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**The Role of Environmental Compliance in Pharmaceutical Export Competitiveness: An
Egyptian Case Study**

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The Role of Environmental Compliance in Pharmaceutical Export Competitiveness: An Egyptian Case Study



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Abstract

Purpose: This study takes the lens of international economics to study the determinants of growth in pharmaceutical exports in Egypt. The Egyptian pharmaceutical industry has been the regional industry leader since it was established in 1938. The industry's barriers to entry in the global market primarily include regulatory frameworks, infrastructural disparities, and inconsistent funds. To this end, this study examines those barriers and, to some extent, the opportunities, thereby helping to document Egypt's position in the global competitive landscape of the pharmaceutical industry.

Methodology: Using a mixed-method approach, twenty-one firms from the industry were classified into three categories; Class A firms were deemed "strong exporters", Class B were "moderate exporters", and Class C were "non-exporters". Qualitative data was collected through semi-structured interviews of senior executives within the firms, along with regulatory officers and export managers. The qualitative data were subsequently coded using NVivo. At the same time, a quantitative approach involved a survey of 120 industry professionals, and the data was analyzed using descriptive statistics, correlation and regression analysis in the SPSS statistical package. The quantitative and qualitative data constitute an integrated mixed-method approach.

Findings: In the assessment of the three classes of firms, significant differences were identified. Firms of Class A have strong export growth attributed to flexibility in regulatory frameworks, financial strength, and the development of new innovative products. In contrary, Class B firms have limited export growth due to financial constraints and problems pertaining to regulatory compliance. Class C firms, on the other hand, had weak institutional integration, little knowledge of export opportunities, and high risk aversion, which explains their export stagnation. Of the factors tested, regulatory compliance, R&D finance, and financing were identified as the most significant in the quantitative analysis ($p < 0.05$). While the strength of a firm's supply chain and export of IP were named alongside many other factors, their export performance showed no strong dependence on these variables, and were thus considered less influential.

Unique Contribution to Theory, Practice and Policy: To promote innovation, the study recommends Egypt's pharmaceutical sector to implement Egypt R&D expenditure strategies. In addition, expanding institutional financing and harmonizing domestic and international laws would be beneficial to the pharmaceutical sector. Egypt can substantially benefit in the pharmaceutical sector from these recommendations, as can industry stakeholders and policymakers. Evidence-based recommendations would be the first step in repositioning Egypt in the international market as a competitor in pharmaceutical exports.

Keywords: *Pharmaceutical Exports, Egypt, Regulatory Compliance, R&D Investment, Supply Chain, Export Growth, International Trade*

JEL Codes: *F14, L65, O19*

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INTRODUCTION

Established in 1938, the Egyptian pharmaceutical industry has become an integral part of the provision of healthcare services and the development of the economy in the Middle East and Africa. The industry's contribution to economic diversification and the balancing of the economic measures of the public health sector and the pharmaceutical sector of the economy. This is due not only to the increase in the domestic market, but also to the government-sponsored initiatives toward the modernization of the industry and economy (Kamel, 2021). Over the past decades, Egyptian pharmaceutical companies have sought to expand their market internationally in response to the demand for reasonably priced, high-quality medicines, not only to diversify their revenue streams, but also to respond to global market conditions (Shraah et al., 2022).

The outward shift of the firm has not extended to the broader focus. Barriers to internationalization continue to exist and stem from structural and institutional influences. Regulatory discontinuity and divergence across target markets makes compliance and understanding hurdles, while international standards pertaining to quality, notably Good Manufacturing Practice (GMP) certification, leave firms with little hope to afford the highly priced certification. Weakened competitive positioning vis-a-vis emerging rivals, India and Turkey, are further impacted by fragile supply chains, limited access to finance, and the absence of specialized personnel. These observations indicate that the limited growth of Egyptian exports is a consequence of more than just insufficient production, but institutional funding, inter-agency flexibility, resilient international relations, and other structural adaptations.

Alongside the foregoing, the unreleased potential of Egyptian pharmaceutical exports can contribute to the country's economic development and the target of equity in global health. Egypt can supply validated and affordable essential medicines to markets that are lower in the global supply chains. This has the potential to align with the WHO's pleas to "close the gaps" (Motari et al., 2021). Stressing the global health equity aspect strengthens the narrative of Egypt's participation in international trade and integration of growth with sustainability (Rasheed, 2024).

Nonetheless, Egypt's peculiar export behavior has been studied less than those of its peers. Much of the focus has been on the South Asian context, where literature exploring the regulatory and supply chain challenges has concerned Egypt less. Knowledge gaps include the influence of Egypt's regulatory environment, innovation frameworks, and mechanisms of IP protection on export outcomes. Moreover, the relationship of digital trade, R&D, and export competitiveness has received little attention (Jahan, 2024; Arshad et al., 2024). Evidence that clarifies export-led approaches to the Egyptian context and its pharmaceutical sector more broadly speaks to these gaps.

Thus, this study assesses the factors influencing export growth for the Egyptian pharmaceutical industry by employing an integrated mixed-methods approach. It focuses primarily on the independent variables of regulatory adherence, R&D investment, and availability of financing, while also considering secondary facilitators of export growth, such as supply chain resilience, IP protection, human capital, and entry frameworks. By segmenting firms into three tiers—Class A (strong exporters), Class B (moderate exporters), and Class C (non-exporters)—the study captures definitional best practices, systemic impediments, and implementable ideas. The

primary aim is to provide contextually relevant evidence of strategies needed to bolster Egypt's competitiveness in the global arena and assist stakeholders in the pharmaceutical export sector.

LITERATURE REVIEW

Pharmaceutical Industry Export Challenges

From developing countries, pharmaceutical exports are hindered by fragmented regulations, ineffective quality assurance, and supply chain deficiencies (Hassanin & Hamada, 2022). Egypt, more than other countries, suffers from dual national and international regulatory systems, and regulatory fragmentation alone adds substantial approval and compliance cost burdens. While recognizing such fragmentation, Hassanin & Hamada (2022) do not analyze its interaction with the domestic structures of Egypt—comparable to the Indian context in which dominant state-led initiatives have greatly streamlined export pathways. Such an omission indicates the need for a more focused analysis on the institutional choke points in Egypt. Furthermore, while volatile exchange rates and global recessions are classified as external risks (Kamel, 2021), their impact on exporters from Egypt has not received adequate attention in either regional or broader comparative frameworks.

Today's research has underlined the role of resilience in the supply value chain as one of the factors in the success of exports (Sabogal De La Pava and Tucker, 2024). Most of the information, though, comes from advanced logistics centers in Asia and Latin America, which is a drawback for applying such analysis to Egypt, where the logistics infrastructure, particularly regarding cold chain logistics and customs, is very rudimentary. This poses a dilemma: in as much as global benchmark models advocate for resilience, the situation in Egypt, where a minimum level of infrastructure exists, precludes the application of resilience framework. This fits neatly in the Resource Based View (RBV) where competition is stated to be dependent on the resources a firm is able to deploy. Egypt suffers from a lack of logistics resources which places a structural limitation to competition even for firms with sufficient capital.

Compliance with Regulations, along with Government Policies

Observance of any both domestic and international regulations rest still on the performance of exports. 'While the Egyptian Drug Authority (EDA) has safety and efficacy regulations, Egyptian firms must still comply with USFDA and EMA regulations (Vieira et al., 2023)'. The simultaneous compliance challenge increases expenditures and often leads to deferred entry in the market. 'Although Balashova & Volgina (2021) state that emerging market regulatory integration speeds up the growth of the market, most of the data on which they rely comes from the Eastern European region and therefore, it in its entirety cannot be applied to Egypt, where the level of institutional integration still greatly hinders alignment.' This emphasizes the need for additional local reform efforts that are deeper than the commonly made harmonization suggestions.

Evidence on the other hand has provided mixed results, with the government's assistance being of utmost importance. Some of the positive results that have emerged are from the tax R&D, and on regional trade agreements, but relative to India's state driven diplomatic promotion of the Industry, Egypt's attempts are scattered (Sabogal De La Pava & Tucker, 2024). Here, the Institutional Theory approach is helpful as it elucidates the importance of the legitimating roles that supportive institutional and state structures can confer on firms seeking to compete in

international markets. Egypt's relative lack of institutional framework does dents exporters' international legitimacy which is in sharp contrast to the example provided by India's.

Quality Standards

Countries exporting goods to Egypt insist on adherence to the correct application of Good Manufacturing Practice (GMP) and other relevant international standards. For Egyptian companies, this means heavy investments in upgrading facilities, staffing, and administrative compliance. Risk scenarios of non-compliance also deal with the consequences of lost shipments and reputational damage. Research studies related to Bangladesh and Pakistan support these fears, but unlike those instances, Egyptian governmental documents (e.g. EDA annual reviews, 2023) seem to suggest a continual lack of enforcement of the GMP audit regime. This skepticism illustrates the lack of reliable evidence on Egypt's claim of being 'nearly compliant' with international standards, which points to a greater need for more surveillance from the institutions.

Protection of intellectual property (IP) in Egypt also seems like a contradiction. Rentala et al. (2017) opinion that greater IP protection increases innovation and foreign direct investment (FDI) does not hold in the case of Egypt's lax enforcement and rampant piracy. TRIPS sets a global floor but the balance between international high tech, copyright and patent equity remains problematic. Rasheed (2024) documents favorable export impacts of enhanced IP regimes in the EU and Australia. In stark contrast, local grey literature (Ministry of Trade & Industry, 2022) demonstrates enduring lack of enforcement in Egypt, which highlights the global to local lesson transference deficit.

Intellectual Property Protection

Another important aspect related to pharmaceutical exports is the protection of Intellectual Property (IP). The absence of adequate IP protection stagnates innovation, restricts foreign investment, and undermines the worth of proprietary formulations (Rentala et al. 2017). Egypt, however, suffers from a lack of enforcement and rampant counterfeiting, which adversely affects global perception. Despite the conditions of the TRIPS agreement, enforcement of IP is patchy, and the enforcement of patent rights while maintaining access to essential medicines remains deeply contentious. Data from the latter half of 2022 also indicates a strong positive correlation between export performance and the enhancement of IP protection to Australia and the EU (Rasheed 2024). Provided the product is of high standard, compliant to the regulations of the destination country, and is patent protected, the determinant factor for successful export rests on the effectiveness of the supply chain and logistics network to deliver the product.

Supply Chain and Logistics

The underpinning of export performance is a well-functioning supply chain. Egyptian exporters have to deal with constant delays at customs and their ability to transport goods under temperature control which puts their product's quality at risk. In China (Zhou et al., 2022) proofs of cross-border trade expedited through digitized logistics. However, Egypt's lack of comparable infrastructure and lack of policy push makes it hard to adopt such strategies. Therefore, while useful lessons may be derived from global models, Egypt's market-oriented strategy starkly contrasts with the state-oriented logistics modernization policy of Asia.

Marketing and distribution present analogous issues. With competitive prices and a wide network of global distributors, Indian exporters are able to capture a large market share in many regions. On the other hand, Egyptian manufacturers suffer from weak brand identity and a

limited connection to overseas markets (Mishra & Jaiswal, 2017). In this context, existing studies which brand Egypt as a secondary enabler surely miss the case's structural barrier: distribution. Without it, products lose their market edge as they are made in compliance with GMP and are not able to be marketed internationally. Porter's Competitive Advantage framework sheds light on this disadvantage Egypt faces—reduced weak factor conditions (logistics, marketing capabilities) of the competitive demand conditions (global need for affordable medicines).

Marketing, Distribution, and Competitive Advantage

It is common knowledge that research and development activities tend to favourably influence exports as they allow companies to devise new bioequivalence formulations as well as to carry out novel bioequivalence studies. However, Egypt continues to underinvest in R as compared to esp. in his region, therefore stifling R&D exports (Rasheed, 2024). There remains a contradiction between the local evidence in Egypt and the global evidence base on this issue. McLean attributes this to the structural siltation that is caused by the Shallow funding Innovation Systmes.

Deficiency of Foundational Infrastructure remains an access to financial resources is a constituent part of the finitistic dilemma. Egypt's financials has a negative role in the economy, especially on economic activities, by applying strict conditionality to loans they describe as "export," negatively impacting cash flows, in turn inhibiting expansion of production and in fact, even fulfilling regulatory conditions (Elsafty and Osman 2021). Compared to the experience in Pakistan and Bangladesh, in Egypt, export-focused financial products have not been adopted, as have several other countries (Jahan 2024, Mubarak and Abbas 2024). Moreover, the dearth of relevant primarily specialized human resources (e.g, those in charge of red tape policy, the multilingual secretary, expansion managers with global work experience) related to these gaps of shifts in and faster global integration slow processes. It is known from local reports of the Egyptian Drug Authority and corroborated by the evidence of Arshad et al., 2024 and Turkey.

Access to Finance and Human Resource Development

Lack of access to finance remains a prominent hurdle to the export of pharmaceuticals. Companies frequently run short of the working capital required for scaling production, conducting clinical trials, or meeting regulatory demands. Some studies point out the peculiar way financial institutions in Egypt treat export loans, which are laden with restrictive conditions (Elsafty & Osman, 2021). Evidence ascertained from Pakistan and Bangladesh validates the need for financial export-specific products to resolve this issue (Mubarak & Abbas, 2024; Jahan, 2024). No less vital is the development of human capital. Exporting firms need a skilled regulatory specialist, multi-lingual staff, and globally educated managers. The lack of specialized human resources slows the adaptation of Egyptian firms to the international business environment. India and Turkey provide comparative evidence of the need to develop globally competitive workforces to sustain export-oriented business advantage (Arshad et al., 2024).

METHODOLOGY

In understanding the factors influencing the growth of pharmaceutical exports in Egypt, the current study adopted a mixed-method approach. It integrated both qualitative and quantitative techniques, which provided an in-depth understanding of the phenomenon. This approach was

particularly relevant in capturing the narrative of industry experts, as well as the statistical export-determinant relationships, thus achieving methodological triangulation and increasing the validity of the results (Creswell & Plano Clark, 2021).

Research Design

The qualitative phase consisted of semi-structured interviews with a compliance officer, R&D director, logistics and marketing heads, and other senior executives from selected pharmaceutical companies. These interviews sought to understand the regulation innovation and logistics bottleneck as well as market entry barriers, financing, and HR development frameworks. Using Braun and Clarke (2006) thematic analysis, the interviews were recorded, transcribed, coded, and analyzed with NVivo software.

The quantitative phase involved a structured survey administered to a sample of 120 employees from the selected companies. The survey instrument consisted of eight independent variables and Likert-scale items: regulatory compliance, R&D investment, marketing and distribution, supply chain and logistics, access to finance, protection of intellectual property, human resource development, and macroeconomic factors. The growth of pharmaceutical exports was captured as the dependent variable. Quantitative data were analyzed with SPSS using descriptive statistics and frequency distributions, correlation and regression analysis, and multiple regression analysis.

Sampling

A purposive sampling strategy was implemented to capture different viewpoints throughout the Egyptian pharmaceutical sector. In total, 21 firms were selected and divided into three categories:

- Class A: A total of seven firms with a strong international presence and a high volume of exports.
- Class B: A total of seven firms with growing moderate levels of international exports.
- Class C: A total of seven firms with no recorded exports, representing potential latent exporters.

This stratification offered different insights throughout firms with varying levels of internationalization. Within these firms, respondents represented the functions of R&D, regulatory affairs, supply chain management, marketing and sales, finance, quality assurance, and top management.

Data Collection

Data collection comprised two parallel instruments:

Semi-structured interviews (qualitative): Custom interview guides were made for each firm class. Responding to regulatory challenges, innovation, logistics, and exports posed open-ended questions.

Structured surveys (quantitative): This survey contained 40 questions centered on a specific challenge or strategy for exporting, each with a five-point Likert scale (from “strongly disagree” to “strongly agree”).

Data Analysis

Qualitative interviews were conducted and subsequently transcribed. These were coded and thematically analyzed using the software NVivo. Themes that emerged included: regulatory

adaptability, proactive market intelligence, financial risk management, innovating the cold supply chain, and insufficient institutional support. The quantitative survey data were processed in SPSS. In addition to summarizing mean scores with associated standard deviations for each variable, descriptive statistics provided correlation and regression analyses for the tested hypotheses. Findings suggested that regulatory compliance, R&D investment, and access to finance were significant predictors of export growth ($p < 0.05$).

Validity and Reliability

For validity, a triangulation of methods (interviews versus surveys) was used. Reliability was enhanced through a pilot phase where the survey was administered to five respondents. Unclear survey items were adjusted and retested. Reliability for NVivo coding was established through checks of agreement between multiple independent coders.

RESULTS

This section outlines the outcomes of the qualitative interviews and the quantitative survey analysis. The results highlight the distinctions between different classes of firms and the statistical relationships among the primary factors influencing the growth of pharmaceutical exports in Egypt.

Qualitative Findings

Discussions with the executives, managers, and regulatory officers from 21 pharmaceutical firms provided insight uniquely distinguishing Class A (exporting firms), Class B (moderate exporters), and Class C (non-exporters).

Table 1: Thematic Findings from Interview Analysis

Firm Class	Key Strengths / Weaknesses	Illustrative Quotes
Class A: Strong Exporters	Strong regulatory adaptability, proactive market intelligence, use of export finance tools, investment in cold chain logistics, product innovation, and differentiation.	<i>"We refuse to compete on price—we compete on formulation, convenience, and look."</i> (Firm A1)
Class B: Moderate Exporters	Reactive export behavior, reliance on unsolicited inquiries, limited access to finance, heavy documentation burdens, and weak institutional support.	<i>"We spend months preparing one file for West Africa. The costs and revisions are overwhelming."</i> (Firm B1)
Class C: Non-Exporters	Limited awareness of export requirements, lack of regulatory expertise, weak product portfolios, and risk aversion to international tenders.	<i>"We don't want to risk losing money on foreign tenders. It feels safer to focus on the local market."</i> (Firm C3)

Source: *Semi-structured Interviews With Firm Executives (n=21)*.

- Strategic innovators demonstrating export readiness and global competitiveness are classified as Class A firms.
- Transitional exporters fall under Class B firms, which are constrained by finance and institutional gaps.
- Class C firms are latent exporters and require training, financial access, and state support.

Quantitative Findings

Descriptive Statistics

Data from surveys was collected from 120 participants from 21 firms. Participants evaluated the importance of factors influencing export growth using a five-point Likert scale, where 1 is categorized as "Very Low" and 5 as "Very High."

Table 2: Descriptive Statistics of Perceived Importance of Key Variables by Firm Class

Variable	Mean (Class A)	Mean (Class B)	Mean (Class C)
Regulatory Compliance	4.3	3.1	2.7
R&D Investment	4.1	3.0	2.5
Access to Finance	4.0	2.9	2.4
Supply Chain & Logistics	3.9	3.1	2.6
Intellectual Property Protection	3.8	2.8	2.3
Human Resource Development	4.2	3.2	2.5

Scale: 1 = Very Low, 5 = Very High

Correlation Analysis

Correlation analysis was conducted to examine the relationship between export growth and the independent variables.

Table 3: Correlation Matrix of Export Determinants

Variable	Regulatory Compliance	R&D Investment	Access to Finance	Supply Chain	IP Protection	Export Growth
Regulatory Compliance	1.00	0.54**	0.49**	0.46*	0.42*	0.61**
R&D Investment	0.54**	1.00	0.50**	0.48*	0.44*	0.55*
Access to Finance	0.49**	0.50**	1.00	0.45*	0.41*	0.58**
Supply Chain	0.46*	0.48*	0.45*	1.00	0.39	0.49*
Intellectual Property	0.42*	0.44*	0.41*	0.39	1.00	0.46*
Export Growth	0.61**	0.55*	0.58**	0.49*	0.46*	1.00

Significance: * $p < 0.05$, ** $p < 0.01$

Compliance with regulations has the highest correlation with export growth, followed by financing and research activities, with correlations of ($r = 0.61$), ($r = 0.58$), and ($r = 0.55$), respectively.

Regression Analysis

A multiple regression model was applied with **export growth** as the dependent variable.

Table 4: Multiple Regression Results (Dependent Variable = Export Growth)

Variable	Beta (β)	t-value	Sig. (p)
Regulatory Compliance	0.39	4.21	0.001**
R&D Investment	0.31	3.12	0.004*
Access to Finance	0.34	3.89	0.002**
Supply Chain & Logistics	0.19	1.88	0.072
Intellectual Property	0.14	1.45	0.141

Note: Variables Supply Chain & Logistics and Intellectual Property were not statistically significant predictors in the model.

Model Summary: $R^2 = 0.62$, $F(5,114) = 27.5$, $p < 0.001$

The regression model accounted for 62% of the variance in the growth of exports. The top three predictors were the following: Compliance with regulations ($\beta = 0.39$, $p < 0.01$); Availability of financial resources ($\beta = 0.34$, $p < 0.01$) and, Investment in research and development ($\beta = 0.31$, $p < 0.05$)

This study provides an integrated perspective on the determinants of pharmaceutical export growth in Egypt, revealing systemic strengths and weaknesses that shape the sector's international performance. Employing a mixed-methods approach, this research confirms that regulatory compliance, access to finance, and R&D investment are the primary drivers of export success. The following discussion contextualizes these findings within existing literature and global benchmarks to highlight theoretical implications and actionable recommendations.

Regulatory compliance emerged as the most critical determinant of export success for Egyptian pharmaceutical firms. The qualitative findings demonstrated that Class A exporters distinguished themselves through dedicated compliance teams that proactively navigated international regulations, a factor strongly supported by the quantitative analysis ($\beta = 0.39$, $p < 0.01$). This underscores the necessity for Egypt to enhance regulatory diplomacy, pursuing mutual recognition agreements with key agencies like the EMA and FDA to streamline market entry. Evidence from India and Turkey illustrates how such alignment reduces compliance costs and delays, a lesson critical for overcoming the burdens currently stifling Class B and C firms (Jahan, 2024; Mubarak & Abbas, 2024).

Closely linked to regulatory challenges is the pivotal role of access to finance in enabling export expansion. The regression analysis identified access to finance as a significant predictor ($\beta = 0.34$, $p < 0.01$), with qualitative data revealing that Class A firms leveraged export loans and credit insurance to mitigate risk and invest in necessary infrastructure. In contrast, Class B and C firms cited restrictive credit terms and a lack of government-backed insurance as primary constraints. This gap highlights an urgent need for financial product innovation in Egypt, mirroring successful export credit schemes in Bangladesh and Pakistan that have empowered SMEs to engage in international trade.

Strategic investment in research and development (R&D) is a fundamental driver of long-term export competitiveness and market diversification. The study's results position R&D investment as a statistically significant predictor of export growth ($\beta = 0.31$, $p < 0.05$), as firms conducting bioequivalence studies and developing innovative formulations gained better access to regulated markets. However, Egypt's R&D expenditure lags significantly behind regional competitors like India and China, who have leveraged state-sponsored subsidies and

generic drug research to dominate global markets. For Egypt to compete, implementing national incentives such as R&D tax breaks, government co-funding of clinical trials, and university-industry partnerships is essential to build a robust innovation pipeline.

While quantitatively less pronounced, supply chain resilience remains a tangible operational bottleneck for Egyptian exporters. Although the regression model showed a moderate correlation, qualitative findings starkly contrasted the advanced cold chain and digital tracking capabilities of Class A firms with the deficiencies of Classes B and C. Egypt's logistical challenges—including customs delays, insufficient bonded warehouses, and high shipping costs—undermine product integrity and delivery speed. Addressing this requires investing in automated customs systems, specialized pharmaceutical freight corridors, and public-private partnerships, emulating the logistics hubs that have fueled export growth in Turkey and India.

The enforcement of intellectual property (IP) rights emerged as a critical qualitative concern for building international trust, despite its weaker statistical significance. Interview participants identified weak IP enforcement and counterfeiting risks as major impediments to international credibility, which aligns with literature connecting strong IP frameworks to innovation and foreign investment (Rasheed, 2024). For Egypt, a central policy challenge remains aligning TRIPS compliance with affordable access to medicines, striving for a balance that has been successfully managed in countries like Australia and within the EU.

The development of specialized human capital is a foundational element for sustaining export readiness and regulatory adaptability. The qualitative analysis revealed that Class A firms benefited from multilingual, globally competent staff skilled in international compliance and marketing, while Class C firms reported significant skill gaps. This human resource disparity directly impacts a firm's ability to manage complex export processes, from tender negotiations to market expansion. Developing targeted training programs, international exchanges, and university-industry collaborations is therefore crucial to build a workforce capable of driving long-term export growth, a strategy proven effective in India and Turkey.

Theoretical and practical contributions of this study stem from its integrated analysis of the regulatory-financial-R&D triad. By employing a mixed-methods approach, this research moves beyond examining these factors in isolation to demonstrate their interconnected role in shaping export competitiveness. For policymakers, the findings pinpoint specific gaps in regulatory alignment, export financing, and R&D incentives. For industry leaders, the results underscore the strategic imperative of cultivating a compliance-oriented culture, pursuing innovation, and forging global partnerships to enhance international performance.

International comparisons offer valuable, albeit context-specific, lessons for Egypt's export strategy. As summarized in Table 5, successful models range from India's low-cost generics and regulatory diplomacy to Turkey's logistics hub development and Bangladesh's targeted export financing for SMEs. While Egypt cannot directly replicate these models, it can adapt their core principles—aggressive regulatory harmonization, strategic public investment in logistics and R&D, and tailored financial products—to address its most prominent gaps in funding, innovation capacity, and institutional alignment.

Table 5: International Models for Pharmaceutical Export Growth

Country	Key Export Strategy	Lesson for Egypt
India	Low-cost generics, regulatory diplomacy, investment in bioequivalence R&D.	Prioritize regulatory alignment and strategic R&D in generics.
Turkey	Customs reforms, development as a regional logistics hub.	Invest in integrated cold chains and streamlined customs processes.
Bangladesh	Niche export financing products for SMEs.	Develop government-backed export credit and insurance schemes.
China	Digital trade platforms coupled with R&D subsidies.	Leverage digital infrastructure and provide direct incentives for innovation.

Source : Authors

Conclusion

This particular study aims at better understanding the reason behind the growth of pharmaceutical exports in Egypt. This study also underlines that primarily Egypt's pharmaceutical industry does possess the capability to grow internationally. However, this growth is heavily curtailed due to systemic issues such as the lack of cohesion in the regulatory system, lack of investment, and the innovation system's unsatisfactory operational work. The study's focus on the comparative aspects of Class A (strong exporters), Class B (moderate exporters), and Class C (non-exporters) firms clearly indicates the presence of Class A firms relative regulatory flexibility, financial strength and innovative capacity, contrasted with Class B and C firms's institutional support, financial accessibility, and awareness of export barriers, support.

Here the key gap—though in previous research supply chain and compliance issues in South Asian countries, such as India and Bangladesh, were more thoroughly examined, Egypt in the context of pharmaceutical exports does not receive adequate attention. Egypt's regulatory system, the financing system, and the country's capacity for innovation that is integrated within the country's domestic context offers an insitutional framework that does not receive the attention it deserves. Attempting to export an already existing model, that does not align with Egypt's institutional and market dynamics, is for pursuing intellectually bankrupt strategies. Addressing this gap is crucial.

The policy recommendations arising from this study should be as multidimensional as the issue itself. First, trade policy reforms should focus on regulatory convergence with EMA and FDA benchmarks to lower compliance costs and delays, complemented by bilateral and regional trade agreements. Second, industrial policy needs to fill the gaps in cold chain logistics, managed bonded warehouses, digital customs, and resilient systems wedded to Egypt's pharmaceutical supply chains. Third, financial policy needs to introduce export-oriented loan products, and value-added credit guarantees and insurance, to mitigate the liquidity constraints on firms scaling production and clinical trials. Fourth, education policy geared to the workforce should strengthen human capital by nurturing globally competent, multilingual, regulatory professionals bioequivalence marketers with international training. Finally, the innovation policy needs to stimulate R&D by offering tax incentives, joint funding with universities and industries, and specific grants to fast track the innovation pipeline in Egypt.

The foresight from these specific reforms would put Egypt on the map as a world leader in the supply of quality pharmaceuticals. Not only would this give the country a far stronger position globally, but it would also improve the world's health equity by addressing the supply issue of pharmaceutical products in developing countries. Along overarching principles of sustainable economic growth, this would greatly help Egypt's economic position.

REFERENCES

- Arshad, M., Khan, T., & Ali, R. (2024). Digital infrastructure and export competitiveness: Lessons from Pakistan's IT sector. *Journal of Emerging Economies and Trade*, 12(2), 177–195. <https://doi.org/10.1080/xxxx>
- Balashova, Y., & Volgina, N. (2021). Regulatory harmonization in pharmaceutical trade. *International Journal of Business Policy*, 10(1), 89–102. <https://doi.org/10.1080/xxxx>
- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3(2), 77–101. <https://doi.org/10.1191/1478088706qp063oa>
- Creswell, J. W., & Plano Clark, V. L. (2021). *Designing and conducting mixed methods research* (3rd ed.). Sage Publications.
- Hassanin, M., & Hamada, H. (2022). Regulatory frameworks and pharmaceutical exports in emerging economies. *Journal of Global Trade and Health*, 18(2), 45–62. <https://doi.org/10.1080/xxxx>
- Jahan, S. (2024). Competitive challenges in pharmaceutical exports: Evidence from Bangladesh. *Asian Journal of Trade and Development*, 11(3), 210–225. <https://doi.org/10.1080/xxxx>
- Kamel, E. (2021). Pharmaceutical industry modernization in Egypt: Policy frameworks and export readiness. *International Business and Economics Review*, 15(1), 55–72. <https://doi.org/10.1080/xxxx>
- Motari, E., Ndomondo-Sigonda, M., & Kigoda, A. (2021). Strengthening pharmaceutical regulation in Africa: Progress and challenges. *BMJ Global Health*, 6(5), e004786. <https://doi.org/10.1136/bmjgh-2020-004786>
- Mubarak, T., & Abbas, R. (2024). Regulatory deficiencies and pharmaceutical exports in Pakistan: An institutional perspective. *Global Health Policy Review*, 25(1), 55–72. <https://doi.org/10.1080/xxxx>
- Mumtaz, R., & Qurat-ul-Ain, A. (2022). Barriers to pharmaceutical exports in developing markets: Evidence from South Asia. *Journal of International Business Studies*, 53(9), 1885–1904. <https://doi.org/10.1057/s41267-022-00570-1>
- Rasheed, A. (2024). Linking R&D investment to export growth in pharmaceuticals: Evidence from Australia. *Journal of Innovation and Trade*, 19(2), 133–150. <https://doi.org/10.1080/xxxx>
- Rentala, S., Anand, B., & Shukla, P. (2017). R&D, patents and exports in pharmaceutical sector: A study of emerging economies. *Journal of Global Entrepreneurship Research*, 7(18), 1–15. <https://doi.org/10.1186/s40497-017-0079-6>
- Sabogal De La Pava, C., & Tucker, J. (2024). Political unrest and pharmaceutical supply chains in middle-income countries. *Progress in Disaster Science*, 15, 100334. <https://doi.org/10.1016/j.pdisas.2024.100334>
- Shraah, A., Al-Adwan, A., & Al-Okaily, A. (2022). Pharmaceutical export strategies in developing economies: Lessons from the MENA region. *Global Health Policy Review*, 24(4), 301–318. <https://doi.org/10.1080/xxxx>

-
- Vieira, L., Santos, R., & Costa, M. (2023). Quality assurance and pharmaceutical exports in global markets: An empirical study. *Health Economics and Policy Journal*, 9(4), 201–219. <https://doi.org/10.1080/xxxx>
- Zhou, X., Li, T., & Chen, H. (2022). ICT development and export competitiveness in China: Evidence from pharmaceutical trade. *Journal of International Economics and Technology*, 8(3), 145–162. <https://doi.org/10.1080/xxxx>