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How to Boost Egyptian Pharmaceutical Exports? Challenges and Opportunities

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HOW TO BOOST EGYPTIAN PHARMACEUTICAL EXPORTS? CHALLENGES AND OPPORTUNITIES

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Abstract

One of the key pillars of the Egyptian economic reform adopted in 2016 was to raise the export rate. Since the pharmaceutical sector is one of Egypt's most established industries, the Egyptian government worked on a national plan to support the exports of medicines. Despite the impact of pharmaceutical exports on economic growth, there was limited research on this topic in Egypt. This study aims to provide a better knowledge of the problems of exporting medications in Egypt by investigating barriers and Covid-19 influence on pharmaceutical export. In-depth semi-structured interviews with representatives from pharmaceutical exporting companies have been conducted. The study's main findings are divided into four groups; problems connected to the export country, such as procedural restrictions in the regulatory bodies; restrictions related to importing countries, such as information barriers and drug smuggling; issues related to the company, such as the qualification of the manufacturing site and the staff; problems with intellectual property rights. The data also demonstrated that the Egyptian government exerted significant efforts to support export. Finally, some recommendations for the government and companies are suggested to overcome these barriers and enhance pharmaceutical exports.

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List of Abbreviations

CPP	Certificate of Pharmaceutical Product
EDA	The Egyptian Drug Authority
EEA	European Economic Area
EMA	European Medicine Agency
EU	European Union
FAMPH	The Belgian Federal Authority for Health and Medicinal Products
FDA	Food And Drug Administration
FTA	Free Trade Area
MOH	Ministry of Health
GATT	General Agreement on Tariffs and Trade
GCC	Gulf Cooperation Council
GDP	Gross Domestic Product
GMP	Good Manufacturing Practices
HEC	High Export Companies
IMS	In-Market Sales
IPR	Intellectual Property Rights
IRB	Institutional Research Board
JFDA	Jordanian Food and Drug Administraton
LEC	Low Export Companies
MEC	Middle Export Companies
MENA	Middle East and North Africa
MOU	Memorandum of Understanding

ODF	Oral Dispersal Film
PHARMEXCIL	Pharmaceutical Export Promotion Council
PPE	Personal Protective Equipment
R &D	Research and Development
SPC	Supplemental Protection Certificate
SME	Small and mid-size enterprises
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization
WHO PQ	World Health Organization Prequalified
WTO	World Trade Organization

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Chapter One: Introduction

1.1. Study Overview

Integration into global markets is an essential step for firms and countries. It offers a high potential for increasing the gross domestic product (GDP) and promoting economic growth in countries (*Martinez, 2004)*. Hence, many firms and governments target increasing export, promoting sustainable growth (*Sraha, 2014*). Egypt has exerted much effort to boost economic growth. Consequently, it started an economic reform program in 2016 *(Momani, 2018).* One of Egypt's strategies is exchange rate devaluation to manage foreign currency scarcity, enhance competitiveness and boost exports *(Momani, 2018).* While the devaluation of the currency in 2016 was a fundamental approach to addressing the shortages in foreign currency, guaranteeing a significant improvement in export performance was not feasible *(Youssef & Zaki, 2019)*. It indicates that meaningful market improvements should start there, with solid and unambiguous regulations to support the manufacturing sector and improve the operating environment for exporting businesses.

Consequently, the Egyptian government has begun working on a national strategy to encourage the export of pharmaceuticals, one of the essential product pillars. (*State Information Service, 2019*). Thus, a precise analysis of the challenges that hinder the export of Egyptian medicines is required to start an appropriate implementation of the national plan. Additionally, analyzing the export market's drivers is essential for assessing a company's global competitiveness *(Morgan, 2011*).

On the other hand, some research in this field has been conducted to illustrate export performance determinants and focus on different challenges that affect the export of medications. There are several different obstacles that affect the export of medications. For instance, it could be a shortage in suitable infrastructure, as in the case

of Bangladesh. There are insufficient centers to conduct bioequivalence studies which are a prerequisite to registering a medicine (*Sheel, 2015*). The exchange rate instability also negatively impacts exports as in the Colombian context *(Escandón Barbosa et al., 2016)*. Moreover, intellectual property rights play a significant role in enhancing or limiting exports, as in the case of European countries. In addition, tariffs and non-tariff may hamper EU pharmaceutical exports *(Blanc, 2015)*. Covid-19 pandemic has an impact on export of pharmaceuticals. Several countries have applied export restrictions, but various governments' reliance on such measures differs. Export restrictions reduce worldwide supply, which drives up prices on the international market *(Blenkinsop, 2020; von der Burchard and Gray, 2020).*

As the pharmaceutical industry is one of well-established industries in Egypt *(N Gage, 2017).* This research aims to examine the main barriers that affect drug export in the Egyptian context, and the impact of devaluation of the currency on export. In addition, it contributes in investigating the impact of covid-19 on pharmaceuticals export. Thus, proper policies are suggested to address these challenges.

1.2. Drug Regulatory System Egypt

The Egyptian Drug Authority (EDA) is the drug regulatory body in Egypt. It was established recently in 2019. Like the Food and Drug Administration (FDA) operates in the United States, EDA is in charge of all pharmaceutical-related operations. Registration and pricing of pharmaceutical products, licensing for manufacturers, and controlling of export and import of medicines are examples of functions of EDA (*EDA, 2021*)[1].

[1] EDA website: https://www.edaegypt.gov.eg/ar/%D8%B9%D9%86-%D8%A7%D9%84%D9%87%D9%8A%D8%A6%D8%A9/%D9%86%D8%A8%D8%B0%D8%A9-%D8%B9%D8%A7%D9%85%D8%A9/. Accessed November 2021

In February 2021, The Egyptian Drug Authority announced the launch of the "Export Support" initiative, which aims to support the Egyptian exports of medical products and work to raise the global competitiveness of Egyptian products. In this regard, the export procedures have been reviewed and updated to ensure that they align with the global rules of the control procedure. In addition, EDA has issued a regulatory guide for the export process with all the rules, procedures, documents, and forms that companies should use to export their pharmaceutical products. Moreover, the procedures of the "Manufacture for Export" system have been reviewed and updated. This system allows the production of medical products and supplies registered abroad on local production lines without registering them by EDA, provided that it is wholly exported abroad and not traded in the local market *(EDA, 2021)*[2].

In March 2022, EDA reached maturity level three by World Health Organization Global Benchmarking Tool. It means that EDA has been found to function effectively and is eligible for inclusion in WHO-listed authorities in the field of vaccines. The "Global Benchmarking Tool" is an evaluation tool that compares regulatory functions to a set of more than 260 indicators to determine their level of maturity and functionality. It covers core regulatory functions like product authorization, testing of products, market surveillance, and the capacity to detect adverse events. After further performance review, regulatory authorities that attain maturity levels 3 and 4 will be qualified for inclusion among WHO-listed agencies. WLA list includes national drug regulatory authorities recognized as meeting WHO and other international standards (*WHO,2022*). This level of maturity that EDA reached increases the trust of other countries in Egyptian pharmaceuticals and enhances the export opportunities.

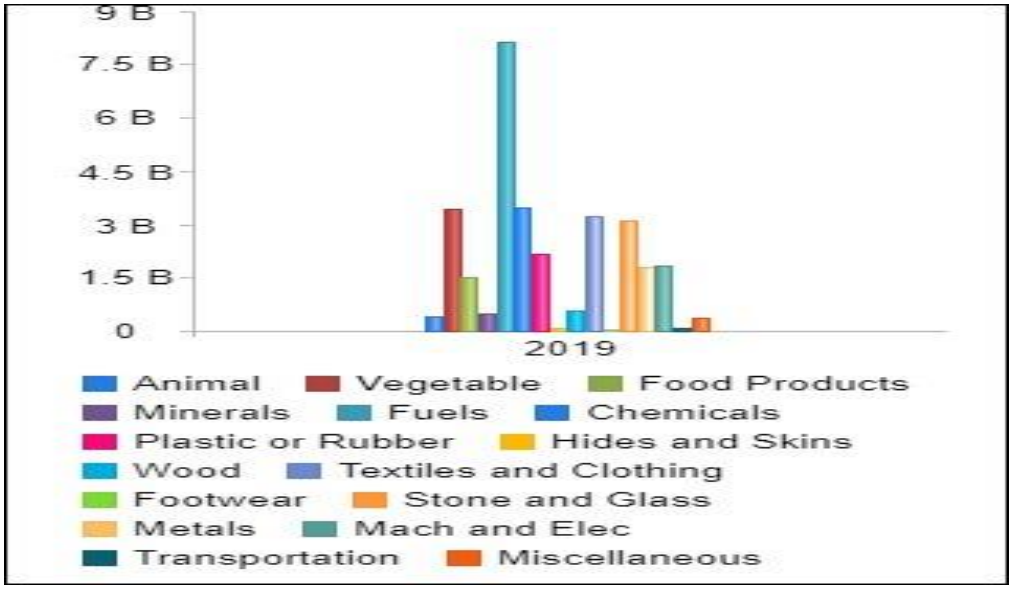
[2] EDA website: mfe-guidline-01-2021.pdf (edaegypt.gov.eg).Accessed November 2021

EDA announced in July 2022, the creation of a new technical consultation service in accordance with the head of EDA decree No. 221 for 2022. The purpose of this service is to assist Egyptian companies to be able to apply their products for prequalification by the World Health Organization (Prequalified products), and growing the number of Egyptian products approved (EDA, 2022)[3].

1.3. Egyptian Pharmaceutical Market

The majority of export in Egypt historically used to be oil exports. However, according to Hoda Youssef and Chair Zaki (2019), oil exports accounted for around a third of the country's overall exports in 2017. Nearly 70% of all exports in FY2017 were non-oil related (*Youssef & Zaki, 2019*). However, exports are primarily centered on conventional or low-value-added goods.

Figure 1 Value of Export Per Product in USD - 2019

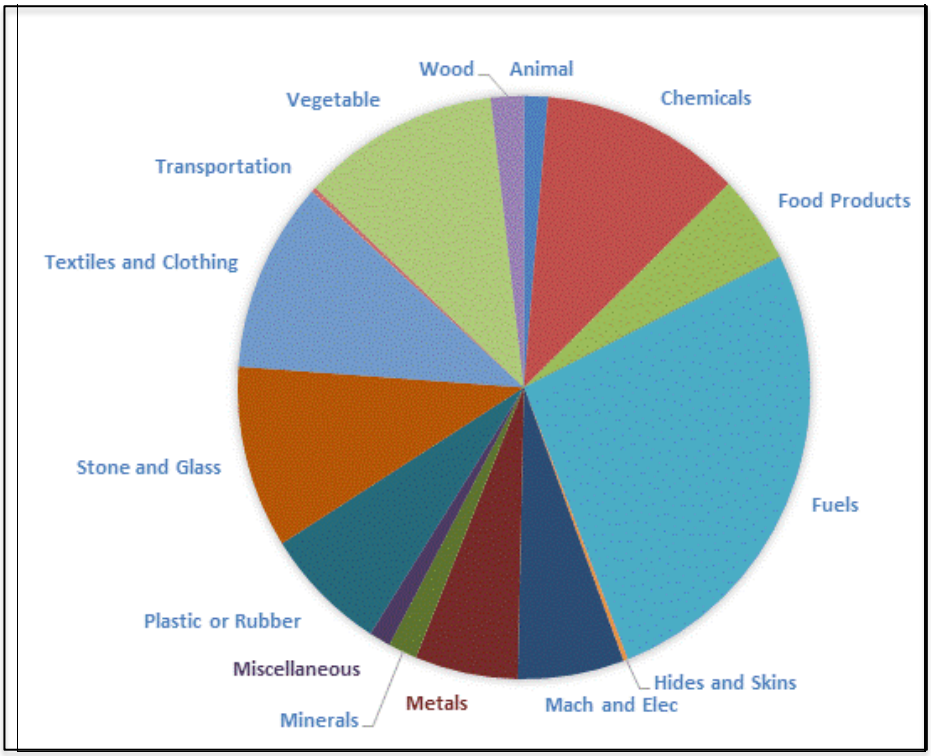


Source:(WITS,2022)

On the other hand, for the share of export per sector, figure 2 illustrates shares of export per product% of total export in 2019.

[3] EDA website: Egyptian Medicines Authority - EMA or FDAconsultancy services to support Egyptian companies to obtain international accreditation by the World Health Organization / or accreditation (edaegypt.gov.eg) Accessed July 2022

Figure 2 Export Product Share % of Total Export in 2019



Source: developed by the researcher according to published data by WITS.worldbank

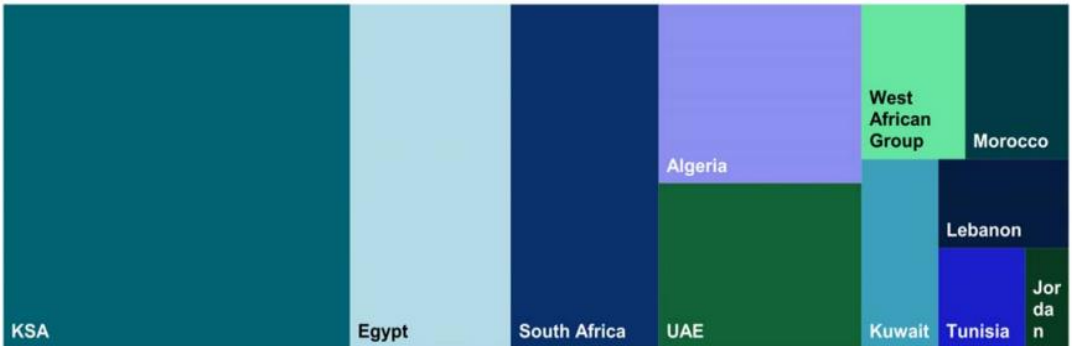
On the other hand, for pharmaceutical products, due to Egypt's high demographic growth and urbanization, Egypt has become among the largest producers and consumers of pharmaceuticals in the Middle East and Africa. This is because any industry's growth, especially the pharmaceutical industry, depends on factors like rapid population expansion, the rise of the generic medication market, and raising public awareness of health issues (*N Gage, 2017*).

As a result, Egypt is considered to have the most substantial drug manufacturing base in the Middle East and North Africa (MENA) region. Egypt's market consists of more

than 90% of units produced locally. Moreover, more than 75% of the value of the market is produced locally (*The council of ministers, 2022*)[4] .

According to in-market sales (IMS), Egypt had the highest increase rate of drug consumption in the Middle East in 2018. Egypt ranks second after Saudi Arabia in terms of the overall market value of drug sales in the area, followed by South Africa, Algeria, and the United Arab Emirates as illustrated in figure 3. Jordan lags with a small share *(ECES, 2020).*

Figure 3 Countries' share in sales of pharmaceuticals in the MENA area in 2018



Source: (ECES,2020)

The situation is different when it comes to pharmaceutical exports. Jordon comes second after Saudi Arabia, ranking 53th globally. Egypt ranked 58th globally in 2021. Egypt has jumped 11 ranks compared to 2019 *(Workman, 2022).* For pharmaceutical products, Egypt primarily exports to Asian countries, mainly Yemen, Saudi Arabia, Iraq, and Kazakhstan, in addition to, Sudan as of 2014 (*N Gage, 2017*). Before 2011, there were political barriers to exporting to some African countries. However, after the 2011 revolution, Egypt's foreign policy has undergone a significant transformation, and it is now making a tremendous effort to tap into African markets (*N Gage, 2017*). According to an infographic report developed by the Egyptian council

[4] The council of ministers Facebook official page: https://www.facebook.com/100064812882317/posts/431849398985486/?d=n. Accessed July 2022

of ministers in June 2022, the percentage of pharmaceutical exports increased in 2021 by 28.7% compared to the exports in 2016 *(The council of ministers, 2022)*[5].

Egypt has confronted various obstacles that affect its export, especially after 2011. One of these challenges is a shortage in foreign currency and limits on its transactions. Thus, a black market has emerged with a reduction of the international reserve, resulting in a decrease in Egypt's competitiveness (*Youssef & Zaki, 2019*). Hence, exports have been affected negatively. It hit its lowest level of 5.6% of GDP in 2015 and 2016 since the early 2000s. An economic reform program was started in 2016 to decrease the dependence on imports and increase exports; however, it has not been reflected positively on pharmaceutical exports. Dr. Maged George (*2019*), the chairman of the Egyptian Export Council of Medical Industries, has highlighted some challenges that affect the export of Pharmaceuticals after currency devaluation.

One of these obstacles is the official prices of the Egyptian pharmaceuticals compared to their actual cost. The manufacturing costs increase as the industry relies mainly on Egypt's imported raw materials and packaging materials. Moreover, Egypt has removed subsidies for energy, which makes production in the country more expensive (*George, 2019*). In addition, as cited by Hafez (*2016*), the regulatory system in Egypt hampers pharmaceuticals export. It does not align with international standards. Lack of investment in research and development (R&D) of pharmaceuticals has an impact on meeting international advancement in the left field. Furthermore, there is not an established clinical trials law. Hence, it is difficult for local companies to follow international requirements and be able to penetrate foreign markets (*Hafez, 2016*).

[5] The council of ministers Facebook official page: https://www.facebook.com/100064812882317/posts/431849398985486/?d=n. Accessed July 2022

1.4. Problem Statement

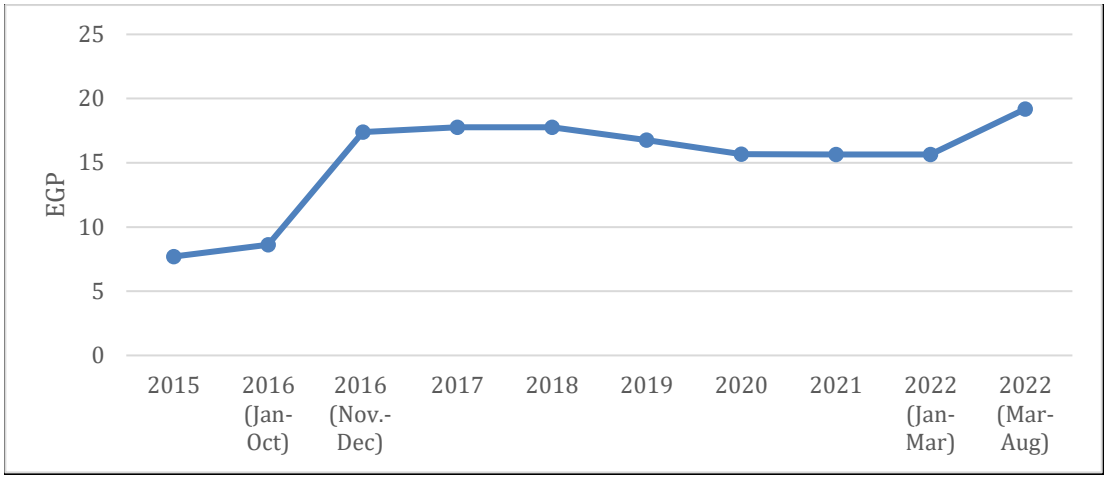
The medications industry is rooted in Egypt. Many factories and companies are in the market (*N Gage, 2017*). Egypt ranked 58th in medication exporting countries worldwide (*Workman, 2022*). It was the 3rd Arab country after Saudi Arabia, and Jordan (*Workman, 2022*). So, according to statistics and available data, there are unknown causes for such a gap in exports compared with other Arab countries.

The performance of the pharmaceutical business has been impacted by the Egyptian government's decision to float the currency rate in November 2016. The EGP to USD exchange rate was 17.4 after the flotation as opposed to 8.62 before the floatation (*CBE, 2022*) figure 4. Thus the high cost of importing intermediate inputs has increased the production costs. Over the past decade, exports have fluctuated around the same rate (*ECES, 2020*). While imports continued to grow, except for 2016-2017*(ECES, 2020).* As the Egyptian pound's flotation increased the cost of imports and industrial inputs.

Floating the local currency in November 2016 has had additional negative consequences, such as decreasing the growth rate. The growth rate fell to the lowest level in 2017, causing a sharp decline in the pharmaceutical sales growth rate by - 6 percent *(ECES, 2020).* There were concerns about high import costs and foreign firms' stranglehold on the market, despite the strong comeback of the growth rate in 2018, which did not endure for very long. The growth rate again decreased to 7 percent in 2019 *(ECES, 2020).*

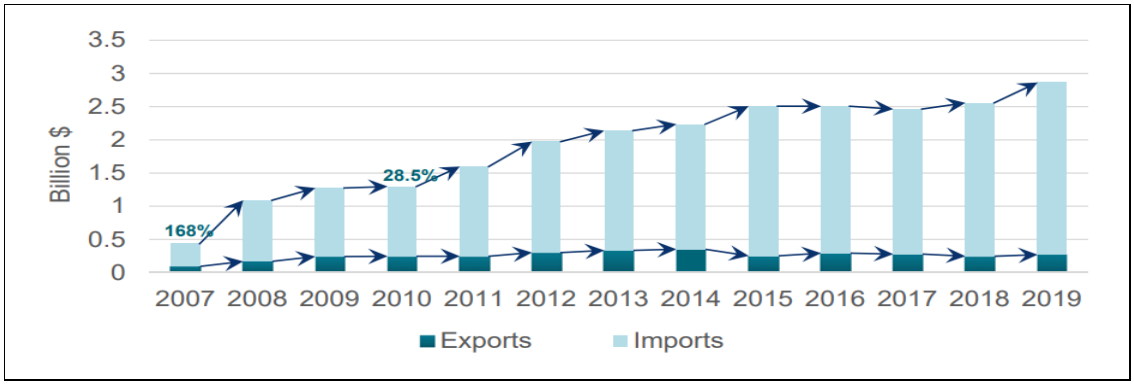
According to the UN COMTRADE database, there is a significant gap between Egypt's imports and exports of pharmaceutical products in 2019 as illustrated in figure 5. Egypt's exports of pharmaceutical products were only $272 million, while the imports were nine times bigger, accounting for approximately $2.61 billion *(ECES, 2020).*

Figure 4: EGP to USD exchange rate from 2015- to Aug 2022



Source: developed by the researcher according to published CBE data

Figure 5: Pharmaceuticals exports and imports in Egypt from 2007 to 2019



Source: (ECES,2020)

1.5. Policy Relevance

Export is an essential tool for enhancing the GDP of a country. The pharmaceutical industry has high potential and is a well-established industry in Egypt. Hence, a national plan to support the exports of medicines as one of the critical pillars of products has started as announced by the Prime Minister (*State Information Service, 2019*). Secondly, to implement the economic reform program, Egypt has adopted a strategy to decrease import dependence and increase exports *(Youssef & Zaki, 2019)*. In addition, the government is working on increasing non-oil exports. Finally, according

to Egypt's vision 2030 (*Ministry of planning and economic development,2021)*[6], objective three emphasizes that Egypt aims to achieve specific targets. These goals include achieving knowledge-based economic growth, digital transformation, improving the business environment, fostering a culture of entrepreneurship, increasing employment rates and decent employment opportunities, increasing the economy's resilience and competitiveness, achieving financial inclusion, and incorporating the environment and social dimension into economic development. Thus, this thesis is proposed to play a considerable role in Egypt's economic growth by identifying the challenges and obstacles that hinder pharmaceutical exports despite the existing potential of the Egyptian market.

1.6. Structure of The Thesis

The thesis is organized into five chapters. The first introduces the subject, focuses on the Egyptian pharmaceutical market and regulatory environment, establishes the importance of the study, and concludes by illuminating the research questions. The second chapter thoroughly analyzes the literature, discussing issues with drug export in Egypt and other nations' approaches to the issue. The third chapter includes operational definitions in addition to the ideas that serve as a framework for the study's knowledge and how they are used in the Egyptian setting. Additionally, it provides information on the general study design and strategy, sample selection, data collecting, and data analysis procedures to characterize the research process. The thesis also elaborates on ethical issues, study restrictions, and delimitations in the third chapter. The fieldwork results are given and carefully examined in the fourth chapter to identify the key

[6] Ministry of Planning and Economic Development Egypt's: https://mped.gov.eg/EgyptVision?lang=en#:~:text=Egypt%20Vision%202030%20focuses%20on,life%2C%20in%20conjunction%20with%20high%2C accessed Novemver, 2021

obstacles preventing the export of pharmaceuticals and the steps the government has taken to address the issue. The fifth chapter provides a conclusion and some remedies .

1.7. Research Questions

The key question this study will attempt to answer is:

What are the challenges that affect the export of pharmaceuticals in Egypt?

Sub-questions include:

- How could the readiness of the company affect its exports?
- To what extent does the regulatory system in Egypt affect the export of medicines in Egypt?
- What factors related to importing countries hinder the export of Egyptian drugs?
- How could applying TRIPS agreement affect pharmaceutical export?
- How did the Covid-19 pandemic affect the export of pharmaceuticals?

Chapter Two: Literature Review

The worldwide growth of businesses is a vital engine of economic activity *(Leonidou & Katsikeas, 2010*). Companies' engagement in international markets boosts national competitiveness, produces foreign currency revenues, and produces higher-paying employment, all of which contribute to long-term economic growth. (*Abor, 2011*). While certain firms may have intrinsic-proactive motivations to participate in foreign operations (*Leonidou, Katsikeas, et al., 2007*), external triggers play an essential role in early promoting or continuing engagement in international activities (*Owusu-Frimpong & Mmieh, 2007*). The effectiveness of external stimuli, such as export aid, is determined by how clearly exporter requirements are defined and how accurately policymakers can meet those needs through tailored support. (*Miocevic, 2013*).

2.1. Export Performance

Improving export performance is critical for developing country businesses in the global marketplace to ensure competitiveness, development, or survival (*Matanda and Freeman, 2009*). As a result, it is crucial to determine the impediments to businesses' export performance in order to enhance their worldwide competitiveness.

One of the most crucial indicators of a company's success is its performance in the export market. Research on export performance has significantly increased during the last few decades. (*Sousa et. al, 2008*). Several pieces of research have been done to understand export performance and its determinants. Export performance results from a company's activities in export markets (*Papadopoulos & Martn Martn, 2010*). In addition, the performance of export may be described as the results of a company's overseas activity.

Most academics such as Cavusgil and Zou (*1994*), Katsikeas et al. (*2000*), Lages and Lages (*2004*), Lages et al. (*2005*), Leonidou et al. (*2002*), Matthyssens and Pauwels (*1996*), Shoham (1998, 1999), Styles (*1998*), and Zou et al. (*1998*) agree that the performance of export is multidimensional. However, those academics argue about which indicators should be utilized to quantify the variable. Many research takes into account two separate dimensions: an objective (economic) and a subjective (strategic). It is considered that both objective and subjective metrics are complementing each other and that it is best to utilize both in tandem to offer a complete picture of export success (*Stoian and Rialp, 2011*).

Due to the multidimensionality of export performance, it is tough to distinguish and analyze the conclusions of other researches (*Sousa, 2004*). To offer a reliable evaluation, it is required to have measurements for different export performance aspects in addition to the usage of several measures. Those measurements will capture the narrative of the success of a firm's export (*Solberg and Olsson, 2010*).

2.2. Export Barriers

The barriers of export should be investigated and well-studied as they could waste the firms' resources and threaten both the effectiveness and efficiency of firms' operations. Researchers in international business have been strongly focusing on studying the negative impacts of the export barriers on the internationalization behaviors and activities of medium and small enterprises (*Ortega, 2003*). Many studies have employed diverse viewpoints to construct a set of noticeable obstacles. Researchers have categorized the barriers into different categories.

2.2.1. External and internal barriers classifications:

Leonidou (*2004*) and Koksal and Kettaneh (*2011*) have found that there are both internal and exterior obstacles.

2.2.1.1. Internal factors:

Leonidou (*2004*) has classified the Internal barriers into three sub-groups

Informational barriers:

According to Winter's study from 1987, of all the resources needed for small and mid-size enterprises (SMEs) to enter international markets successfully, the most important and challenging to acquire is information about the target market that would provide SMEs a competitive advantage (*Liesch & Knight, 1999*). Firms with appropriate levels of information experience less uncertainty than other firms with less knowledge *(Liesch & Knight, 1999).*

Johanson and Wiedersheim-Paul (*1975*) assert that for SMEs with little resources to effectively enter abroad markets, having the appropriate quantity of information is crucial.

In their research, Kneller, Pisu, and Yu *(2008)* confirm that companies face potential obstacles. Asymmetric information or insufficient data dissemination between buyers and sellers results in additional costs to gather crucial data about export markets and cultural differences.

Functional barriers

The primary functional barriers that prevent a company from exporting are those relating to human resources, production, and finances (*Vozikis & Mescon, 1985; Leonidou, 2004*). The experiences of managers abroad are an invaluable resource. It contributes to specialized knowledge that is tough for rivals to imitate. The manager's exposure to the world and time spent there. Living, working, and traveling abroad aid in a manager's acquisition and retention of information about world events. (*Athanassiou & Nigh, 2000; Ruzzier et al., 2007).* Learning about international business

possibilities and practices through travel is highlighted by researchers Leonidou et al. *(1998),* Reid *(1981), and* Ruzzier *et al. (2007*).

Mpinganjira's study, on the other hand, emphasized the relevance of personnel obstacles, such as insufficient awareness about the prospects of export in addition to employees' shortage skilled in exporting. (*Mpinganjira, 2011*).

Marketing barriers:

Marketing barriers include those related to the product, price, distribution, logistics, and promotion (*Vijay,2015*). The capacity to recognize and seize new market opportunities abroad is the primary success aspect for new projects so that they could successfully compete in the global markets (*Ren et al., 2014*), according to earlier research on the contribution of the marketing to SMEs' internationalization (*McDougall & Oviatt, 2000*).

According to the research by Kubková et al. (*2014*), the majority of SMEs internationalize their businesses due to factors such as increased client product portfolio, decreased local demand, sales pressure, and a fiercely competitive domestic market. The same study also revealed that Austrian businesses expand internationally due to comparable characteristics, such as higher sales prices in overseas markets or minor rivalry (*Kubková et al., 2014*).

2.2.1.2. External factors

External barriers have been classified into four groups according to the Leonidou model (*2004*).

Procedural barriers:

New procedures and/or techniques, inadequate payment collection on the global market, and communication challenges are some of the operational challenges that firms face (*Leonidou, 2004*). Some studies categorize export procedural-related

constraints into controllable and uncontrolled categories. Because controllable obstacles are regular duties that may be conquered by managerial experience, they can be learned to regulate with time and practice. On the other hand, non-controllable obstacles are problems that must be addressed on a case-by-case basis (*Ramaswami & Yang, 1990*). Consulting companies can offer the necessary help to get over operational challenges (*Ramaswami & Yang, 1990*).

Governmental barriers:

Governmental obstacles describe the government's stance toward exporters, which can be either supportive or unsupportive. These refer to two relevant difficulties; The first is the inadequate aid and incentives offered to the companies. Secondly, the regulatory framework's challenges and constraints affect export practices (*Leonidou, 2004*).

Task barriers:

Globally, various product requirements exist because of various factors, including terrain, climatic conditions, a nation's economy, taste, and customs (*Vijay,2015*). Task barriers are challenges related to the previous requirements. Therfore, companies have to invest a lot of time and money to adapt to all these developments (*Leonidou, 2004*). If a business wants to outperform its competitors, it must create products that are widely used. Levin, Klevorick, Nelson & Winter (*1987*) and Baumol, Nelson & Wolff (*1994*) suggested that creating such products with shorter lead times would help companies keep a competitive edge over their rivals.

External environmental barriers

External environmental (or exogenous) constraints include problems with the external market's economic, political-legal, and socio-cultural environment (*Leonidou, 2004*). According to Wach and Wehrmann (*2014*), the external environment of business

may be studied at all scales, from the local to the global. Most of these obstacles are brought about by rival businesses entering the market, currency fluctuations, supply and demand changes, etc.

2.2.2. Other classification of export barriers typology:

Leonidou (*1995*); and Morgan (*1997*) have classified the barrier into other four types; Internal-Domestic, Internal-Foreign, External–Domestic, and External– Foreign. Internal obstacles are related to the local market and are present within the company. Secondly, barriers in the residential environment are external and beyond the company's control. The third group is barriers that affect a company's marketing strategy in a foreign setting, including internal and foreign. Finally, the uncontrollable boundaries in a foreign environment are external.

Leonidou (*2000*) proposed 20 different barriers to exporting, such as strong competition abroad, lack of ability to offer fair prices, decline of economic conditions abroad, and inadequate government assistance. Moreover, insufficient information for locating and analyzing foreign markets, high political risk or instability abroad, understanding the high business risks and costs abroad, high tariff and non-tariff barriers, lack of working capital, insufficient transportation, and infrastructural facilities are among barriers proposed by Leonidou. Restrictions resulted from rules and regulations, diversity in the attitudes and habits of customers, unfavorable foreign exchange rates, complications in obtaining and locating representation, dissimilarity in the standards and specifications of products, untrained and incompetent staff, the ignorance of the practices of foreign business, other cultural traits and language abroad, and problems with handling documentation are the rest of challenges. Leonidou' categorized those 20 barriers into main six main groups: constraints related to corporate resource, differences in environments, the bureaucracy and legislation of export,

government indifference, foreign market entry, operating difficulties, and competitive pressures. Leonidou's conclusion declared that the most significant obstructing effect relied on issues associated with the competitiveness of export such as strong competition abroad and the lack of ability to offer reasonable prices (*Leonidou, 2000*).

Ahmed, Craig, Baalbaki, and Hadadian are researchers who conducted a different study in Lebanon that explored the issues and difficulties of exporting (*Ahmed et al., 2004*). The researchers interviewed 61 exporters and non-exporters so that they could identify barriers to export. They have concluded that five factors significantly contribute to export barriers: inadequate government assistance, competition from firms in abroad markets, policies related to pricing and promotion, high foreign tariffs, and insufficiency of financial capital (*Ahmed et al., 2004*). Interestingly, one year later, Craig and Ahmed have undergone the same research on the barriers to export in Australia (*Craig and Ahmed, 2005).* They have repeated the same interview method but focused only on exporters. Export venture management characteristics and adapting to foreign market needs were the two main findings of their new research paper (*Craig and Ahmed, 2005*). The disparity between the two research projects' conclusions about the two countries' economies can be attributed to a few factors: the specific environmental factors and political and economic conditions. As a result, testing concepts in various institutional, economic, political, cultural, and political locations produce contextual meanings which may assess the validity of popular hypotheses (*Koksal and Kettaneh, 2011*).

In Turkey, Altinas, Tokol, and Harcar have also studied the barriers to export (*Altinas et al., 2007*). The researchers have identified 20 different barriers and were able to categorize them into five groups: barriers related to diversity, procedures, internal inefficiency, competition, and government. The researchers have identified that

the procedural barriers, then the competition in the foreign markets, have been the most impactful factors on export performance. Moreover, the researchers have revealed that the most significant factors in export barriers were bureaucracy requirements and competition in markets abroad.

Another classification for typology barriers is based on knowledge, resources, procedures, and exogenous factors by Arteaga–Ortiz & Fernandez-Ortiz (*2010*). Lack of knowledge about export aid programs and knowledge hurdles are major export impediments. On the other hand, barriers caused by a lack of financial resources inside the company are known as resource barriers. Inadequate manufacturing capacity, a lack of credit or financing to support export sales, a lack of local banks, and a shortage of professionals and people for exports are just a few examples of resource obstacles. Finally, procedural barriers include bureaucracy, cultural, language, and logistical impediments. Exogenous impediments include uncertainty in global markets, competitive behavior, government measures, currency rate volatility, etc.

Thus, barriers could be categorized in different ways. It could be classified as challenges related to the company, for instance trained staff and quality and safety standards. The second category is barriers related to the domestic country, such as the demographic of the county and the adopted policies. Finally, the factors related to the importing country, for instance, the available data about the external market and international competition, are other kind of barriers

2.3. Barriers to Export of Pharmaceuticals

Constraints and barriers that influence the export of pharmaceuticals have been studied in the literature. These constraints are almost the same barriers that companies confront in other industries. The studies can be categorized into four themes: those focusing on the effect of the quality of the products or facilities, Intellectual property

rights for medicines, those related to the internal system in the exporting country, and finally, external factors in the importing country.

2.3.1. Barriers related to company/ product:

First, factors related to the product and the company are one of the main challenges that may have a negative impact on exports. For example, in Iran, Fardazar and his colleagues have assessed the pharmaceutical industry policies of Iran *(2019*). They wanted to identify issues in addition to providing strategic solutions to overcome such challenges. They found a lack of good manufacturing practices in Iranian facilities. Moreover, the absence of qualified personnel in export teams, who would be responsible for marketing the products, is a big challenge for Iranian companies. Another reason is the unfamiliarity with international markets (*Fardazar et al., 2019*). On the other hand, in China, Huang, *et. al* have highlighted that the absence of WHO PQ for Chinese pharmaceutical products could hamper entering new markets (*2018*). WHO has established a prequalification program to guarantee the quality of medicines. Thus, for many international tenders and public sector procurers, WHO PQ sets an essential requirement for entering the market, which opens new external markets and increases the export rate of pharmaceuticals. It also highlights factors related to the company's readiness and/or the product that affect its eligibility to export.

2.3.2. Barriers related to intellectual property rights (IPR):

Developing new medicines consumes too much time and costs millions of dollars. Therefore, there is a tremendous difference between the characteristics of the medicines industry, particularly the pharmaceutical sector, from other manufacturing industries. This can appear in the industry's strict patent protection (patent laws cover procedures, materials, and products) along with the corporations' enormous R&D spending. These two significant differences are due to the risky, long, and costly

process for developing new products for markets. As a result, the world's pharmaceutical production and exports are led by advanced economies with resources and facilities, qualified infrastructure in addition to high levels of capital stock. Thus, several European countries, the USA in addition to Japan, are critical actors in the world pharmaceutical market. In addition, a few developing countries, such as India and China, are also significant manufacturers in this market. Europe and the US economy appear to preserve their leading status in the global market due to the multinational firms' dominance of this industry *(Muratoglu, 2017).*

IPR protection may either have a good or negative influence on exports since it can result in the market growth effect, the cost reduction effect or the market power effect when external patent protection is in place (*Maskus and Penubarti, 1995).* In countries with strong patent laws, such as European countries, it is not allowed for companies to manufacture generic products for drugs with valid patency. If the export of these goods is intended for a nation where the appropriate patents have either expired or were never obtained, this has a negative impact on the export rate. Nonetheless, European Commission is studying to introduce a Supplemental Protection Certificate (SPC) manufacturing waiver, which will allow exporting of these generic products under certain conditions (*Minssen et al. 2019*). On the contrary, Boring *(2015)* has found that the TRIPS agreement would positively influence the United States of America's exports of pharmaceuticals to non-advanced economies. Empirical findings indicate that a critical export determinant for Indian pharmaceutical exports is the strong patent protection in importing nations. In other words, the higher the patent protection’s strength, the better the export performance will be. But this finding cannot be generalized for other Indian goods (*Pradhan, 2007).*

2.3.3. Barriers related to domestic country:

Challenges related to the exporting countries are another main pillar influencing the export of medicines. It could be a limitation in the established regulation or a shortage of suitable infrastructure. In the case of India, it sets as one of the significant generic distributors all across the world. India, however, confronts difficulties in establishing a standard export and distribution network in India (*Gupta, 2018*). The lack of rules and data regulating exports' distribution chain is a challenge. Uncertainty of information and absence of recognition of the regulatory authority of India by any international organization are also limitations for export (*Gupta, 2018*).

On the other hand, for Bangladesh, the absence of modern laboratory and bioequivalence centers are major limitations in the infrastructure of Bangladesh. In addition, restrictions on customs for sending drug samples and constraints of Bangladesh bank to remit transfers are internal challenges for export (*Sheel, 2015*). In the case of the Colombian market, the Colombian pharmaceutical industry depends on importing raw materials. Consequently, there would be instability in the drug supply and export depending on economic changes in the countries that export supplies to the Colombian market *(Escandón Barbosa et al., 2016)*.

2.3.4. Barriers related to importing country:

Finally, not only internal barriers and quality issues hurt export, but also external challenges play a substantial role in hindering the export of medications. For instance, in the case of Bangladesh, external limitations, country image, and high fees for registration in importing countries hinder the easy penetration of international markets (*Sheel, 2015*). Rental & Anand (*2013*) have found that the absence of an established healthcare system in importing countries impacts the export rate. It is observed that developed countries with mature healthcare systems have a higher

preference for importing generic medicines with lower costs in order to lower healthcare costs. On the other hand, the study reveals that transport costs and tariff and non-tariff barriers in importing countries tend to hamper the European exports of medicines to other countries *(Blanc,2015*). For Sweden's pharmaceutical exports, it has been found that land-locked countries import a smaller amount. In addition, increasing the distance between importing and exporting countries has a negative impact on export (*Adolfsson,2007)*

2.4. Export Policies for top exporting countries:

This section reveals some adopted policies and initiatives by the two countries. India and Jordan are leading countries in the export of pharmaceuticals worldwide and in the middle east, respectively.

2.4.1. India

The pharmaceutical industry in India is among the top three countries in terms of volume and among the top 13 countries in terms of value. This could be attributed to the enormous base of raw material in addition to the accessibility of a skilled workforce. Generic drugs constitute approximately 70% of the Indian pharmaceutical market. As a result, India is also one of the largest global generic drug suppliers, accounting for 20%-22% of the global export volume *(IBEF, 2022*). From 2018/2019 to 2019/2020, India's pharmaceutical exports, such as drug formulations & biologicals, bulk drugs & drug intermediates, surgical products, and herbal products, have expanded by 7.59% (*Ministry of Commerce and Industry in India. 2020*)[7]. In 2004, India established the Pharmaceutical Export Promotion Council (PHARMEXCIL) by the Ministry of

[7] Ministry of commerce and Industry in India website: https://commerce.gov.in/about-us/divisions/export-products-division/export-products-pharmaceuticals/ accessed March 2022

Commerce and Industry Government of India in order to promote pharma export *(IBEF, 2022)*. Since PHARMEXCIL is an industry body which enjoys autonomy in administration such the creation of posts, service matters, it is not under the administrative control of the government.

India has undergone amendments in the intellectual property rights regime, which helped the Indian pharmaceutical industry be more export-oriented, which will help counter the threat of reduced domestic operability. Furthermore, the Indian pharmaceutical industry shifted exports into export formulations more than bulk exports. In addition, Indian firms have reduced costs to maintain their price competitiveness globally. As a result, firms directed their imports towards cheaper sources of bulk drugs, their intermediates, and raw materials *(Joseph, 2012*).

2.4.2. Jordan

The pharmaceutical industry in Jordan considers a well-established industry. It is the second largest export industry there. Jordon ranks 53th globally *(Workman, 2022)*. Jordan has developed the National Policy since 2014, which helps promote drug exports. For instance, one of its main objectives is to promote the local pharmaceutical manufacturers' technical, productive, and marketing capacities to make them competitive in local and export markets. As a result, a few steps should be taken, such as encouraging the research and development of the domestic industry toward the production and marketing of new and improved products. In addition, high-quality production in the domestic medicine industry should be ensured. Jordan should also encourage the establishment of plants to produce basic raw materials in order to achieve its target of promoting local medicine production (*JFDA, 2014*).

Moreover, the Jordanian government aims to take action to increase the competitiveness of the local pharmaceutical industry. The government should also

encourage local industries to help achieve self-sufficiency in essential medicines. Most importantly, pharmaceutical manufacturers should be encouraged to maximize the use of their installed production capacity for export purposes. Lastly, in order to keep pace with the constant evolution in the pharmaceutical industry, the government should train technical staff in the domestic drug industry (*JFDA, 2014*).

2.5. Impact of Covid-19 on Export

In 2020, COVID-19 brought about economic and social disruptions which greatly affected global trade. According to the report "Global trade Update" published by UNCTAD (Nov. 2021), world trade documented a drop in value in 2020 by 9%, a 6% decrease in trade in goods, and a 16.5% decrease in trade in services. During the first half of 2020, the COVID-19 effect on global trade was very severe, with a 15% drop in value. In the third quarter of 2020, global trade began to recover with an even more robust recovery in Q4 2020. In Q3 2020, the recovery was significant because of the increase of trade in commodities; however, trade in services continued to significantly lag below averages. In Q4 2020, there was an 8% growth in global trade in goods on a quarter-over-quarter basis. Nevertheless, trade in services continued to be the same as Q3 2020 levels *(Global Trade Update | UNCTAD, 2021).*

A slowdown in trade recovery in goods was projected for Q1 2021 with a 1.5% drop comparative to Q4 in 2020. Moreover, further decline in service trade continued as there was a 7% drop comparative to Q4 in 2020. The slow recovery is primarily attributed to the continuous disruptions in the travel sector *(Global Trade Update | UNCTAD, 2021).*

Import and export figures for some of the largest trading economies throughout the world serve as examples of how trade patterns altered in 2020. All major economies have been exposed to substantial recessions in both imports and exports of goods, with

an exacerbated effect in services trades in the first half of 2020. Although laws have been improved earlier in the year, trade value continued to be lower for almost all major economies in the Q3 of 2020 compared with in the same period of 2019. Chinese goods exports showed an exception to this trend as they grew by approximately 3%. In Q4 of 2020, in many major economies, trade in goods has substantially ameliorated; however, trade in services remained below averages. Throughout 2020, China and India have relatively better exports of services than other major economies *(Global Trade Update | UNCTAD, 2021)*.

In the second half of 2020, except for energy and transportation equipment, most product sectors have seen a resurgence in trade. As the value of their trade was about one-third lower than the same period of 2019 *(Global Trade Update | UNCTAD, 2021)*.

While COVID-19 has increased demand for certain commodities, such as textiles (including personal protective equipment (PPE)) and (home) office equipment, the trade recovery in Q3 2020 was primarily driven by these industries. However, in Q4 2020, the rebound has been much more extensive, with trade across most industries recording significant growth. During the COVID-19 pandemic, China was capable of capturing market share in many sectors, especially the industries that have been most badly impacted, such as transportation technology and motor vehicles. However, China's exports are less competitive in several industries that had a boost in trade during COVID-19, such as communication equipment and office machinery. Moreover, VietNam, Thailand and Taiwan, Province of China have relatively succussed in capturing the additional demand in these sectors *(Global Trade Update | UNCTAD, 2021)*.

On the other hand, according to a UNCTAD report published in Feb 2022, all economic sectors, except for transportation equipment, had a sizeable year-over-year growth in the value of their trade-in Q4 2021. The significant increase in the value of commerce in the energy industry results from high fuel costs. Metals and chemicals had above-average trade growth as well. The global shortage of semiconductors had a muted effect on Q4 2021 trade growth in communication equipment, automobiles, and precision instruments *(Global Trade Update | UNCTAD, 2022).*

2.5.1. Effect of Covid-19 pandemic on the export of pharmaceuticals in different Countries

At the beginning of the pandemic, 75 countries restricted the exports of essential pharmaceuticals and medical products including face masks, antimicrobials, and medical ventilators (*Pelc, 2020*). Banning export decreases supply globally, which surges prices in the world market. As a result, these measures may have eventually impacted human lives. While many nations have imposed the export ban, the dependence of different governments on such policies varies. Governments also seemed to pursue a determined plan by banning export to some trading partners while excluding others. Respirators and a variety of PPE, such as gloves and surgical masks, have been restricted for export by the United States. However, Mexico and Canada have been excepted from this rule. After some of European Union (EU) member states put their export bans on one another, harming nations such as Italy, which had massive need for PPE, the EU imposed an everyday licensing regime on its exports. The EU then took action to ignore Iceland, Liechtenstein, Norway, and Switzerland. Exemptions were subsequently granted to the Balkan nations which four of them are EU candidate countries *(Blenkinsop, 2020; von der Burchard and Gray, 2020).*

India, the United Kingdom, Germany, Norway, Belgium, China, Turkey, Italy, Brazil, France, Russia, Israel, Argentina, Poland, Belarus, and the United States of America have put the most significant restrictions on the export of vital medical supplies, in that order respectively *(Pelc, 2020).* The United States has imposed much fewer export bans than European countries such as the United Kingdom and Germany.

On the other hand, India has been the most rigorous in imposing export bans during the outbreak. Considering India currently serves as the world's pharmaceutical supplier, providing the majority of generic drugs and more than half of the world's immunizations. Although India has taken the greatest steps to limit its exports, it has also granted exceptions to a few of its neighbors. After discussions with the White House, India agreed to eliminate its prohibition on exporting hydroxychloroquine to the US while keeping other limitations in place (*Haidar, 2020*).

In April 2020, the Belgian Federal Authority for Health and Medicinal Products "FAMPH" banned exporting drugs outside the European Economic Area (EEA) in order to overcome possible insufficiencies in medicines and raw materials that were used to treat COVID-19. Moreover, in order to permit exports to EEA countries, FAMPH should be notified first, in addition to the intention of supplying medicine or raw material to an EEA member state (*Vooren, 2021*). However, on April 8th, 2020, Belgium reversed its decision to ban exporting drugs to non-EEA countries. Belgium instead installed a system of export controls (*Vooren et al.,2020*).

However, a nation like Canada, which relies heavily on imports of medicines and PPE due to a lack of local manufacturing capability in both sectors (*Lipkus,2020*), cannot afford to impose export restrictions.

Export restrictions are forbidden by general agreement on tariffs and trade (GATT)’s article XI while allowing for temporary measures in order to "prevent or

relieve critical shortages" (*WITA, 2020*). As a result, these exclusions would probably apply to all the export restrictions the various nations had throughout the pandemic. This allowed guaranteeing the availability of new drugs and vaccines for treatment and protection of the Covid-19 virus to all countries, not only restricted to innovative countries,

2.5.2. Effect of Covid-19 pandemic on the export of pharmaceuticals in Egypt

Pandemic has negatively affected the availability of raw materials, finished products, and medical devices. As mentioned before, many countries have imposed limitations on exporting their products; therefore, importing the needed raw materials and finished products by the Egyptian companies was not easy. There was a noticeable shortage in protective items, including medical masks, gloves, and alcohol. As a result, their costs doubled (*ECES, 2020*). Consequently, as a part of the government's efforts to battle the new coronavirus, Egypt decided in March 2020 to halt exports of face masks, anti-infective supplies, as well as alcohol for three months. In addition, companies should supply their commodities to the Unified Procurement and Medical Supply Authority to ensure the availability of these goods in the governmental sector (*ECES, 2020*). The minister of trade and industry emphasized that the new decisions aim to meet the residents' demands for these items while also taking preventive measures to shield them from any potential consequences of the COVID-19 outbreak (*Asharq Al-Awsat, 2020*). After six months of banning, the ministry of trade has removed the restriction on exporting all forms of alcohol and its derivatives, as well as face masks and equipment to combat coronavirus (*Egypt forward, 2020*).

According to the last infographic report posted by the council of ministers (*The Council of ministers, 2022*)[8], the indicators of the drug trade in Egypt, where the volume of sales of the Egyptian pharmaceutical market reached 149 billion pounds in 2021 compared to 62 billion pounds in 2015, an increase of 140.3 percent. Moreover, the volume of exports of medicines and medical devices reached $691 million in 2021 (The peak of the outbreak in Egypt), up from $537 million in 2016, a 28.7 percent increase. This highlights that the pandemic positively impacts the export of medicines in Egypt in 2021.

As there are not many available data sources and literature reviews that cover the challenges that could hinder the export of medicine in Egypt. This study aims to dig deeply and point out the challenges that impact the export of medications in Egypt to give a precise situational analysis. It attempts to clarify What are the challenges that affect the export of pharmaceuticals in Egypt? This is through answering five sub questions. First, how could the readiness of the company affect its exports? Second, to what extent does the Drug Regulatory system in Egypt affect the export of medicines in Egypt? Third, what factors related to importing countries hinder the export of Egyptian drugs? Finally, how could applying TRIPS agreement affect pharmaceutical export? And how did the Covid-19 pandemic affect the export of pharmaceuticals?

[8] The council of ministers Facebook official page: https://www.facebook.com/100064812882317/posts/431849398985486/?d=n accessed June 2022

Chapter Three: Methodology

3.1. Conceptual Framework

Operational definitions

Throughout the study, the following terms are used as follows:

Export is defined as "The goods and services produced in one country and purchased by residents of another country" (*Amadeo, 2020*).

Export barriers are "Attitudinal, structural, operational and other constraints that hinder a firm's ability to initiate, develop or sustain international operations" (*Koksal and Kettaneh, 2011*).

Export performance is "The extent to which the firm achieves its objectives when exporting a product to a foreign market" (*Navarro et al., 2010*).

Intellectual Property Rights (IPR) are the rights that people have over the works of their thoughts. Typically, they grant the inventor a time-limited, exclusive right to utilize their invention. (*WTO, 2022*).

Product/ Company Barriers are barriers related to the quality of the products, their prices in addition to the staff's capabilities, and the facility's qualification.

Importing Country Barriers obstacles brought forth by the importing nation's actions or inaction concerning the export process.

Exporting Country Barriers: obstacles brought forth by the exporting nation's actions or inaction concerning the export process.

Informational Barriers: are issues in locating, choosing, and contacting global markets as a result of information inefficiencies.

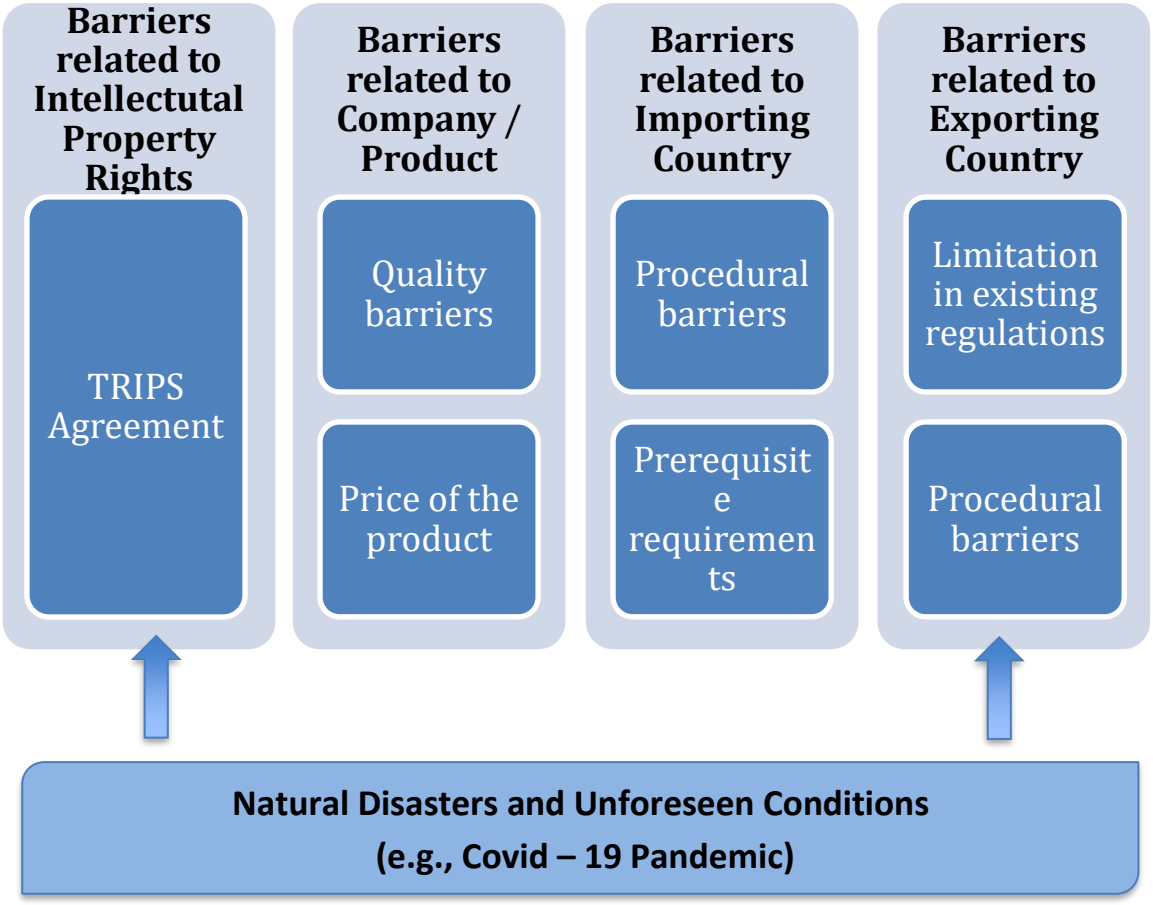
Human Resource Barriers: human resources ineffectiveness in light of globalization.

Governmental Barriers: barriers brought about by the home and foreign governments' actions—or lack thereof—concerning its exporters and domestic enterprises.

Procedural Barriers: are difficulties related to the practical elements in the export country for conducting business with overseas clients.

Drug export challenges are an issue with a complex origin and negative impact on economic growth. Identifying the reasons and causes behind the limitation of drug export is essential in solving it.

Figure 6 Conceptual Framework



*Source: developed by researcher guided by the "Assessment of Challenges in Export Marketing: The Case of Ethiopian Vegetable and Fruit Commercial Growers" paper by Sisay (*2018*).*

The figure above represents this study's conceptual framework, which includes the barriers to drug export issues. All conceptualizations are based on research from studies carried out in various nations and reports from international organizations and drug regulatory bodies.

There is little research offering a conceptual framework in the pharmaceutical field addressing export challenges. This conceptual framework is based on the "Assessment of Challenges in Export Marketing: The Case of Ethiopian Vegetable and Fruit Commercial Growers" paper by Sisay (*2018*). It highlights the critical global issues in the export marketing of vegetables and fruits and the internal and external obstacles, such as post-harvest management, food safety, quality, certification, and competition. The authors in this paper have classified the conceptual framework into internal and external problems that affect Export Marketing Strategy. Internal issues have been categorized into product and company barriers, while External problems include industry, market, and macro environment barriers. Hence, based on literature and previous studies in different countries, walls of drug export could be divided into four main categories.

First, prices of the medicines compared with their cost, lack of engagement with Good Manufacturing practices in pharmaceutical factories, absence of experienced individuals, and unawareness of international markets are challenges related to the company and the product (*Fardazar et al., 2019*).

A second challenge is related to exporting countries. For instance, adopted regulations do not align with international standards (*Gupta, 2018*), activities of R&D are not strategically disciplined, and rules for conducting clinical trials are not established (Hafez, 2016). In addition, there are deficiencies in the infrastructure of the exporter country, such as the absence of laboratory and bioequivalence centers (*Sheel,*

2015). Furthermore, international recognition of regulatory authority impacts the export rate (*Gupta, 2018*).

On the other hand, some factors originated from the importing countries, influencing export. For instance, international accreditation for the products is required in some countries to enter the market (*Huang et al., 2018*). In addition, fees for registration in some countries are high (*Sheel, 2015*). The fourth pillar of the main barrier is the negative impact of Intellectual property on export (*Minssen et al., 2019).*

Finally, the pandemic of Covid-19 impacted the export of pharmaceuticals. Some exporting countries have set a group of restrictions (*Vooren, 2020*).

3.2. Research Methodology

3.2.1. Study Design

A qualitative analysis methodology is adopted in this research to explore the leading causes hindering pharmaceutical export. It is found that the available papers that deal with factors that drive the export of medicines are through a quantitative approach. Hence, this study's qualitative methodology gives a more profound analysis behind such a gap in exports despite the potential factors enhancing exports of medicines in Egypt (*Marshall & Rossman, 2014*). In addition, it is chosen as it creates knowledge and discovers unknown findings. It sheds light on identifying possible hidden causes that hinder the export of pharmaceuticals. This has been achieved by designing open-ended, semi-structured interviews.

3.2.2. Overall research strategy

In-depth interviews with several respondents who have contributed to the issue are the primary method of data collecting for the study. Meetings are held one-on-one for the interviews. Additionally, the interviews allow for straightforward inquiry, which enables the researchers to examine the responses thoroughly. Further, because the

interviewer is present during the process, one-on-one interviews reduce the chance that participants may misinterpret the question (*Babbie, 2013*). To gather data for the study, semi-structured interviews are conducted. This satisfies the study's aim and responds to the qualitative research questions. This technique, therefore, strikes a compromise between the adaptability of unstructured interviews and the concentration of structured interviews. Interviews are performed with various companies to correlate different viewpoints to accomplish triangulation. Additionally, those interviews confirm the collected primary data by looking at secondary data. Finally, a pharmaceutical industry job makes it easier for the researcher and participants to engage personally.

3.2.3. Study population/sampling

To identify the key interviewees in this study, a non-probability, the goal-directed sampling technique is used. Goal-directed sampling makes use of a variety of techniques to locate every potential case that meets the requirements of the research to reach a target population. (*Neuman, 2000)*. In light of this, goal-directed sampling mainly aids in-depth analyses and exploratory research, as in the present study. Additionally, the selection process is carried out in a way that ensures the participation of a variety of individuals. As a result, 8 individuals were interviewed one-on-one, as shown in Table 1.

The respondents were divided into groups based on their respective occupations. Participants are from local industry to collect their opinions and feedback discussing the main obstacles facing the export of medications in Egypt. These companies include top and middle exporters of medicines in Egypt, along with these companies that export in low quantities. Interviewees are selected to collect data from different perspectives. It helps in determining the various constraints that confront

companies. Interviewees are the leading key players in working or planning for export in companies.

Table 1 Interviewee's Profiles

	Representatives of Pharmaceutical companies	
	Position	**Organization**
1	The Director of Registration Department and Deputy of the Chairman	Local manufacturer of Pharmaceuticals-Low export companies (LEC)
2	The Director of Export Department	
3	The Head of Business Development Unit	Local manufacturer of Pharmaceuticals-Middle export company (MEC)
4	The Director of Export Department 1	Local manufacturer of Pharmaceuticals-High export companies (HEC)
5	General Manger	
6	The Director of Export Department 2	
7	The Director of Export Department in a group of 7 companies	
8	The Director of International Markets	

3.2.4. Data collection

The study profoundly relies on primary data because there is little information in the literature about the export of drugs from Egypt. However, pertinent secondary data was examined. To collect primary data, semi-structured in-depth interviews were held with every participant (Appendix II). The interview technique is used in this research as it is a substantial method of gaining insight into people's perceptions. It contributes to in-depth data collection. Each interview ranged around 45 minutes, and it was conducted in Arabic. Interviews were performed in order to discuss the main obstacles facing the export of medications and propose practical solutions to handle this issue. It attempts to answer five main questions. First, how could the readiness of the company affect its exports? Second, to what extent does the Drug Regulatory system in Egypt affect the export of medicines in Egypt? Third, what factors related to importing countries hinder the export of Egyptian drugs? Finally, how could applying

TRIPS agreement affect pharmaceutical export? And how did the Covid-19 pandemic affect the export of pharmaceuticals?

Secondary data collection is collected through reviewing different publications in policy documents, internal structural documents, and various articles, in addition to governmental/ organizational websites. The data is used to get information about the volume and type of Egyptian medicines exported to different countries, besides getting insights on policies adopted in other countries and companies for exporting medicines.

3.2.5. Data analysis

The researcher translated the interviews into English. According to the conceptual framework, a manual categorization method was first created. Each interview transcript section was then grouped according to the initial themes. Subthemes were created during the process, and the original categorization scheme was changed. All data were coded in accordance with the final thematic index that was produced.

3.3. Ethics Consideration

Before beginning the data gathering procedure, the researcher received acceptance from the International Review Board (IRB) of the American University of Cairo (AUC) on October 25, 2021 (Appendix 1). To ensure the participants' safety and maintain their identities' anonymity, all participants were identified by their professions. Interview subjects provided their informed consent. The purpose of the interview, the procedure, and the participants' freedom to opt out at any moment were explained well throughout the interview. The interview subjects were made aware that participation was optional and that the researcher would not profit from the study *(Babbie, 2013).*

3.4. Limitations and Delimitation of The Study

Some participants were reluctant to speak openly since the researcher is a government official from the drug regulatory body, even though most participants were amenable to speaking freely because the researcher works in the same field. Additionally, the thesis skipped over the opinions of the agents and distributors in the exporting countries. It was challenging to reach as they are not located in Egypt. The researcher focused on interviewing participants from Egyptian pharmaceutical businesses to emphasize the majority of the image of export hurdles in Egypt and export markets. Exporters are the key player and the primary stakeholder in this process. The venues of the interviews were yet another logistical barrier. Unavoidable interruptions occurred during several discussions at the participants' places of employment, which may have impacted the level of information revealed. Furthermore, an unintentional bias cannot be completely disregarded because the researcher works in the same industry.

The delimitation of this study is on identifying the significant obstacles to pharmaceutical export; thus, a more thorough investigation and deeper analysis are required to fully comprehend the effects of these obstacles on the Egyptian economy.

Chapter Four: Data Analysis and Findings

According to the study approach outlined previously in the preceding chapter, this chapter offers the data gathered through interviews with the critical players in the pharmaceutical industry. To better understand the issue in the Egyptian context, the interviewees offered a thorough account of the barriers that limit the export of pharmaceuticals. According to the conceptual framework, the primary data was arranged under four major themes: the influence of intellectual property rights on export, obstacles connected to export nations, barriers related to import countries, and barriers related to the firm or its product. The first part outlines the challenges caused by the exporting nation's actions—or lack thereof—with regard to the export process. This theme is categorized into three subthemes; drug shortage in the domestic country, procedural barriers, and the Covid-19 pandemic. The difficulties in exporting medications made in the various import countries are highlighted in the second part with four themes; informational barriers, registration requirements and fees, smuggling of medicines, and exploitation of local agents. The third subject is about export-related obstacles that originated from the company itself classified into local prices, qualification of the facility, and human resources barriers. The last subject demonstrates how intellectual property rights and TRIPS agreement affect export. The four main divisions play a crucial role in providing answers to research questions because they make it possible to identify gaps and provide better ways to solve problems.

4.1. Barriers Related to The Export Country

The Egyptian government has recently taken several steps to facilitate the process of registration. For instance, decree no. 645/2018 (*EDA, 2022*)[9] has been issued in 2018, which offers incentives for companies to register products to be exported. In

[9] EDA website: rptImg (edaegypt.gov.eg). Accessed July, 2022

addition, there is the export initiative which aims to simplify some regulatory processes related to export; therefore, the export rate increases. The initiative is described in detail in the first chapter. There are, however, some challenges participants have highlighted concerning this issue. According to literature review, lack of regulations and infrastructure, informational uncertainty, procedural barriers, and absence of international recognition for the local drug regulatory authority affect export negatively (*Gupta, 2018 & Sheel, 2015*). Constraints in the exporting country are one of the extracted themes from the interviews. This theme is classified into three subthemes as following:

4.1.1. Drug shortage in the domestic country:

To regulate and control the market, companies must submit a request to EDA before exporting their pharmaceutical products (*EDA, 2022*)[10]. As highlighted by the participants, part of issuing an export permit is checking the availability of the domestic generic product market. They have mentioned some limitations in this process. One participant has mentioned:

> *"One of the required steps before exporting is to go to the shortage department, where they have to check the availability of the medicine in the local market. This step delays the process of exporting our products" (The Director of Export Department 1, HEC).*

The respondent declared that the referral to the drug shortage department in EDA prior to securing the export permission is as a rate-limiting procedure for export.

On the other hand, another point has been highlighted by participants. The export permit issuing may be delayed not only because the exporting firm does not meet

[10] EDA website: export-guidline-01-2020.pdf (edaegypt.gov.eg) accessed April 2022

the local market's needs but also because the other companies do not produce their part of the market. *A participant said:*

> *"Shortage is done because a company that produce a similar product is not committed to cover its share in the domestic market. Hence, the Shortage department postpones our export permit until we fulfil the gap of production by our products. We are punished for the mistakes of others" (The Director of Export Department in a group of 7 companies, HEC).*

The director of export department in a group of 7 companies- HEC, claimed that if a particular medicine is scarce, even if this is not their product, they produce similar to the insufficient product. The issuing of the export permission is delayed until the product is available on the market. Before enabling the exporting firm to export, EDA required them to meet local needs.

It is essential to highlight that drug shortage is a global problem (*WHO, 2016*). It is not restricted to a particular country or region. It has negative health impacts and adversely affects drug therapy. Hence, EDA has established a framework for allowing the export of pharmaceutical products as mentioned by participants. Firstly, If the drug is red labelled which means it suffers from a shortage in the local market, the export request is reviewed by the Drug shortage department. This step is required to ensure the product's availability in the local market in reasonable quantities that cover the market's needs. Then the export permit is issued. The participants have expressed that this cycle delays the export process. As a result, the rate of export is affected. Their point of view concerning the delay in the process is valid; however, this step could not be removed. It is vital for Egyptian citizens. The EDA should consider accelerating this step in a way that does affect neither the exporter nor the local market. It is worth noting that drug scarcity in the domestic country has not been identified as an export concern

in prior research; nonetheless, the delay in receiving the export authorization might be considered a procedural obstacle.

On the other hand, participants have elaborated another point concerning the drug shortage. They mentioned that in checking the stock for the domestic market, some companies fail to achieve the required target to be produced from their pharmaceuticals in the domestic market. In this case, the shortage department suspends the export of similar products to other companies until the market is satisfied and the shortage in these products is overcome. Companies believe that they are punished for the mistakes of others.

4.1.2. Procedural barriers

The export process requires the fulfilment of some documents from the local drug regulatory authority, for instance, issuing of the import permit, good manufacturing practices (GMP) certificate from the inspection department, and certificate of pharmaceutical product (CPP) from the registration department. Although, the participants have elaborated that the environment in the Egyptian drug regulatory authority is enhanced, they still need more improvements as they confront some logistical barriers. The director of export department in a group of 7 companies-HEC, mentioned:

> "*The validity of CPP certificate and GMP certificate is one to two years; this is a short time. It is obliged to reissue them now and then. This issue wastes time and money.*"

Some parties have raised concerns about procedural hurdles within the drug regulatory authorities. Specific certificates relevant to the export procedure have a relatively short validity period. Companies have particular difficulties in this matter since re-releasing these documents takes time and may disrupt the export process.

EDA has adopted strategies to facilitate the registration process for pharmaceutical products. For instance, the Minister of Health in 2018 has announced that companies are allowed to register a number of products exceeding the identified number per each drug (according to the regulation, each drug is allowed to be registered by 12 companies only) (*EDA, 2022*)[11]. These drugs are targeted to be exported. Participants have commended the efforts exerted by the EDA. However, participants highlighted some shortcomings in the regulatory system in the pharmaceutical sector. For instance, the validity of certain documents related to the export process is relatively short. Companies confront some challenges in this issue as it consumes time to re-release these certificates and may affect the export process. This extracted sub theme aligns with the previous studies (*Gupta, 2018 & Sheel, 2015*).

On the other hand, the director of the export department- LEC, has suggested automating the process of applying for and issuing the import permit. The participant has suggested this recommendation to facilitate the process of releasing import approval.

Some companies have highlighted some difficulties in the clearance process in the ports. Employees in custom release asked to inspect the goods before shipping. The general manager- HEC, has mentioned that the inspection process and the repackaging of goods lead to damage to some medicines. Hence, the staff in different ports should be trained on the process of inspection without causing damage to the goods, which costs money and negatively affects the process of export.

[11] EDA website https://www.edaegypt.gov.eg/media/zfgf330p/2018-645.pdf. Accessed July 2022

4.1.3. Disasters – The covid 19 pandemic:

The covid-19 pandemic started in 2020. The pandemic has affected the export of medicines. Some countries have set some restrictions on the export of medicines, especially at the beginning of the pandemic (*Pelc, 2020*). COVID-19 significantly impacted global commerce during the first half of 2020. Global trade began to rebound in the third quarter of 2020, with an even stronger recovery in the fourth quarter of 2020 *(Global Trade Update | UNCTAD, 2021)*. Participants have explained the pandemic in impact of Covid-19 on export in Egypt. The general manager- HEC, has mentioned:

> "*The pandemic has a positive impact on the export of our products; the registration process has been accelerated; new regulations have been developed. These regulations facilitate the access of medicines*".

The participant explained that during Covid – 19 pandemic, regulatory authorities have established new tracks. The registration procedure has been sped up. Consequently, these regulations make drugs more accessible. This has a good influence on pharmaceutical exports.

On the other hand, Covid-19 pandemic has a dual impact on the export of other countries for different reasons. The director of export department in a group of 7 companies- HEC, said:

> "*The effect is both negative and positive. The negative impact is because of the increase in raw material pricing. In addition, shipping was stopped. The production decreased, so the offered goods is less.*
>
> *However, there was a positive impact. The sales of local manufacturers that produce medicines presented in the medication protocol for Corona increased; consequently, the export increased* ".

The director of export department in a group of 7 companies – HEC, discussed how the pandemic affects export positively and negatively. Egypt relies heavily on imported raw materials to produce final goods. The pandemic has an impact on raw material availability. Shipping has also been impacted. On the other hand, the export rate of specific products used to treat covid-19 infection has increased because of increased worldwide demand.

The situation is different for the low exporting companies, especially those don't produce pharmaceuticals presented in the Covid-19 treatment. They affected with the restrictions and lock down in other countries. The director of export- LEC said"

> "*We were affected negatively by the pandemic. The price of the raw materials increased, there was a delay in our two previous shipments. The outbreak impacts all countries. There was a recession*".

Companies that do not have drugs in the Covid-19 protocols are adversely affected. The director of export- LEC noted that raw material prices had risen. Furthermore, there was a shipment delay. All of these things have a detrimental impact on the process.

Regarding the implications of Covid on pharmaceutical products' exportation, surprisingly, Covid has had positive and negative impacts on exportation, as mentioned by the interviewees.

For the negative impact, Covid has raised the prices of imported raw materials. When the supplying countries restricted the exportation of raw materials to manufacturers, it led to a shortage in raw materials. In addition, there was a leap in the shipment prices during the pandemic. Therefore, the total cost of the imported raw materials increased, consequently impacting the cost of the final product for exportation. It is consistent with the literature review that during the start of the

pandemic, certain nations imposed limitations on the export of medications (*Pelc, 2020*). It had an influence on world trade in the first half of 2020.

On the other hand, When the WHO released the standard protocol for Covid management, which included plenty of locally produced products in Egypt, such as Azithromycin, Vitamin C, Zinc, Molnupiravir, and Favipiravir. The immense global need for these products made the manufacturers able to export these products in substantial quantities, which did not happen before. It declared the increase in the export of pharmaceuticals as presented in the last infographic report posted by the council of ministers; the volume of exports of medicines and medical devices had a 28.7 percent increase (*The Council of ministers, 2022*). In addition, the rapid global response to the pandemic facilitated the rapid authorization of Covid products in a concise duration in multiple countries. This process is called an emergency use authorization (EUA). The EUA is an expedited pathway for the authorization of some products urgently required for a particular public health concern (*FDA, 2022*). Therefore, the global demand for locally manufactured products in the presence of the pandemic enhanced.

Consequently, companies affected by the Covid-19 pandemic depend on whether they have medicines included in the protocol or not. If they produce covid-19 treatment, they export more and vice versa.

4.2. Barriers Related to the Importing Country

External barriers have a significant impact on impeding drug export. For example, high registration fees in importing nations impede the simple entry of international markets *(Sheel, 2015*). Transport expenses, as well as tariff and non-tariff impediments in importing nations, tend to stymie exports to other countries *(Blanc,2015*). Furthermore, extending the distance between importing and exporting nations reduces exports (*Adolfsson,2007)*. Thus, penetrating the foreign markets is an

extracted theme from interviews. Participants have mentioned that there are external challenges that hinder export activities. This would hinder the export rate, as well. They have presented the challenges of invading new markets along with the suggested solutions to overcome them. Hence, this theme is classified into four sub-themes.

4.2.1. Informational barriers

For Market penetration, companies should establish a work plan followed by strategies proposed to be adopted. Hence, for setting such a plan, data and information are required. Participants have mentioned that the availability of data about the country and the pharmaceutical market is not achieved easily. One respondent has stated:

"Penetrating a potential market need data, information is not always easily available. IMS is expensive" (The Head of Business Development Unit, MEC).

Participant has highlighted the importance of data for accessing the new potential markets. He, however, mentioned some obstacles to accessing this information, which hamper penetrating new countries. One of the tools used for evaluating a potential pharmaceutical market in a country is the IMS Program by IQVIA. It is a program that includes the market share of the marketed products. Respondents have stated that IMS is expensive. Thus, it hampers penetrating new countries.

Lack of connectivity and information is crucial to draw a road map to export products. Nonetheless, this leads to hampering the introduction of pharmaceuticals in any country. The availability of data about the external market is essential. Knowledge of foreign markets is essential and strongly encourages export. Therefore, it is necessary to get rid of this barrier. Participants provided solutions for overcoming this obstacle. The director of export department, LEC stated:

"*We need EDA or another governmental organization to provide data and information about the external markets, for instance, the tenders that are held*

there, type of products that are needed in these countries, trusted agents located there, etc."

The director of export department, LEC has suggested a governmental intervention to provide databases and data about external markets in order to mitigate this issue. Some interviewees agree with this viewpoint.

Hence, the lack of credible information has a negative impact on the process of exporting pharmaceuticals in Egypt. The unfamiliarity with international markets impact export negatively as explained in the literature review (*Fardazar et al., 2019*). Representatives of companies have highlighted the importance of the availability of data about different countries that have the potential to export to. They asked for governmental support to provide these data in order to facilitate access to foreign countries.

4.2.2. Registration requirements and fees

For accessing a new market and starting to sell medicines in a particular country, registration of the medications at the drug regulatory authority in the importing country is a prerequisite. One respondent has mentioned:

"The most challenging issue in any exporting activities is the registration process and requirements. And the cost of registration process" (The Director of Export Department, HEC).

Interviewee has focused on registration fees and processes in the importing countries as the main obstacles to exporting their products. It hinders the ability of companies to access these markets. Some other interviewees shared the same opinion and emphasized in this issue. In addition, this is consistent with the findings of the literature analysis; high registration fees in importing countries inhibit straightforward access to foreign markets (*Sheel, 2015*).

Moreover, interviewees have highlighted that some external markets, especially the regulated ones, ask for specific requirements. For instance, the general manager-HEC mentioned that in some countries, they asked for performing a bioequivalence study in specific accredited centres, and the local study cannot replace it. Furthermore, some countries ask for an inspection of the local manufacturer before importing from this company. These issues consume time in addition to cost too much money.

On the other hand, respondents have suggested several solutions to overcome this type of challenge they confront. One of the respondents suggested the following:

> "*Some countries classified Egypt as category B and C. Hence, registration in such countries consumes time. Suppose the Egyptian government held agreements with these countries. Egypt will be categorized as class A. Therefore, Egyptian products could be registered in these markets within few months and vice versa." (The Director of Export Department in a group of 7 companies - HEC).*

The respondent has proposed solutions to simplify the process of registration. This is through signing more Memorandum of Understanding (MOU) and treaties with diverse countries. Participants mentioned that if different governments recognize Egypt's registration and inspection process, this could facilitate the registration process in the importing country.

Moreover, a participant spotlighted the importance of governmental intervention. He suggested that the government should share in the fees of the registration. Furthermore, they highlighted that global tender is crucial for building bridges of partnership relations between companies and the countries that will receive our Egyptian products. This suggestion aligns with what has been stated by Huang *et al*. (2018).

A point should be declared that Egypt currently shares different agreements with different countries, such as COMESA, EFTA, GAFTA, Agadir, the EU partnership, and QIZ (*Gafi. 2021*)[12]. Many members of these agreements are supposed to be potential export markets for local pharmaceutical firms. For instance, In Common Market for Southern and Eastern Africa (COMESA) agreement, member states trade on a whole duty-free and quota-free basis, and there is a free trade area (FTA) (*MCCI,2021*)[13].

4.2.3. Smuggling of medicines:

Medicine registration is not a prerequisite for accessing these markets in some deregulated countries. These markets mainly rely on medicines with the lowest prices. Some interviewees spotlight some challenges about this issue. The director of export department in a group of 7 companies, HEC has mentioned*:*

> *"In some dysregulated countries, registration licenses are not needed for the pharmaceuticals to be marketed there. Some people in importing countries utilize this situation and smuggle Egyptian pharmaceuticals into their local market. They exploit that these smuggled products have a lower price. We attempted to mitigate this issue by restricting the distribution of our products via certain distributors with controlled amount but we still confront this problem ".*

The respondent clarified that there had been reports of drug smuggling in various nations. Due to the low prices in Egypt, this phenomenon impacts the company's financial status. The participant emphasized that while steps are being taken to address

[12] Gafi website: gafi.gov.eg/English/Sectors/Pages/Trade-Agreements.aspx. Accessed January 2021

13 MCCI website: https://www.mcci.org/en/global-marketplace/trade-agreements/comesa/. Accessed January 2021

this issue, smuggling still occurs in nations with lax regulations. This subtheme was not previously highlighted in earlier studies.

From this point of view, it is clear that smuggling of the company products into foreign markets harms the manufacturer in Egypt. As clarified by participants that the medicines' prices in Egypt, are one of the lowest in the world. When some people exploit the situation and smuggle this product, this would negatively influence the company's profitability. On the other hand, the effect of smuggled products is not only reflected in the sales and profit of the companies. Nevertheless, it also may cause harm to patients. Smuggled medicines are set as counterfeit drugs. The way of entrance into the country is unknown and illegal. Therefore, it cannot grant that these products are appropriately stored according to the approved storage condition or that their supply chain is handled in the right way. These products may harm the health of the users.

4.2.4. Exploitation of local agents/ distributors:

For accessing a new market, many companies take the approach of contracting local agents in the importing country rather than proceed by themselves with logistic issues of importing process in the foreign market. Those agents are mainly responsible for managing logistic matters, for instance, registering the product in the importing country, applying for tenders, and handling other supply chain and distribution issues. Some participants have emphasized a challenge in this issue.

> "*It is difficult to find a credible and trusted agent in foreign countries; some agents exploit the need of the company to export and ask for high fees. In addition, sometimes, these agents/ distributors do not work efficiently. My company has been affected negatively by one of these agents. We achieve our target in exporting to this country because of its lameness. Choosing*

distributors is the most crucial step in exporting" (The Director of Registration Department and Deputy of the Chairman, LEC).

Participant has elaborated that selecting the distributors and agents in the importing countries play a substantial role in facilitating the export process. The mischoice may lead to wasting money and time. Consequently, it will hinder the process of exporting. This issue is a critical step in the export cycle that should be considered. Exploitation of local agents in importing countries was not identified as an impediment to pharmaceutical exportation in the research review.

On the other hand, an interviewee has elaborated that participating in global tenders is extremely useful in penetrating new markets. To be accepted in global tenders, companies must guarantee their medicines' safety, quality, and efficacy. Hence, different countries trust these companies because firms are allowed to share in global tender and meet international requirements. However, two participants have mentioned that although it is a valuable opportunity to share in these tenders, there is significant competition, especially from Indian and Turkish companies. In addition, they are not highly profitable tenders, and in some cases, they ask to supply high quantities that a company cannot produce alone.

4.3. Barriers Related to The Company/ Product

One of the critical issues that may have a negative influence on exporting is product and business barriers. According to the reviewed literature, lack of good manufacturing practices, in addition to, the lack of trained employees in export teams, who would be in charge of marketing the products, have a negative impact on export (*Fardazar et. al, 2019*). On the other side, the absence of international recognition for pharmaceutical products may make it difficult to access new markets (*Huang, et. al, 2018*). Export competitiveness is also hampered by inability to offer acceptable pricing

(*Leonidou, 2000*). This theme has been categorized into three sub themes: Local prices of medications, the qualification of the facility/ product, and human resources.

4.3.1. Local Prices of medicines

The drug regulatory authority in Egypt, determines medicines' prices. It is a compulsory price; the company cannot sell its product for less or more than that price (*Wanis, 2016*). The Egyptian pound was devaluated in 2016. Theoretically, this should enhance exports from Egypt as the prices of medicines manufactured in Egypt would be less than in other countries. Thus, the exporting company becomes more competitive, and exports increase. However, participants stated that there are some challenges in exporting medicines with regard to their prices. An informants said:

> *"It is a huge and disastrous issue. It is accepted that the price in Egypt is low because of the economic level of the patients in Egypt. However, these prices set great barriers to exporting. A registration license and a pricing certificate in the country of origin are essential documents to export a pharmaceutical product. For instance, our oral dispersal film (ODF) product was priced at 3 EGP equivalents to 0.75 Saudi Riyal. This price is meagre compared to the price of a normal tablet for the same product with 20 Saudi Riyal. Moreover, the cost of registration and marketing in Europe is high; consequently, there is a need for having a price which covers all these expenses." (The Head of a Business Development Unit, MEC).*

The informant made it clear that domestic prices influence the export process. When a product is given a compulsory pricing, the importing country refers to the local price as a benchmark. As a result, if the local price is low, so will the export price. The participant explained that because Egypt's costs are cheap, their products are also low in the nation where they are imported.

Egypt, on the other hand, has been undergoing economic reform since 2016. One of the steps of the program is the reform of energy subsidies (*IMF, 2016*). Egypt has begun an energy subsidy reform approach, gradually phasing out the subsidy. Subsidized energy has an impact on local medication pricing and consequently affect the price in importing country. The director of export department in a group of 7 companies, HEC mentioned:

> *"Although in some markets, medicines are freely priced, still the Local restricted prices of products have a tremendous negative influence on export. The prices in Egypt are cheap compared with other countries. Electricity and gas are still somehow subsidized. Unfortunately, some countries set the domestic price as a reference when they price the product in their market. So, Egyptian products are priced at a lower value compared with similar products. Some people in these countries prefer to buy medicines at higher prices. They believe the low-price products have low quality".*

The director of export department in a group of 7 companies – HEC agreed with the earlier participant. He said that because medicine prices are subsidised in Egypt, they are low and impact export pricing. In several areas, customer preferences encourage them to choose more expensive items than cheaper ones for the same medicine.

As pointed out by the participants in the research, "Local prices for drugs in Egypt" is one of the significant issues that affect exports. It aligns with the conceptual framework. It is a barrier related to the product, as discussed before. Egypt devaluated the currency in 2016 (*The economist, 2016*). This has been reflected in the prices. They become cheaper than the prices in the other countries, which boosts exports. Participants, however, have expressed that this is not what happens in reality. The local prices for pharmaceutical products hurt export. They stated that a reason for this lies in

the low prices of the local products in Egypt. As in some importing countries, one of the required documents for registration is the price certificate issued by the drug regulatory authority in the country of origin (Egypt) (*George, 2019*). This means that the price certificates will be directly reflected in the export prices. Thus, if the product has a low price in Egypt, export prices will be low and vice versa. According to the adopted pricing policy by EDA, compulsory pricing for pharmaceutical products has been implemented since 1962 (*Wanis, 2016*). In addition, decree no. 499 of 2012 has been issued, which sets as a regulating tool to ensure that the price for medicine is reasonable in Egypt (*Wanis, 2016*). Hence, according to the implemented policy, products are priced for the local markets, considering the economic standards of most of the Egyptian population. On the other hand, EDA has not employed a specific policy for pricing drugs for the export market that would cover companies' expenses with a reasonable profit. Some participants have suggested special or free pricing for export products. It is worthy to mention that this subtheme is contradicting what have Indian companies sought. They have reduced costs to maintain their price competitiveness globally *(Joseph, 2012*).

On the other hand, some participants have suggested a solution for such a challenge. One of the interviewees said:

> *"It would be more helpful to have special export prices" (The Director of Export Department 1, HEC)***.**

They have recommended a new policy for pricing medicines for export. In other words, drug regulatory authorities in the external market do not have to link the price certificate for export to the local market prices.

Hence, the EDA should consider the pricing of export pharmaceuticals. The EDA should find alternatives to overcome the compulsory pricing problems by establishing a new policy for pricing these products with some flexibility.

4.3.2. The qualification of the facility / Product:

The infrastructure of the facilities which produce the pharmaceuticals could be a challenge or an opportunity to export the products. The importer is mainly concerned with ensuring that the manufacturers meet international standards. The process mainly relies on inspecting the facility by the importing country's regulatory body to guarantee the application of all good manufacturing processes, which consume time and money. Nonetheless, participants have highlighted that this step could sometimes be skipped. The respondent stated:

> "*The degree of certification that the facility has, opens new markets. Having a GMP certificate from a domestic country opens certain markets. However, getting the GMP certificate from Jordanian food and drug administration (JFDA) or gulf cooperation council (GCC) countries opens more markets. The top certificate is got from European Medicine Agency (EMA); in this case, the country you export to will not ask to inspect your facility. This is not only applied to the manufacturers of finished products but also applied to the raw materials. The certificate of raw materials manufacturer also has grades. The high grade one, for instance FDA certificate, facilitates the process of export. I can say that any aspect related to export cycle, the degree of certification plays a substantial role in offering new opportunities for export even the shipping line degree has an impact on the export process*". (*The Director of Export Department 2, HEC*)

The respondent explained that enhancing export depends heavily on how well-equipped and qualified the manufacturing sites are. He stated that degree of the manufacturing certificate for raw materials or finished products defines which nations the product may readily reach. For instance, manufacturing certificate that obtained from international bodies facilitates entering countries without need if inspection by the importing country. Other participants have the same point of view. The director of export department in a group of 7 companies – HEC, shared the viewpoint of the former participant. He clarified that the company's ability to export would be supported if the facility receives WHO accreditation.

Any element presented in the exportation cycle could facilitate or hinder the export process. For instance, the qualification of the production site for the finished product or the raw material is crucial in opening new markets. This aligns with the literature review concerning how the quality of products and manufacturers affect the export of medicines (*Fardazar et. al, 2019* & *Huang, et. al, 2018*).

4.3.3. Human resources barriers

Human resources in any business are an essential pillar in succussing this business. This is the case in the export process as well. How human resources are chosen, deployed, trained, paid for, and encouraged significantly impacts how well exports perform. The participants highlighted in the interviews how the qualified staff could raise the company's export rate and vice versa.

> "*The human element in a company is not visible to the country to which the company exports, but its impact reflects on the quality of the product. Staff who work in export should have experience in sales and marketing. They should have a sense of emergency and excellent communication skills to deal with foreign markets with their need" (The Director of Export Department 2– HEC).*

The interviewee has emphasized on the importance of the qualification and the professionalism of the export team in the company. They should have certain skills to be able to manage the export issues in the importing country. They play an indirect role in export process as the importing country mainly concern with the end product.

A company's employees responsible for producing medicines, handling regulatory issues, or opening new markets should be well trained and qualified. These qualifications have an important influence on the export process. They are the main gate to ensure the quality of the products. This is clear as, in GMP guidelines, there is a module that the manufacturer should fulfil to ensure the qualification of the personnel during the manufacturing process (*WHO, 2014*). On the other hand, for the staff who work in the export department and are responsible for dealing with foreign countries, communication skills are essential qualifications they should have. As the staff who work in the manufacturing site is the main gate to guaranteeing the quality of the product, those working in the export department are the main gate for finding opportunities for the company to export. This aligns with the literature review regarding how the qualified personnel influence the export of pharmaceuticals (*Fardazar et. al, 2019*).

4.4. Intellectual Property Rights and TRIPS Agreement Effect

Members of the World Trade Organization WTO are required by the TRIPS Agreement to offer protection for a pharmaceutical product or process for at least twenty years. According to the literature review, applying TRIPS agreement may affect the export of pharmaceuticals negatively or positively along with the context (*Minssen et al. 2019 & Pradhan, 2007*). In the case of Egypt, participants have elaborated that exporting medicines the affected negatively in case of export to a regulated country that applies TRIPS agreement. An informant has stated:

"It is difficult to manufacture a patented drug in Egypt because the Innovator company can charge you. Approximately 90% of the countries signed the GATT Agreement. Therefore, they have to respect patents and apply the TRIPS agreement. We have a generic product whose patency of the innovator product is expired in Egypt; however, in another country, it is still valid for two years. Therefore, our company cannot export it to this country" (*The Director of Foreign Market, HEC).*

The director of foreign market – HEC, illustrated that majority of countries are applying TRIPS agreement which considers with the IPR of innovative products. Hence, producers of generic medicines are not allowed to access these markets until the expiry of the patency.

The reasons for not importing generic items that their innovative product is still protected for intellectual property rights vary between developed and developing nations, as participants underlined. The director of export department, HEC mentioned:

"Products that have patents when exported to developed countries; these countries refuse to register the generic of these products because the innovator is still under protection; therefore, countries do not permit its importation. However, In the case of less regulated countries, they do not apply the TRIPS Agreement but are interested in registering new molecules. First, these new molecules are supposed to be expensive. They will not be able to afford them, or the physicians in these countries do not know how to use these new molecules. So, they return to the old generics.".

The opinion of the director of export department – HEC, is similar to the opinion of the previous participant concerning this issue. Moreover, he has highlighted that countries which are not applying TRIPS agreement, are not interested in importing the new

molecules. The main reasons were the country’s budget to pay for new treatments or the less trained physicians in this country.

The participants' views align with the literature review in terms of Intellectual property rights, and applying TRIPS agreements patency has a negative impact on the export of pharmaceuticals (*Minssen et al. 2019)*. Companies are not allowed to market their generic medicines in countries with valid patency for innovative products. They elaborated that the dysregulated countries are not concerned with applying the TRIPS agreement. They are not interested in importing these new molecules due to the ability to afford the price or the less professionality of health care providers in using new innovative molecules.

Chapter Five: Conclusion

Export is an essential tool for enhancing the GDP of a country. One of the crucial industries with a high potential in Egypt is the pharmaceutical industry, which is well established in Egypt (*Gage, 2017*). This research examines the challenges that impact the export of medicines in Egypt. In addition, it aims at proposing solutions to handle this issue as well.

Qualitative research has been conducted by interviewing 8 participants representing exporters from the pharmaceutical industry. Semi-structured, open-ended interviews were used to get the data. Secondary data has been used to examine triangulation. In reference to the research questions and in accordance with the conceptual framework, the study's findings are divided into barriers related to the export country, barriers related to the importing country, barriers related to the company/ product, and intellectual property rights.

Participants in this study have the main factors that hamper drug export in Egypt. First, for challenges related to the domestic country, companies' representatives have mentioned that drug shortage in the domestic company is one factor hindering the company from exporting. EDA refuses any request for exportation until they guarantee the satisfaction of the market with reasonable quantities. In addition, they have mentioned that the process of checking the availability consumes time. Furthermore, if a product is not produced in sufficient quantities, the request for export for other similar products is suspended until they produce quantities that cover market needs. Participants have emphasized some procedural barriers in the regulatory system, for instance, the short validity of the certificates issued from EDA (e.g., GMP and CPP). Companies request to increase the validity time of these documents. Hence, the number of renewals of these certificates will be decreased. Finally, the pandemic of Covid-19

has affected the export negatively and positively at the same time. There was a shortage in raw materials globally and a lockdown in some producing countries. Consequently, the prices of these materials increased dramatically, which reflects in the manufacturing and export processes. Companies that produce medicines presented in the treatment protocols benefit from this issue. The global need for these products is the main trigger for enhancing the export rate.

The second main pillar of barriers extracted from the interviews is related to the import countries, which are divided into four subthemes. The absence of data concerning the foreign markets is a challenge; participants highlighted the need for a governmental organization that helps them to supply data and information about these markets. This will help them to penetrate new markets. Furthermore, some difficulties while registering a product in foreign countries are raised—the high fees of registering and the availability of trusted, qualified agents. The smuggling of locally produced medicines into other markets is also challenging. This issue affects the economic situation of companies.

Barriers related to the company and the products significantly impact the export. Compulsory prices in the domestic country are used as a reference price in some external markets. These prices are low compared to similar products globally. The Egyptian government is concerned with the economic situation of its citizens. Therefore, the prices are subsidized indirectly. Some services are still subsidized as energy which is a kind of support for local producers. The qualification of the manufacturing site and the staff are essential factors in the export process. Having highly qualified accredited production lines from global entities enhances the export and facilitates penetrating the foreign markets and vice versa.

For the fourth theme, if the innovator product's patency is still valid in the importing country, the TRIPS agreement hinders the ability to market any other generics. So, companies are not able to export their generic products.

On the other hand, the government exerts efforts on the Export issue. An initiative for facilitating export has been developed. It targets simplifying the process of getting approval for export from the regulatory authority. In addition, it modifies the process of manufacturing for export without registering the product in the local market. A registration track for products registered for export has been developed, which offers some incentives for the companies.

Some recommendations to overcome these challenges are suggested. For barriers related to the exporting country, participants illustrated that there are procedural barriers within the exporting country. The regulatory body should reconsider the procedural barriers illustrated by the participants inside the regulatory body. A quality system should be in place to monitor the process and ensure no deviation or delay. In addition, automating the processes of issuing certificates such as GMP and CPP is recommended. Thus, the time consumed for renewing these documents is shortened.

For the drug shortage issue, it is extremely important to ensure the availability of the products in the local market before allowing the export. However, EDA should establish a sanction system for companies not committed to producing their share in the market without a justified accepted reason. As some interviewees mentioned that their export is negatively affected if other similar products owned by other companies do not commit to covering their share in the local market.

For the staff in different ports who are responsible for inspecting the goods should be trained on the process of inspection without causing damage to the goods, which costs money and negatively affects the process of export.

The Egyptian government should pursue the strategic aim of localizing the raw material industry. Egypt today relies heavily on raw material imports. The pandemic exposes Egypt's raw material manufacturing shortfall. Many businesses have been impacted by global scarcity and high pricing.

Moreover, EDA should benefit from being categorized as a maturity level three in the global benchmarking tool by WHO in vaccines. It is a positive step that should be used to enhance export from Egypt. Furthermore, EDA should extend this progress to get the recognition of WHO in medicines.

For the challenges related to importing country, as highlighted by the participants that there is lack of data regarding the potential external market which influence the export negatively. Companies should benefit from commercial accessories in embassies. The role of commercial accessories in the embassies should be encourged to raise awareness of the investors and provide companies with information and advice. In addition, providing investors with data on the investment climate, prospects, and licensing procedures will be critical in handling the informational barrier.

For the barriers related to the registration and inspection in foreign countries as declared by the participants, Egypt should employ the signed agreements and sign more treaties that support Egyptian companies to market Egyptian pharmaceutical products in these countries without restrictions with lower fees. These agreements should also consider the local pricing issue, and the external countries should not rely on this price as it is indirectly subsidized for the Egyptian patient. Furthermore, this international

cooperation is vital to overcoming the smuggling of medicines. The countries should work together to eliminate it.

On the other hand, for barriers related to the company / product, a different pricing policy for exporting products should be formulated as declared before by interviewees that the local compulsory price affects the export. Interviewees elaborated how these local prices hurt the export rate. The Egyptian Drug Authority should formulate a pricing policy after discussion with different stakeholders and companies to overcome this critical barrier.

Manufacturers should seek to recognized from international organizations. As many countries rely on the international recognition of these manufacturing sites, this will simplify the process of accessing new markets. Furthermore, as personnel is a critical element in the process of export and manufacturing. Companies should invest in human resources, since human resources are regarded as assets.

Companies should benefit from the new service of technical consultation that has been offered recently by EDA to support companies in getting WHO PQ. Having WHO PQ products facilitate accessing different markets with less requirements from those countries. Countries trust WHO prequalified products as they have been evaluated by WHO. Moreover, EDA should monitor this service. The following up of this new service is crucial to ensure its effectiveness. Therefore, EDA could expand its efforts to include technical support for other international certifications. It will aid in the access of Egyptian products to global markets.

Finally, for IPR, Egypt should adopt a strategy for reducing the local industry's reliance on the generic industry and requiring businesses to provide a percentage of their earnings to invest in R&D and innovate new products. Thus, companies will be able to export their innovative products.

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Appendices

Appendix I: Interview Guide

General Questions:

- Name of participant
- Name of the Company
- The profession of participant

Questions related to the company:

1. How can you categorize your company sales in local market and in foreign countries?
2. How many countries does your company export to?
3. How other countries evaluate or categorize your company, and the quality of your products?
4. Is there a dedicated team for export in the company? If yes, how many candidates there?
5. Do the candidates in export team take special trainings? If yes, what are these training?

Challenges

6. How can the regulatory issues in EDA affect the export of your company?
7. What about clearance and custom release issue, to what extent does the applied system have an impact on exports?
8. How can prices in Egypt affect the exports of the company?
9. What about the challenges you face in the foreign markets?
10. Which countries (or continent) are easier to be accessed? Why?
11. Are there any treaties or trade agreement between Egypt and other countries that help your exports? If yes, how these agreements influence the exports?
12. How can you evaluate the initiative that has been taken by EDA regarding export?
13. How can participation in WHO and UNICEF tenders affect exports? Is there a considerable profit or any other benefits that encourage companies to share in these tenders?
14. What are the requirements needed by a company to participate in these tenders, quality or financial issues, etc?
15. Does Covid-19 pandemic have an influence on your export performance? How?
16. How could applying TRIPS agreement affect pharmaceutical export?

Solutions

17. What are your suggestions for increasing exports rate?

Appendix II: IRB Approval

THE AMERICAN UNIVERSITY IN CAIRO
INSTITUTIONAL REVIEW BOARD

Case# 2021-2022-028

To: Shereen Mohamed Abdelgawad Mohamed
CC Prof Ghada Barsoum
Menna Youssef
From: Heba Kotb Chair of the IRB
Date: 25th October 2021
Re: IRB approval

This is to inform you that I reviewed your revised research proposal entitled

"How to boost Egyptian Pharmaceuticals Exports? Challenges need to be overcome"

It required consultation with the IRB under the "expedited" category. As you are aware, it required minor revisions. Your new version addresses these changes successfully. The revised proposal used appropriate procedures to minimize risks to human subjects and adequate provision was made for confidentiality and data anonymity of participants in any published record. I believe you will also make adequate provision for obtaining informed consent of the participants.

This approval letter was issued under the assumption that you have not started data collection for your research project. Any data collected before receiving this letter could not be used since this is a violation of the IRB policy.

Please note that IRB approval does not automatically ensure approval by CAPMAS, an Egyptian government agency responsible for approving some types of off-campus research. CAPMAS issues are handled at AUC by the office of the University Counsellor, Dr. Ashraf Hatem. The IRB is not in a position to offer any opinion on CAPMAS issues, and takes no responsibility for obtaining CAPMAS approval.

This approval is valid for only one year. In case you have not finished data collection within a year, you need to apply for an extension.

Thank you and good luck.

H. Kotb

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