenomenon.

Data Structure

An important feature of the Gioia methodology is the development of a data structure. This is usually presented as a visual diagram that shows how the analysis moved from first-order concepts to second-order themes and then to aggregate dimensions. It helps make the research process more transparent and shows how the findings are grounded in the data. In this study, the data structure is presented in the findings chapter.

Cross-Case Analysis

Since this study includes multiple case companies, cross-case analysis was also used to compare findings across cases (Miles et al., 2014). This involves looking at patterns that appear across all or most companies, as well as differences between them. By comparing

cases, the researcher can identify which findings are common and which are specific to certain firms. This strengthens the overall analysis and provides deeper insights into the internationalization process.

Ensuring Rigor and Trustworthiness

To ensure the quality and reliability of the research, several steps were taken (Lincoln & Guba, 1985; Gioia et al., 2013). The research process is described clearly so that readers can understand how the data was collected and analyzed. Real examples from interviews are used to support the findings. Using multiple cases increases confidence in the results, and selecting information-rich cases ensures that the data is meaningful. In addition, detailed explanations are provided so that readers can understand the context and assess how the findings may apply to other situations. The researcher also reflects on their role in the analysis, while following a systematic and careful approach throughout the study.

5. Analysis

This chapter presents the analysis of interview data collected from four Bangladeshi pharmaceutical firms. Using the Gioia methodology, the interview data were first coded into first-order concepts, which were subsequently grouped into second-order themes and broader aggregate dimensions. This process enabled systematic interpretation of the qualitative data while identifying recurring patterns shaping the internationalization of pharmaceutical firms from a Least Developed Country.

The Gioia data structure generated several second-order themes reflecting different aspects of pharmaceutical internationalization. For analytical clarity, these themes are grouped into broader aggregate dimensions representing barriers to internationalization, internationalization processes, enabling factors, and business model adaptations.

The overall data structure resulting from the Gioia analysis is presented in Table 8.

Table 8: Data Structure: Gioia Analysis of LDC Pharmaceutical Internationalization

First-Order Concepts	Second-Order Themes	Aggregate Dimensions
Made in Bangladesh label disadvantage	Liability of LDC Origin	Barriers to Internationalization
Country image skepticism from buyers		
Quality doubts despite certifications		
No cold room at airports	Institutional Void Effects	
Limited testing lab facilities		
Port delays affect shipments		
Regulatory requirements trump culture	Regulatory Distance Primacy	
Documentation varies by market		
Inspection requirements differ		
5-7 years planning to first sales	Extended Regulatory Timelines	Internationalization Process
500-700 page product dossiers		
Multi-year approval processes		
Start with less regulated markets	Stage-Based Market Selection	
Progress to stricter markets		

WHO prequalification opens doors	Certification as Legitimacy	Enablers
FDA approval changes perceptions		
Certifications override origin concerns		
Patent-free product development	TRIPS-Enabled Capability	
TRIPS waiver enables generics		
Transfer pricing model used	Business Model Flexibility	Business model adaptation
Profit sharing 70:30 arrangements		
Percentage of launch price model		
Partner solves 50% of market issues	Partnership Dependency	Internationalization modes
Local partner knowledge critical		

Table 8 illustrates the progression from interview insights to broader theoretical dimensions. The themes indicate that internationalization for Bangladeshi pharmaceutical firms is strongly shaped by institutional context, regulatory complexity, and strategic partnership arrangements.

Liability of LDC Origin

One of the most prominent patterns emerging from the interviews is the disadvantage associated with Bangladesh's status as a Least Developed Country. Respondents consistently indicated that the label "Made in Bangladesh" often triggers skepticism among international buyers, even when firms possess internationally recognized certifications.

International buyers frequently associate Bangladesh with labor-intensive industries such as garments rather than high-value pharmaceutical manufacturing. As a result, Bangladeshi firms must invest significant effort in building credibility and demonstrating product quality. The limited international recognition of the national regulatory authority (DGDA) further contributes to this challenge, as local regulatory approvals often carry limited legitimacy in foreign markets.

A respondent from explained this challenge:

"*Made in Bangladesh label creates disadvantage. Even with all our certifications and quality standards, many buyers are skeptical. They associate Bangladesh with textiles, not pharmaceuticals. We must work twice as hard to prove quality compared to products from India or other Asian countries. This country image is our biggest challenge*."

- Company A

This perception affects firms in several ways, including difficulties securing initial meetings with potential partners, increased scrutiny during regulatory evaluation, and reduced pricing power even for products with comparable quality.

Partnership Dependency

Another central theme identified in the interviews is the strong reliance on local partners and distributors in foreign markets. For Bangladeshi pharmaceutical firms, partnerships play a critical role in facilitating market entry and operational execution.

Local partners provide essential capabilities including regulatory expertise, distribution networks, customer relationships, and market knowledge. These capabilities allow exporting firms to navigate unfamiliar regulatory environments and establish commercial presence without building costly local infrastructure.

A respondent emphasized the importance of partnerships:

"Partner status is critical—a strong partner can resolve many challenges. In many cases, 50% of market issues are solved solely because the partner functions properly. If your partner is weak or unreliable, even good products fail. Partner selection is one of our most important decisions."

- Company B

These partnerships therefore function as a key mechanism through which firms overcome both resource limitations and credibility challenges associated with their country of origin.

Internationalization Modes

Across all four case companies, export remains the dominant internationalization mode. Firms primarily rely on distributor-based export arrangements when entering foreign markets due to limited resources and the complexity of pharmaceutical regulation.

Respondents described the process of identifying buyers and negotiating agreements with international partners.

"First, we have to find a buyer — through internet, social media, pharmaceutical exhibitions, or direct visits. We select a partner from the big companies. We agree on products and price, negotiate until it's a win-win situation. Then we sign a formal agreement with terms including payment — whether bank-to-bank LC or TT."

— Company A

Although export is universal, firms employ various pricing and partnership arrangements within these export relationships.

"With third parties there are three models: transfer pricing, profit sharing with 70:30 or 60:40 splits, and percentage model based on final market launch price."

— Company C

The entry mode patterns across companies are summarized in Table 9.

Table 9: Entry Mode Patterns Across Cases

Entry Mode	Company A	Company B	Company C	Company D	Cross-Case Pattern
Distributor Export	Primary	Primary	Primary	Primary	Universal
Own Subsidiary	Yes (3)	Limited	Selective	No	Selective, resource-dependent

Donor Procurement	Major	Recent	Major focus	Limited	Growing importance
Transfer Pricing	Yes	Yes	Yes	Yes	Most common model
Profit Sharing	Some	Some	Yes (multiple)	Limited	Used selectively
Direct Export	Selected	Selected	Selected	Some	Rare, specific cases

The findings indicate that exporter–distributor relationships represent the most common internationalization pathway for Bangladeshi pharmaceutical firms.

Extended Regulatory Timelines

Another striking finding is the length of time required for pharmaceutical internationalization. Respondents consistently reported that the process from initial planning to actual product sales can take between five and seven years.

"From planning to actual filing and product launch, it takes a minimum of five years, sometimes seven."

— Company B

These extended timelines are largely driven by regulatory requirements including product dossiers, stability studies, facility inspections, and ongoing compliance monitoring.

A respondent described the regulatory documentation involved:

"For every product we submit a Product Dossier — a 500 to 700-page document containing formulation, stability data, microbiology tests, and machine diagrams."

— Company A

The regulatory environment therefore plays a central role in shaping the pace and sequence of international expansion.

Certification as Legitimacy Mechanism

International certifications emerged as a critical factor enabling Bangladeshi firms to overcome credibility challenges in global markets. Certifications such as WHO prequalification and US FDA approval provide internationally recognized signals of product quality and regulatory compliance.

A respondent explained the transformative impact of these certifications:

"FDA approval changed everything for us. When we tell potential partners we have FDA approval, their attitude completely changes."

— Company A

The main certifications and their strategic benefits are summarized in Table 10.

Table 10: Certification Benefits Identified by Respondents

Certification	**Primary Benefits**	**Timeline**	**Investment Level**	**Strategic Impact**
WHO-GMP	Basic quality signal, market access	12-18 months	Moderate	Foundational
WHO Prequalification	Donor procurement access	2-3 years	High	Transformative
US FDA	Global credibility, USA market	3-5+ years	Very high	Transformative
EU GMP	European market access	2-4 years	High	Significant

Certifications therefore function not only as regulatory requirements but also as strategic tools that enable firms to overcome country-of-origin disadvantages.

Barriers and Institutional Constraints

Despite several enabling factors, firms face multiple barriers during international expansion. These include country-of-origin perceptions, regulatory complexity, infrastructure limitations, and resource constraints.

One of the most frequently mentioned challenges relates to infrastructure gaps in Bangladesh, particularly for temperature-sensitive pharmaceutical products.

"No airport cold room for 2–8 degree products. We have many injectable products that require refrigeration during transport."

— Company C

Additional challenges include port delays, limited availability of specialized testing laboratories, and dependence on imported active pharmaceutical ingredients (APIs).

These barriers and mitigation strategies are summarized in Table 11**.**

Table 11: Barriers and Mitigation Strategies

Barrier	**Severity**	**Mitigation Strategy**	**Effectiveness**
Country-of-origin liability	Very High	International certifications, partner vouching	Partial
Regulatory distance	High	Specialized expertise, consultants	Moderate
Infrastructure voids	High	Workarounds, selective product portfolio	Partial
API dependency	Moderate-High	Multiple suppliers, some local production	Limited
Resource constraints	Moderate	Prioritization, phased expansion	Necessary

Limited national reputation	High	DGDA strengthening, firm-level certifications	Slow progress

Business Model Adaptation

In response to these constraints, firms adapt their business models to operate effectively in international markets. These adaptations include flexible pricing arrangements, partner-based distribution systems, and selective market entry strategies.

Respondents emphasized that different markets require different pricing models.

"Different markets and partners require different arrangements. In some markets we use transfer pricing, in others we use profit sharing like 60:40 or 70:30."

— Company C

Most firms maintain centralized manufacturing operations in Bangladesh to leverage cost advantages while relying on international partners for distribution and regulatory navigation.

This hybrid model allows Bangladeshi pharmaceutical firms to combine cost-efficient manufacturing with global market access, enabling them to gradually expand their presence in international pharmaceutical markets despite structural institutional constraints.

6. Discussion

This section discusses the findings in relation to existing theoretical perspectives, focusing on three key dimensions: the internationalization process, business model adaptation, and institutional context. The findings demonstrate that while the internationalization patterns of Bangladeshi pharmaceutical firms align with several established theoretical frameworks, they also reveal important deviations shaped by the distinctive institutional and resource constraints faced by firms originating from a Least Developed Country (LDC).

Dimension 1: Internationalization Process

The findings of this study confirm the core prediction of the Uppsala internationalization model that firms expand internationally through a gradual and stage-based process (Johanson & Vahlne, 1977; Johanson & Vahlne, 2009). All four firms initially entered geographically and institutionally closer markets such as Myanmar, Nepal, and Sri Lanka before targeting

more distant markets. Over time, firms accumulate experiential knowledge and capabilities that enable them to operate in increasingly complex regulatory environments. This learning-based progression reflects the experiential knowledge accumulation emphasized in the Uppsala model.

However, several important differences emerge between the classical model and the empirical findings.

First, the timeline of internationalization appears significantly extended. The Uppsala model suggests relatively rapid stage progression, often within one or two years between stages. In contrast, the pharmaceutical firms examined in this study require approximately five to seven years to enter a single market. This delay is largely driven by regulatory complexity rather than gradual market learning. These findings support later extensions of the Uppsala model that acknowledge how institutional environments and industry characteristics influence the pace of internationalization (Johanson & Vahlne, 2009; Vahlne & Johanson, 2017).

Second, the dominant form of distance influencing market selection differs from traditional assumptions. While the original Uppsala framework emphasizes psychic distance—differences in language, culture, and institutions (Johanson & Wiedersheim-Paul, 1975)—the present findings indicate that regulatory distance plays a more decisive role in the pharmaceutical sector. Firms prioritize regulatory compatibility and approval requirements over cultural similarity when selecting markets. This observation aligns with research emphasizing the importance of institutional and regulatory distance in international business strategy (Kostova, 1999; Xu & Shenkar, 2002).

Third, the findings suggest that export does not necessarily represent a temporary stage leading to foreign direct investment. Instead, export-based strategies remain stable even after decades of international experience. This pattern reflects structural characteristics of the pharmaceutical industry, where centralized manufacturing combined with regulatory complexity makes distributed production less attractive.

Finally, the type of knowledge accumulated during internationalization differs from traditional expectations. While the Uppsala model emphasizes experiential market knowledge, the findings show that regulatory knowledge and certification capabilities are equally critical for firms operating in highly regulated industries such as pharmaceuticals.

Taken together, these findings extend the Uppsala model by demonstrating that internationalization timelines are strongly industry-contingent, that regulatory distance can dominate psychic distance in highly regulated industries, and that export strategies may represent long-term equilibrium modes rather than transitional stages.

Dimension 2: Business Model Adaptation

The findings also align with literature emphasizing the importance of business model adaptation during internationalization. Firms adapt pricing structures, partner arrangements, and revenue models in response to varying market conditions and regulatory environments. The use of multiple pricing models—including transfer pricing, profit sharing, and percentage-based arrangements—illustrates how firms adjust value capture mechanisms across markets.

These findings are consistent with research on business model innovation and internationalization, which highlights the need for firms to modify value propositions, revenue structures, and partner relationships when expanding internationally (Teece, 2010; Amit & Zott, 2012; Casadesus-Masanell & Ricart, 2010).

However, the empirical evidence also reveals important differences from existing literature.

First, many business model studies assume that firms can freely choose among alternative strategic configurations. In contrast, the firms examined in this study operate under severe structural constraints arising from resource limitations and country-of-origin disadvantages. These constraints significantly narrow the range of viable business model options.

Second, partnerships emerge not simply as strategic opportunities but as structural necessities. Much of the literature portrays partnerships as mechanisms for value co-creation and strategic flexibility (Zott & Amit, 2010). In the present context, however, partnerships are essential for regulatory navigation, distribution access, and credibility building in foreign markets.

Third, firms often accept reduced control over value creation and market operations. Local partners frequently manage regulatory interactions, distribution networks, and customer relationships. While this arrangement limits direct control, firms accept this trade-off in order to access international markets and mitigate operational risks.

These findings suggest that business model adaptation in LDC contexts is shaped not only by strategic choice but also by institutional and resource constraints.

Dimension 3: Institutional Perspective

The findings strongly support institutional theory's argument that organizational strategies are shaped by the institutional environments in which firms operate (North, 1990; Scott, 2014). Bangladeshi pharmaceutical firms actively pursue legitimacy through internationally recognized certifications such as WHO prequalification and US FDA approval. These certifications function as signals of quality and regulatory compliance, helping firms overcome skepticism associated with their country of origin.

This behavior reflects legitimacy-seeking strategies commonly observed when firms operate under institutional uncertainty (Kostova & Zaheer, 1999).

However, the findings also highlight the distinctive characteristics of firms originating from Least Developed Countries. According to the United Nations classification, LDCs are characterized by low income levels, weak human assets, and high economic vulnerability (UNCTAD, 2021). Firms operating in these environments face structural constraints that shape their internationalization strategies.

First, firms must operate within severe home-country institutional voids, including infrastructure limitations, weak regulatory recognition, and limited access to specialized services (Mair, Marti, & Ventresca, 2012). These gaps affect both domestic operations and international competitiveness.

Second, firms face a strong liability of origin, where the "Made in LDC" label generates skepticism regarding product quality and technological capabilities among international buyers (Ramachandran & Pant, 2010).

Third, firms often face resource and capability constraints, including limited financial resources, technological capabilities, and managerial expertise compared to firms from more advanced economies (Gaur, Kumar, & Singh, 2018).

Taken together, these conditions create what can be described as a double institutional disadvantage, where firms face both institutional voids in their home environment and legitimacy deficits in foreign markets. This combination creates compounding challenges that shape internationalization strategies.

In response to these constraints, firms pursue firm-level institutional substitution mechanisms, most notably through the acquisition of internationally recognized certifications such as WHO prequalification and US FDA approval. These certifications function as legitimacy signals that compensate for weak national institutional credibility and allow firms to gain acceptance in international markets.

Another important mechanism identified in this study is the role of international institutions as bridging mechanisms connecting LDC firms to global markets. Organizations such as the World Health Organization and international donor procurement agencies provide alternative institutional pathways that allow firms to bypass some of the constraints associated with national institutional weaknesses.

An important implication of this institutional context concerns Bangladesh's upcoming graduation from LDC status. Bangladesh is expected to graduate from the LDC category by 2026, which will eventually result in the loss of several policy flexibilities currently available to LDC economies. In the pharmaceutical sector, the most significant change relates to the expiration of TRIPS-related pharmaceutical exemptions by 2033, after which Bangladesh will be required to fully comply with international pharmaceutical patent regulations (Labonté et al., 2021).

Respondents in this study indicated that firms are already adjusting their strategies in anticipation of this transition. Many firms are accelerating international expansion efforts and pursuing global certifications in order to strengthen their international presence before stricter patent obligations take effect.

One respondent explained this strategic urgency:

"We know the TRIPS waiver will end after LDC graduation. This is why we are pushing hard to establish our international presence now, get our FDA approvals, and build our WHO prequalification portfolio.

-Company A

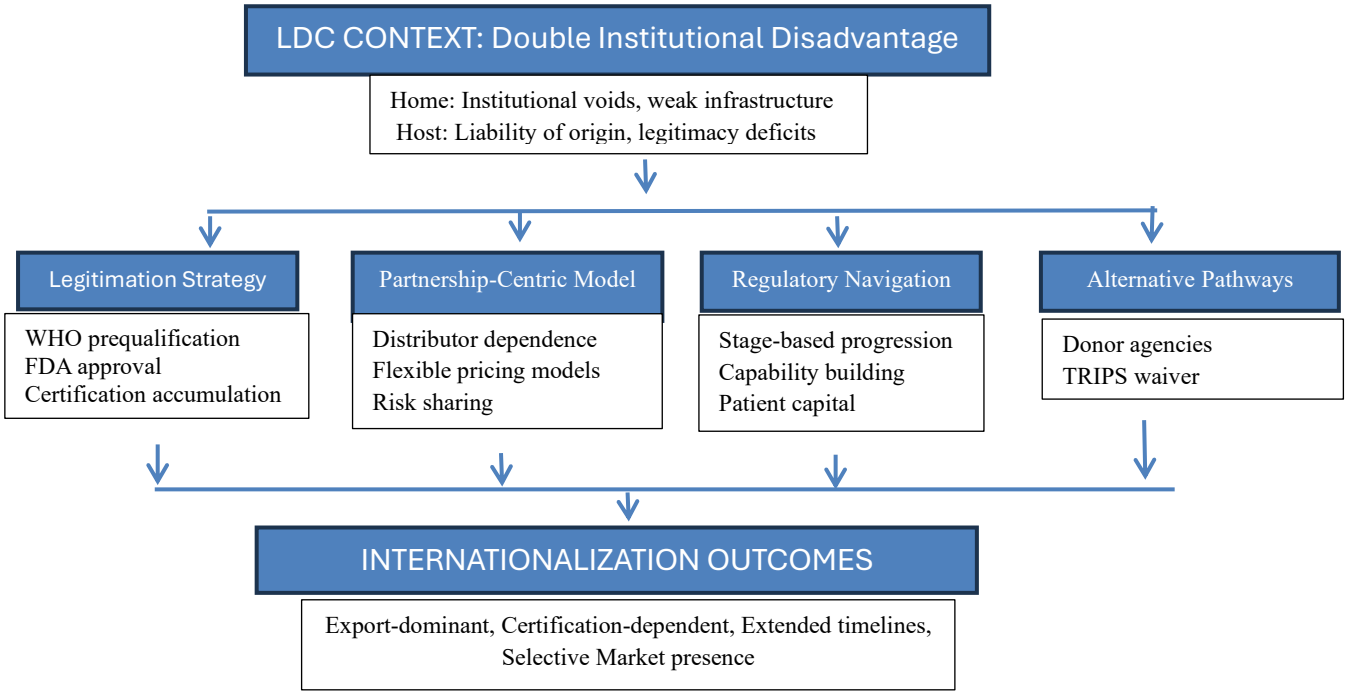
These observations suggest that the current period represents a strategic window of opportunity for Bangladeshi pharmaceutical firms to expand internationally and strengthen regulatory capabilities before the transition to full TRIPS compliance.

Building on these insights, the following section presents an emergent theoretical framework that integrates the institutional constraints, strategic responses, and internationalization outcomes identified in this study.

Theoretical contribution:

We contribute to institutional theory in four ways: (1) by conceptualizing *double institutional disadvantage* as a distinctive challenge for firms from Least Developed Countries (LDCs); (2) by demonstrating firm-level institutional substitution mechanisms in which international certifications substitute for weak national institutional legitimacy; (3) by identifying international institutions as bridging mechanisms connecting LDC firms to global markets; and (4) by extending the concept of institutional voids to show how home-country institutional gaps create constraints on firms' internationalization beyond domestic operational challenges.

Figure 3: Emergent Theoretical Framework: LDC Pharmaceutical Internationalization



This emergent framework proposes that the internationalization of pharmaceutical firms from Least Developed Countries (LDCs) is fundamentally shaped by double institutional disadvantage, defined as the combination of home-country institutional voids and host-country legitimacy deficits. This double disadvantage differentiates LDC firms from both multinational enterprises from developed economies, which typically benefit from stronger institutional environments, and firms from more advanced emerging markets, which face comparatively weaker origin-related disadvantages.

Facing this double disadvantage, firms employ four strategic mechanisms: (1) certification-based legitimation, pursuing internationally recognized credentials such as WHO prequalification and FDA approval to overcome origin-related concerns; (2) partnership-centric value creation, relying on local partners to compensate for firm-level resource and capability limitations; (3) patient regulatory navigation, accepting extended regulatory timelines while gradually building compliance capabilities; and (4) alternative institutional pathways, leveraging donor agencies and policy advantages such as the TRIPS waiver that are typically unavailable to firms from non-LDC contexts.

These mechanisms generate several distinctive internationalization outcomes, including export-dominant expansion rather than progression toward foreign direct investment, strong dependence on international certifications as strategic assets, extended internationalization timelines often ranging from five to seven years per market, and selective market presence, where firms prioritize institutionally accessible markets rather than simply the most economically attractive ones. Overall, the framework explains why pharmaceutical internationalization from LDC contexts follows patterns that differ from established internationalization theories while still remaining grounded in their core insights.

7. Conclusions and Recommendations

7.1 Theoretical Contributions

This qualitative multiple case study contributes to internationalization literature by examining how pharmaceutical firms from a Least Developed Country (LDC) navigate international expansion under conditions of institutional and regulatory constraints. The findings extend

existing theoretical perspectives on internationalization by highlighting mechanisms and patterns specific to LDC contexts.

First, the study provides new insights into the internationalization patterns of firms from Least Developed Countries, a category that remains relatively under-researched in international business literature. Firms from LDCs operate under conditions of double institutional disadvantage, characterized by the combination of home-country institutional voids and legitimacy deficits in international markets. These structural constraints shape internationalization strategies that differ from those typically observed among multinational enterprises from developed economies or firms from more advanced emerging markets such as India and China.

Second, the study provides strong empirical support for the concept of regulatory distance as a critical dimension of internationalization in highly regulated industries. In pharmaceutical markets, differences in regulatory requirements, approval processes, quality standards, and compliance frameworks appear more influential than traditional dimensions of psychic distance such as culture, language, or geographic proximity. This finding suggests that distance dimensions should be conceptualized in industry-specific terms rather than assumed to operate uniformly across sectors.

Third, the study identifies certification-based legitimation as a key strategic response to the liability of origin faced by firms from LDCs. When national institutional credibility is weak and creates negative country-of-origin perceptions, firms pursue internationally recognized certifications such as WHO prequalification and US FDA approval. These certifications function not only as operational requirements but also as strategic legitimacy signals that enable firms to overcome institutional disadvantages and gain credibility in international markets.

Fourth, the study highlights the role of international institutions as alternative internationalization pathways for LDC firms. Donor procurement agencies and global health organizations provide market access opportunities based on standardized quality criteria rather than country of origin. These institutional arrangements mitigate the disadvantages faced by LDC firms and illustrate how supranational institutions can bridge gaps created by weak national institutional environments.

Finally, the study documents extended internationalization timelines in pharmaceutical markets, typically ranging from five to seven years per market. These timelines are

significantly longer than those suggested in traditional interpretations of the Uppsala model and largely reflect regulatory complexity rather than gradual experiential learning alone. The findings therefore suggest that while stage-based internationalization processes remain relevant, the pace of progression is strongly influenced by regulatory requirements and institutional conditions.

7.2 Practical Recommendations

Based on the findings of this study, several recommendations can be proposed for firms, policymakers, and development organizations involved in the pharmaceutical sector in LDC contexts.

For LDC Pharmaceutical Firms

For pharmaceutical firms operating in LDC environments, the findings suggest that firms should prioritize the accumulation of internationally recognized certifications such as WHO prequalification and US FDA approval. These certifications play a critical role in overcoming country-of-origin liability and strengthening credibility in international markets. Firms should also invest in systematic partner selection and relationship management capabilities, as partnerships with local distributors and market intermediaries remain central to international expansion. Developing regulatory expertise is equally important, either through dedicated regulatory affairs departments or through collaboration with specialized consultants familiar with international pharmaceutical regulations. Firms must adopt a long-term strategic perspective, recognizing that pharmaceutical internationalization often requires patient capital and extended timelines before market entry becomes profitable. A staged internationalization approach may be beneficial, beginning with less regulated markets to build experience and reputation before expanding into more highly regulated markets. In addition, firms should actively leverage opportunities created by international donor procurement systems, as WHO prequalification can provide both market access and reputational benefits that facilitate expansion into commercial markets. Given Bangladesh's upcoming graduation from LDC status and the eventual expiration of TRIPS-related pharmaceutical flexibilities, firms may also benefit from accelerating international expansion during the remaining transition period.

For Policymakers and Development Agencies

For policymakers and development agencies, strengthening the institutional environment surrounding the pharmaceutical sector is essential for supporting international

competitiveness. Investments aimed at strengthening the national regulatory authority, particularly the Directorate General of Drug Administration (DGDA), could enhance international recognition and credibility of Bangladeshi pharmaceutical products. Addressing infrastructure gaps is also critical, particularly in areas such as cold-chain logistics, airport cargo handling facilities, specialized testing laboratories, and efficient port operations. Policymakers may further support firms by providing financial assistance or incentive programs for companies pursuing international regulatory certifications, which often require significant investment. Encouraging domestic API production through industrial incentives could help reduce import dependency and strengthen the domestic pharmaceutical value chain. In addition, the development of specialized export financing mechanisms would support firms facing long regulatory approval timelines and high upfront compliance costs. Investments in regulatory training programs and broader initiatives aimed at improving the global image of "Made in Bangladesh" pharmaceuticals could also strengthen the sector's international competitiveness.

For International Development Organizations

International development organizations can also play a critical role in supporting pharmaceutical sector development in LDC contexts. Continued support through procurement programs, technical assistance, and regulatory capacity building can help maintain international market access opportunities for firms operating in institutional environments with limited resources. Development partners may also consider transitional support mechanisms for countries graduating from LDC status, helping pharmaceutical sectors adjust to the loss of preferential trade arrangements and the transition to full TRIPS compliance. Furthermore, knowledge transfer initiatives connecting LDC pharmaceutical firms with experienced global industry partners could strengthen regulatory, technological, and managerial capabilities within the sector.

7.3 Limitations and Future Research

This study has several limitations that should be acknowledged. The research focuses exclusively on Bangladesh, and although the findings may provide insights relevant to other LDC contexts, generalization should be approached with caution due to country-specific institutional arrangements. The four case companies included in the study represent successful exporters among the leading Bangladeshi pharmaceutical firms, meaning that smaller firms or unsuccessful internationalization attempts are not represented in the analysis.

The research also reflects a temporal snapshot based on data collected during 2024–2025, and longitudinal studies following firms over longer periods could provide deeper insights into internationalization processes and capability development. In addition, the study relies on a single key informant from each firm, and future research incorporating multiple organizational perspectives could provide a richer understanding of decision-making processes within firms. Finally, the research primarily captures the perspectives of exporting firms rather than the perspectives of foreign regulators, distributors, or buyers in host markets. Future research could therefore expand this work through comparative studies across multiple LDC pharmaceutical sectors, longitudinal analyses tracking internationalization processes over time, quantitative testing of the theoretical framework developed in this research, and investigations examining host-market perceptions of pharmaceutical suppliers from LDC contexts.

7.4 Concluding Remarks

This study contributes to internationalization theory by examining how pharmaceutical firms from a Least Developed Country navigate the complex challenges of global expansion. The findings reveal distinctive internationalization patterns characterized by export-oriented strategies, certification-based legitimation, partnership-centric business models, and extended regulatory timelines shaped by institutional constraints.

Beyond theoretical contributions, the research provides practical insights for pharmaceutical firms, policymakers, and development organizations seeking to strengthen the international competitiveness of pharmaceutical industries in LDC contexts. The transformation of Bangladesh's pharmaceutical sector—from import dependence in the 1970s to exporting medicines to more than 160 countries today—represents a significant development achievement. Nevertheless, the industry continues to face challenges including country-of-origin liability, regulatory complexity, and the impending transition to full TRIPS compliance following Bangladesh's graduation from LDC status.

The strategic responses identified in this study—including certification accumulation, partnership development, regulatory capability building, and the use of alternative institutional pathways—provide guidance for firms navigating these challenges. More broadly, the findings highlight the importance of considering institutional context in internationalization research. Firms from Least Developed Countries operate under

distinctive structural conditions that shape their internationalization strategies, and recognizing these differences is essential for developing more context-sensitive internationalization theories and policies that support the global integration of firms from diverse economic environments.

Overall, the study advances understanding of internationalization from LDC contexts by demonstrating how pharmaceutical firms navigate global expansion under conditions of double institutional disadvantage. The findings highlight the importance of certification-based legitimation, partnership-centric market entry, and regulatory capability development in overcoming legitimacy deficits and institutional constraints. By emphasizing the role of regulatory distance and institutional environments, the study contributes to a more context-sensitive understanding of internationalization processes in highly regulated industries and weaker institutional settings.

Appendix

Appendix A: Interview Protocol

The following semi-structured interview protocol guided data collection. While questions were asked consistently across all interviews, the semi-structured format allowed for probing and follow-up questions based on respondent answers, enabling emergent themes to surface naturally.

Opening and Background

Thank you for participating in this research on internationalization of Bangladeshi pharmaceutical firms. This interview will take approximately 60-90 minutes. All responses will be kept confidential, and your company will be anonymized in any publications. The interview will be recorded with your permission for transcription purposes.

Section 1: Company Background and Internationalization History

• Can you tell me about your company's history and when international operations began?

• What motivated the company to pursue internationalization?

• How has your international presence evolved over time?

• Currently, how many countries do you export to? Which are your primary markets?

• What is your role in the company's international operations?

Section 2: Entry Modes and Market Selection

• How do you typically enter new international markets? What entry modes do you use?

• Can you walk me through the process from identifying a market to establishing presence there?

• What factors influence your decision about which markets to enter?

• How do you decide between different entry modes (direct export, distributors, own subsidiaries)?

• Do you use different approaches for different markets? Why?

Section 3: Partnership and Business Model

• How do you select and manage international partners/distributors?

• What business models or arrangements do you use with partners? (pricing, profit-sharing, etc.)

• How important are partners to your international success?

• What challenges do you face in partner relationships?

• Do you adapt your business model for different markets?

Section 4: Regulatory and Quality Requirements

• What regulatory approvals and certifications does your company hold?

• Can you describe the process of obtaining these certifications? (WHO, FDA, EU, etc.)

• How long does it typically take from planning to getting regulatory approval in a new market?

• What documentation and quality standards are required for international markets?

• How do regulatory requirements vary across different markets?

Section 5: Enablers and Success Factors

• What factors have most helped your company succeed internationally?

• How has the TRIPS waiver for LDCs affected your operations?

• What role do donor procurement agencies (UNICEF, UNFPA, etc.) play in your exports?

• How do your cost advantages compare to competitors?

• What capabilities or resources have been most critical for international expansion?

Section 6: Barriers and Challenges

• What are the biggest challenges your company faces in international markets?

• How does 'Made in Bangladesh' labeling affect market acceptance?

• What infrastructure challenges affect your export operations?

• How do you manage API sourcing and supply chain issues?

• What resource constraints limit your international expansion?

Section 7: LDC Graduation and Future Outlook

• How is your company preparing for Bangladesh's LDC graduation?

• What implications will the loss of TRIPS waiver have for your operations?

• What are your strategic priorities for international expansion in the coming years?

• What changes or improvements would most help Bangladeshi pharmaceutical exports?

Closing: Thank you for your time and insights. Is there anything else about your internationalization experience that you think would be important for me to understand? May I contact you again if I need any clarifications?

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