College of Health Sciences

School of Pharmacy

Department of Pharmaceutics and Social Pharmacy

Customs Clearance Practice and Related Challenges in the Ethiopian Customs Commission: A case of Pharmaceutical

By: Kaleab Taye

July 2022

Addis Ababa

Customs Clearance Practice and Related Challenges in the Ethiopian Customs Commission: a case of Pharmaceutical

By: Kaleab Taye

Advisors: Prof. Dr. Denny Cho (PhD)

Mr. Dawit Teshome (BPharm, MSc, MA)

Ms. Angelica Coll (MSc)

A Thesis submitted to the Addis Ababa University, College of Health Sciences, School of Pharmacy, Department of Pharmaceutics and Social Pharmacy in Partial Fulfillment of the Requirements for the Degree of Master of Science in Health Supply Chain Management

July 2022

Addis Ababa

Abstract

Background: Pharmaceutical at ports and/or custom stations need to be cleared in the shortest possible time due to their sense of urgency and requirement of special handling. However, the customs clearance procedure in most countries is time-consuming, leading to unnecessary delays and financial losses. In Ethiopia, there is a paucity of information about pharmaceutical customs clearance practice and related challenges.

Objective: To assess pharmaceutical customs clearance practice and to identify challenges in the Ethiopian Customs Commission (ECC).

Methods: The study was conducted in ECC from September 2019 to January 2020. A concurrent mixed methods design was employed. Quantitative data (using a structured questionnaire, and data abstraction formats), and qualitative data (using Key Informant interview guide) were collected at the same time frame. Quantitative data were analyzed using descriptive (percentage, frequency, mean and standard deviation) and inferential statistics (*t*-test and ANOVA). For the qualitative data, thematic analysis was applied.

Results: Pharmaceutical transaction worth of $574,487,522 were cleared by the ECC in 2019/2020. Of these, more than half of the pharmaceutical were imported from Europe (57.2 %). Ethiopian Pharmaceutical Supply Agency (EPSS) (63%) was the major importer of the products. The overall mean score for customs and trade facilitation standards was 3.13 (±0.6). On the other hand, 2.85(±0.74) was the overall mean score for efficiency of pharmaceutical custom clearance. This study showed that Pharmaceutical Importers (PI), Local Manufacturers (LM) and EPSS face various challenges in dealing with customs clearance procedure. Some of these include: delays and interruptions in the electronic system (Electronic Customs Valuation System (ECVS)), gaps in valuation system (not being invoice based and inconsistent), and poor pharmaceutical handling, and delays in the inspection of pharmaceutical imports by EFDA officers.

Conclusion: Most of customs and trade facilitation standards are not being applied in ECC custom stations and the overall pharmaceutical customs clearance process was found to be inefficient. As a result, EPSS and Pharmaceutical companies are facing numerous challenges and their operations are being affected negatively. Consequently, patients are forced to bear unnecessary costs incurred due to the system inefficiency.

***Keywords*: Customs, Customs clearance, ECC, Ethiopia, Import.**

Acknowledgments

My heartfelt gratitude and appreciation goes to my advisors Dr. Denny Cho (PhD), Ms Angelica Coll (MSc), Mr. Dawit Teshome (BPharm, MSc, MA), for their constructive feedback, and unwavering support starting from proposal development to the thesis completion and motivation during the thesis process.

I then thank Mr. Kassahun Kidane and Ms. Hiwot Fafa for facilitating the data collection at the Ethiopian Customs Commission. .

I would like to appreciate everyone who took part in this study and contributed by sharing valuable information.

I also would like to thank the University of Gondar for sponsoring this study and Addis Ababa University for funding this thesis work. I'm also thankful to all the staff of Addis Ababa University, School of Pharmacy, Department of Pharmaceutics and Social Pharmacy for their support throughout the study

Finally, I'm grateful to my family and my friends for their ongoing encouragement and support.

Contents

List of Tables

List of Figures

Abbreviation and Acronyms

AEO	Authorized Economic Operator
API	Active Pharmaceutical Ingredients
BIA	Bole International Airport
CMD	Contract Management Directorate
COMESA	Common Market for East and Southern Africa
ECC	Ethiopian Customs Commission
eCMS	Electronic Customs Management System
EFDA	Ethiopian Food and Drug Authority
EPSS	Ethiopian Pharmaceutical Supply Service
FMOH	Federal Ministry of Health
FOB	Free on Board
IP	Import Permit
IQR	Interquartile Range
IRP	International Reference Price
KDP	Kality Dry Port
LM	Local Manufacturers
LPI	Logistic Performance Indicator
MDP	Modjo Dry Port
MGA	Manufacturing Goods Customs Clearance Unit
MPR	Median Price Ratio
MSH	Management Science for Health
NRA	National Regulatory Authority
OECD	Organization for Economic Cooperation and Development
PI	Pharmaceutical Importer
POs	Purchase Order
SD	Standard deviation
TRS	Time Release Study
USAID	United States Agency for International Aid
WCO	World Custom Organization

1. Introduction

1.1. Background

Pharmaceutical save lives, improve health and promote trust and participation if they are made accessible (Wiedenmayer, 2004). Pharmaceutical supply chain is a means through which medicines are made available and delivered to patients. It involves a complex process that requires the participation of different stakeholders such as pharmaceutical manufacturers, importers, wholesalers, distributors, information service providers, customers and regulatory agencies (The Health Strategies Consultancy LLC, 2005).

Most countries' rely heavily on imports to meet their healthcare needs. According to one report, in 2019, 70-90% (an estimated $14 billion) of the drugs consumed in Sub-Saharan Africa are imported (Adeniji, 2021). Similarly, in Ethiopia, more than 80% of pharmaceutical and around 95% of the required raw materials (Active Pharmaceutical Ingredient (API), the excipients and the packaging materials) are imported to satisfy countries pharmaceutical demand (MOI and MOH, 2015). During importation, operations such as procurement, contract management, obtaining pre-import permit, and foreign currency approval, and arranging payment issues, custom clearance are some of the critical activities in the supply chain (ERCA, 2017).

Every imported good must be cleared through customs in each destination country. Customs clearance is the completion of customs formalities required to allow goods to enter the country, be exported, or be placed under another customs procedure (WCO, 2006). It involves importers to prepare clearance documents in advance, go through customs procedures, and make imposed payments in order to clear imported or exported goods (Shepa, 2013).

Customs, as defined by World Customs Organization (WCO) is “the government service which is responsible for the administration of custom laws and collection of import and export duties”. The primary goal of customs administration is to balance trade and control by facilitating trade and providing adequate control without jeopardizing the custom objectives of revenue generation and protection of national security (ERCA, 2017). In Ethiopia, the Ethiopian Customs Commission (ECC) is responsible for administration of customs law and collection of duties. It has 22 customs control stations where customs formalities are assessed, taxes and duties on imported and exported goods are collected (ERCA, 2019).

The Ethiopian Pharmaceutical Supply Chain involves several stakeholders including Federal Ministry of Health (FMOH), National Regulatory Authority (NRA), importers (public and

private), customs authority, wholesalers, retailers, bank and insurance, Ethiopian shipping lines, Ethiopian airlines, and freight forwarders. Ethiopian Pharmaceutical Supply Service (EPSS) is the government entity responsible for supplying quality assured essential pharmaceutical at affordable price in a sustainable manner to the public health facilities (PFSA, 2014). It covers nearly 70% of the country's needs, with the rest covered by Pharmaceutical Importers (PIs), and Local Manufacturers (LM). PI import medicines which are registered and permitted by the regulatory authority in the country (MOI and MOH, 2015).

Imported pharmaceutical, like other commodities, must go through customs clearance procedures in order to be cleared and serve their purpose in the imported country. In addition, because pharmaceutical are considered restricted goods (for health and safety reasons), importers must obtain an import permit from EFDA (pre-import permit and import permit) (ERCA, 2017). Furthermore, they are given priority clearance from ports and/or customs stations with the shortest possible time (ERCA, 2002, 2017). Despite pharmaceutical are given priority, studies show that clearance takes longer and is associated with a various challenges (Solomon, 2014; Dawit, 2019; Teklu, 2019). Therefore, the purpose of this study was to assess current practice and challenges of pharmaceutical's custom clearance at ECC branches, Ethiopia.

1.2. Statement of the Problem

Customs clearance processes can have a wide range of effects on supply chain management, including creating bottlenecks in the supply chain, increasing lead time, determining product availability, lowering customer service levels, and causing delays (Al-Haddad, Chuman and Kouki, 2021). It also plays a critical role in enforcing compliance with health and environmental standards and making trade balance (Jones and Seghetti, 2015; Heijmann *et al.*, 2020). Therefore, an efficient and effective importation and custom clearing processes shall be in place. The urgency of this process has a particular importance in landlocked countries like Ethiopia where goods travel long distance overland and may be subject to unexpected delays in less than desirable storage conditions (MSH, 2011).

In the aggregate 2012-2016, the Logistic Performance Index (LPI) showed that Ethiopia is among the least performer in trade facilitation and border management (scored 2.40 out of 5 and ranked 131 out of 167 countries)(The World bank, 2018). Studies conducted in Ethiopia also showed gaps in efficiency (speed, simplicity and predictability) of customs clearance procedures and delays (Solomon, 2014; Chinnapareddy, 2019; Teklu, 2019; Yigletu, 2020).

According to recent studies, EPSS took an average of 201 days (Gobie, 2020) and 227 days (EPSA and R4D, 2021) to receive imported pharmaceutical after a contract agreement was signed in 2017/2018 and 2019/2020, respectively, this is far short of the Management for Health Science (MSH) recommendation of less than 150 days (MSH, 2011). Delayed arrival of pharmaceutical at the warehouse and frequent stock outs of essential pharmaceutical are the common challenges faced by EPSS (Gobie, 2020). The customs clearance process contribute to such challenges. For example, in 2011 E.C., EPSS took 48 days and 10 days, respectively, to clear pharmaceutical shipments from Modjodry port and Bole International Airport (EPSA, 2018). In addition to the delay, an inefficient and time-consuming clearance process may result in deterioration, reduced shelf life, and product packaging damage (MSH, 2011).

Medication prices, on the other hand, are rapidly rising. According to a recent study, four out of five essential medicines were found unaffordable in Ethiopian context with the Lowest Price Generic (LPG) being four times the International Reference Price (IRP) in 30% of the drugs (Sisay *et al.*, 2021). As medications moves along the supply chain additional costs, such as freight, tariffs, and taxes, are add up to the medication selling price. Such fees are often high regularly, accounting for 30 to 45% of the cost of the medication dispensed (WHO and HAI, 2008). This could be exacerbated further by inefficient customs clearance processes, which contribute to landing cost markups by delaying pharmaceutical release and increasing demurrage and handling costs.

Although the government of Ethiopia is said to be undertaken various reforms to improve the efficiency of border control agencies, including customs, import activities continue to face challenges. Moreover, traders claim that the implementation of border management reforms has resulted in no significant changes. Importers' perceptions shall be investigated in order to gauge the clearance process in accordance with international standards, identify potential bottlenecks, and improvement areas. Previous studies explored the challenges faced by PIs in clearing pharmaceutical, but they didn't investigate the challenges encountered by EPSS's, the major pharmaceutical supplier and local pharmaceutical manufacturer's. Besides, there is a paucity of information on reasons for major delays, efficiency of procedures, including the average time to clear shipments, and implication of the challenges. Moreover, the most salient casual explanation for custom clearance complexity, delay and inefficiency are attributed to various parties including customs, importers themselves, clearing agents and regulatory body (Durgavich, 2009). Hence, studies targeting ECC, EPSS and pharmaceutical companies (PI and LM), and their clearing agents is necessary to get the whole picture of current practices

and challenges in custom clearance process. It also help in identifying discordance in how the different parties' perceive the customs clearance. Therefore, this study was aimed at assessing the customs clearance practice of pharmaceutical and identifying key challenges of EPSS and pharmaceutical companies in custom clearing of pharmaceutical in Airport, Kality and Modjo dry port custom branches of ECC.

1.3. Significance of the Study

Evaluating the current practice, identifying weaknesses and potential barriers to pharmaceutical's customs clearance will benefit EPSS and pharmaceutical companies by the improving the existing procedure through the development of effective recommendations and the implementation of necessary improvements. The findings will also be used to urge EPSS and pharmaceutical companies to be proactive about potential barriers that cause unnecessary delays and costs to their operation. It will also guide ECC and EFDA in reviewing the status of their operations in comparison to standard practices, becoming acquainted with cumbersome procedures in their operations, and taking appropriate corrective measures to improve service level. If ECC, EFDA, EPSS, and pharmaceutical companies, respectively) implement the study's findings and recommendations, patients may benefit from shorter lead times, reduction of essential medicine stock outs, and the avoidance of unnecessary costs. Finally, the study may inspire other researchers to conduct additional research in the area, and the evidence from this study will benefit the scientific community.

1.4. Scope of the Study

The scope of this study was to assess current practices and investigate the challenges of pharmaceutical's customs clearance in ECC from an import perspective. By saying practice, it includes application of customs and trade facilitation standard, customs best practice, efficiency of custom clearance procedures, source of major delays and clearance time. The study concentrated on EPSS, LM, and PI, as well as the customs clearance process from border procedures. The study area is limited to ports in land of Ethiopia particularly in Bole International Airport, Kality dry port and Modjo dry port branches of ECC.

2. Literature Review

2.1. Definition of Terms

Customs is described as "the government service which is responsible for the administration of custom laws and collection of import and export duties" whereas custom clearance is a group of procedures that should be commenced by national custom authority to allow commodities enter home use, to be exported or to be placed in another custom procedures. Goods declarations is a statement made in the manner prescribed by customs, by which the person concerned (importer/agent) indicate the custom procedure to be applied and furnish the particulars which customs require for its application (WCO, 2008).

The major activities under custom clearance procedures could be highlighted as: processing of import, export or transit declarations; assessment of origin, value and classification of goods; collection and processing of duties; physical examination, inspection and clearance of cargos; conduct of post-clearance audit; and processing of urgent consignments (ERCA, 2017).

2.2. Roles and Responsibilities of Customs

Customs administrations perform a wide range of important functions that facilitate the movement of goods and services across international borders (WCO, 2008). Traditionally, customs has played somewhat limited role, focusing primarily on the collection of duties and taxes on imported goods. Over time, the role expanded to include ensuring the legitimacy, safety, and security of goods admitted into the country, in addition to revenue collection (Peterson, 2017). Currently, customs in most countries carries out this responsibility in collaboration with other government agencies, by enforcing a range of trade laws, including those governing tariff collection, compliance with sanitary and phytol-sanitary standards, health, environment, and the protection of intellectual property rights (Jones and Seghetti, 2015; Heijmann *et al.*, 2020). This is generally achieved through the implementation of a diverse range of service level agreements, with Customs having regulatory responsibility at the point of importation and exportation (Widdowson, 2007).

Recently, customs administrations worldwide, has been involved on the role of trade facilitator which requires the customs administration to adopt specific practices that allow imports into the country to clear customs checkpoints more efficiently(Peterson, 2017; Heijmann *et al.*, 2020). However, customs administrations often struggle to strike a balance between trade facilitation and border protection, which can often undercut one another. This is especially true when

changes in political or economic circumstances require customs administrations to give immediate priority to either import security or trade facilitation.(Jones and Seghetti, 2015)

In many developing and least developed countries, import duties and related taxes represent a significant proportion of the national revenue. As a result, their customs authority's primary focus is revenue collection(Besley and Persson, 2014), whereas in developed countries, with relatively little reliance on imports as a source of government revenue, there is an increasing emphasis on border protection, with a particular emphasis on the enforcement of import and export prohibitions and restrictions (Widdowson, 2007).

2.3. Risk Management in Custom Procedures

A common characteristic of customs work is the high volume of transactions and the difficulty of checking all of them. Therefore, custom administrations face the challenge of facilitating the movement of legitimate passengers and cargo while applying controls to detect Customs fraud and other offences. To find the balance between trade facilitation and enforcement, the solution is development of custom control that are based on risk management (risk assessment, profiling and analysis) (UNCTAD, 2006).

Risk management is a systematic work on development and practical implementation of measures for the prevention and minimization of risk, and an assessment of efficiency of their application (Elena and Aziza, 2016). It is analytical process that is used to determine both actual and acceptable level of risk and involves the assessment of the probability that goods subject to Customs control may have not been declared or fully declared. Risk assessment factors will include import patterns, duty and tax rates, types of goods, previous examination results and routes and modes of transport (UNCTAD, 2013)).

Depending on the selected risk level, risk management system routs goods through green channel (immediate release without examination), yellow channel (documentary check), red channel (physical examination of goods and documents) and blue channel (examination at later stages, post audit)(ERCA, 2017). When it is implemented effectively, risk management system contribute to improving custom productivity and efficiency through better human resource allocation, increased revenue, improved compliance with rules and regulations, improved collaboration between traders and customs, reduced release time and transaction cost (UNCTAD, 2006).

2.4. Supporting documents for Customs Procedure

Supporting documents are those trade, transport and official documents that either support specific statements made in the goods declaration (import license, commercial invoice (describes the value of imported goods), transportation document (Bill of lading, Airway bill, truck way bill), bank document (L/C, CAD), packing list (describes how goods are packed during transport), and Certificate of origin) or that have to be submitted as a proof of specific import /export conditions being met (pre-import permit for pharmaceutical and other restricted items, health certificates and certificate of conformity with technical standards. Most of these documents are obtained from the supplier via bank except those documents which are obtained from regulatory authorities (WCO, 2008).

2.5. ECC Custom Clearance Formalities

According to Proclamation 622/2009, customs declarations must be prepared in written form, orally, by bodily action, or electronically, and must be filled out in the prescribed form, signed, and contain all of the information required to complete customs formalities. Then, custom declaration supporting documents such as transportation documents, invoices, bank permits, packing lists, certificates of origin, and other necessary documents must be prepared. Once the documents are submitted, the authority shall accept the custom declaration if the declarations and documents are valid and contain all of the information needed to complete the custom formalities. In this manner, the custom value of an imported good is calculated for the purposes of applying the customs tariff and calculating other import charges. Finally. It will then proceed to the clearance process, which includes receiving and checking the goods of declaration against the document produced to see if they are in accordance with the instructions, then accepting or rejecting the document, identifying the risk level of the document using the electronic Customs Management System (eCMS), and examining it (physical inspection of goods). This activity is carried out to ensure that the goods and conditions on the declaration correspond to the nature, origin, quantity, and value of the goods, as well as the release of goods (Federal Negarit Gazeta, 2009).

2.6. Port clearing performance of Ethiopia

2.6.1. Logistic Performance Index of Ethiopia

Logistic performance index (LPI) is a summary indicator of logistics sector performance, comprising six core performance components (indicators) aggregated to a single measure (LPI score) (Arvis *et al.*, 2012) The six core components are: efficiency of customs and border

management clearance; the quality of trade and transport infrastructure; ease of arranging competitively priced shipments; competence and quality of logistic services; the ability to trace and track consignments; frequency with which shipments reach consignee within scheduled and expected. LPI score is rated from "worst" (1) to "best" (5). It provides numerical evidence on how countries efficiently move goods across and within borders (Arvis *et al.*, 2014).

In the aggregate 2012-2016 LPI, Ethiopia scored 2.40 and ranked 131 out of 167 countries. The specific score for core performance components is 2.54, 2.13, 2.54, 2.39, 2.24 and 2.49 for customs, infrastructure, international shipments, logistic quality and competence, tracing and tracking and timeliness, respectively. The high performing countries in LPI are Germany (4.19), followed by Netherland (4.07) and Sweden (4.07). Lower LPI score and ranking is the result of either fragile economies affected by armed conflict, political unrest and natural disasters or landlocked countries naturally challenged by geography or economies of scale in connecting to global supply chains (Arvis *et al.*, 2018b).

2.6.2. Time Release Study (TRS)

WCO believes that it is important for custom administration, in collaboration with other regulatory agencies and stakeholders, to assess the efficiency and effectiveness of border clearing process. Within this consensus, the WCO developed a strategic tool called Time Release Study (TRS) (WCO, 2018). TRS is a systematic and standard tool to measure the average time taken from the arrival of goods to their physical release. It measures the relevant aspect of the effectiveness of operational procedures that are carried out by customs and other government agencies in standard processing of imports, exports and in transit movements (Matsuda, 2012). The principal objective of TRS is to identify bottlenecks affecting the release of good and to take the corresponding necessary measures to improve the effectiveness and efficiency of border procedures (WCO, 2018).

In Ethiopia, there is no independent TRS study conducted so far. But as a member states of Common Market for Eastern and Southern Africa (COMESA), Ethiopia was a part of COMESA's TRS which was conducted in 2016 covering ten pilot member states. Unlike other member states, Ethiopia's average clearing time (for import and export) was not established by the study. However the Average clearing time for the ten countries surveyed was 5 days, 1 hour and 14 minutes for import and 2 days and 6 hours for export (COMESA, 2017).

2.7. Challenges in Clearing Imported Goods at Customs

Studies conducted in African region show that clearing of goods from ports take long time compared to OECD high income countries (ECA, 2013). Importing one standard container on average takes 37 days and costs US$2567. This is high compared to 22 days and US$ 958 in East Asia and pacific; and 19 days and USD 1612 in Latin America and Caribbean (ECA, 2013).

Some of the reasons for taking long time are: issues related to harmonization and simplification of custom procedures, custom automation, and interconnectivity, documentation, national and cross border agencies coordination and cooperation and integrated border management. Problems in electricity, internet, road and bridge infrastructure, customs office facilities and equipment, and capacity, and know-how of custom staff and stakeholders are the other contributors for delays (COMESA, 2017).

Juma et al., (2012) also found that corruption is another reason for slow custom clearance procedures. Clearing agents bribe officers at ports and customs to have their cargo released. Such practice also encourages importation of illegal goods (Juma, 2012; Siwadenti, 2013).

Studies indicate that customs clearance delay is worsened in landlocked countries due to border crossing challenges. These obstacles range from long distances to inadequate transport services and infrastructure, and inefficient institutional and transit frameworks (UNCTAD, 2013). Moreover, in these countries, transit of goods is dependent on their relationship with transit neighbors, on their peace and political stability. In addition, a lack of coordination between transit and landlocked countries contributes to clearance delays (Ariekot and Persson, 2016).

Importation and exportation of goods in landlocked countries also suffer from high trade-related costs. Of which, inland transportation cost account significant share (ECA, 2013). In almost all land locked countries, transportation costs 30 to 90% more as compared with coastal economies (UNCTAD, 2013). In African countries such as Malawi, Rwanda and Burundi, inland transportation cost account for 70% of total importation costs where as in Ethiopia it is around 65%. This is worsened by expensive customs and terminal handling cost (ECA, 2013). Furthermore, as a result of these long delays and uncertainties concerning deliveries, traders in landlocked countries may face significant inventory costs that are sometimes even higher than transport costs, reaching more than 10 per cent of the value of the goods (UNCTAD, 2013).

2.8. Challenges of Pharmaceutical Importers in Customs Clearance

According to a USAID study, customs-related issues include poor planning and communication among agencies during the clearance process, cumbersome and bureaucratic processes, and a weak infrastructure. According to the study, the aforementioned issues are the root causes of increasing costs, longer lead times, and decreased product availability (Durgavich, 2009)..

A study conducted in Tanzania (2013) showed that major reasons for delayed custom clearance of pharmaceutical were bureaucratic import clearance procedures involving different government offices in different location and communication gap between them; inaccessible online processing of customs clearance by all agents and slow system; corruption. This study also mentioned other reasons that emerge form organizations other than custom authority and contribute to retards in custom clearance. Of them, spontaneous delivery of good from donors and smaller number of clearing staff in pharmaceutical importing companies that did not match the work load were identified (Siwadenti, 2013).

In Ethiopian context, customs clearance procedures have also proven to be a challenge for pharmaceutical importers for a various reasons. Some of the reported challenges included a lack of human resource development, delayed release of documents from other institutions, an exaggerated warehouse rent price until the products are cleared and released, and the presence of prolonged, non-transparent, and bureaucratic procedures as major barriers to PI effectively clearing pharmaceutical from customs stations (Dawit, 2019). Another study found that a busy schedule, a low capacity of customs authority, and a lack of pharmacists who can handle the product and communicate with importers professionally were major challenges to customs clearance (Solomon, 2014; Teklu, 2019).

As reviewed above, in Ethiopia few studies were conducted to explore the challenges of PI including the customs clearance related challenges (Dawit, 2019; Teklu, 2019). However, the practice (i.e. the applicability of international standards, customs best practice, efficiency of custom clearance procedures from importers perspective,) and the average time to clear and release pharmaceutical consignments from custom station remain unstudied. Besides, EPSS's, primary supplier of pharmaceutical' and local manufacturer's challenges in clearing custom remain uncovered. In this regard, research is required to provide input by identifying bottlenecks and delays in ECC custom clearance procedures so that recommendations can be made to support efforts being made to make custom clearance procedures a seamless operation.

2.9. Conceptual Framework of the Study

Following an extensive review of the literature, the following conceptual framework was developed for this study. The framework shown below (Figure 1) represents the components of the pharmaceutical customs clearance practice: The applicability of international customs and trade facilitation standards; the implementation of best practices in customs; the efficiency of the customs clearance procedure.

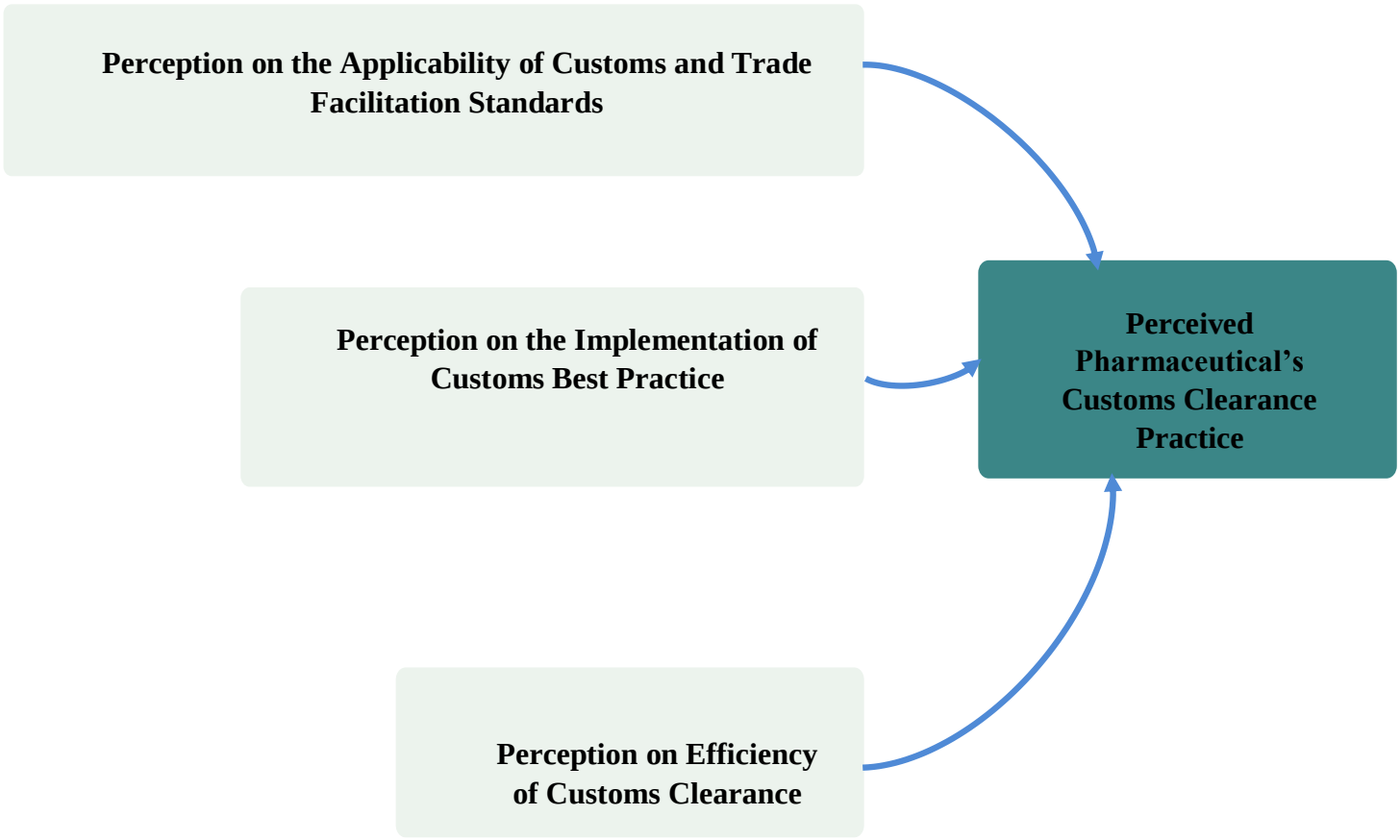

Figure 1: Conceptual framework of the study (own construct) (Moïsé, Orliac and Minor, 2011; Arvis et al., 2018)

3. Objective of the study

3.1. General Objective

- To assess the perception of the pharmaceutical's custom clearance practice in ECC, and to identify challenges associated with pharmaceutical customs clearance

3.2. Specific Objectives

- To describe the value of pharmaceutical cleared from ECC in 2019/2020 G.C
- To assess the perception about the applicability of customs and trade facilitation standards in ECC
- To assess the perception about the implementation of customs best practices in ECC
- To assess the perception of the efficiency of customs clearance procedure in ECC
- To compare participant's perception of the pharmaceutical's customs clearance practice in ECC
- To determine the pharmaceutical customs(port) clearance lead time
- To identify challenges encountered in clearing pharmaceutical from customs station

4. Methods

4.1. Study Area

This study was conducted in the ECC. ECC has sixteen branches and six central offices throughout Ethiopia (ECC, 2020). However, this study was carried out in three branch offices, namely Bole International Airport (BIA), Kality Dry Port (KDP), and Modjo Dry Port (MDP) customs offices. The three branch offices were included since majority of the pharmaceutical pass through these for customs valuation. In addition, Ethiopian Food and Drug Authority (EFDA), EPSS, Pharmaceutical companies (PI and local pharmaceutical manufactures) were included in the study.

EFDA is the national regulatory body mandated to ensure the quality, safety and efficacy of medicines. Its main responsibilities include market authorization/product registration, licensing of premises, market surveillance and inspection, quality control testing, clinical trials, vigilance and medicine and device promotion control (EFDA, 2020a).

EPSS is a public organization under the FMOH mandated to supply pharmaceutical and medical equipment to public health institutions. Its head office is located in Addis Ababa and has 19 branches grouped into seven clusters. The head office has 20 directorate in which each of them have own roles and responsibility and work independently and collectively (EPSS, 2019). The study was conducted in Contract management Directorate (CMD) of EPSS's head office (central) which is directly involved in shipment follow up and clearing process of pharmaceutical from custom station.

Currently, there are nine local pharmaceutical manufacturers and around 382 pharmaceutical importers in Ethiopia.

4.2. Study Design and Period

A concurrent mixed methods design was employed where the quantitative and the qualitative data were collected at the same time frame. The data collection period was from September 17, 2020 to January 30, 2021.

4.3. Source of Data

For the quantitative part, primary and secondary data were collected. Primary data were gathered from study participants using questionnaires to assess the pharmaceutical customs clearance practice. Similarly, secondary data were collected from ECC's electronic Customs

Management System (eCMS), and EFDA's excel report to describe the pharmaceutical cleared in 2019/20 (2012 E.C) whereas customs clearance lead time was calculated from six months performance report of 2019/2020 for EPSS and from eCMS for PI and LM as calculated and reported by them.

For the qualitative part, primary data were collected from Key Informants (KIs) using an interview guide prepared to identify challenges of pharmaceutical customs clearance.

4.4. Source and Study Population

Employees who were working for the ECC, EFDA, EPSS, LM and PI were taken as the source population. On the other hand, those who were working in ECC's branches offices (BIA, KDP and MDP), EFDA's head office, and EPSS central, PI who applied for Import Permit (IP) and got approved in 2012 E.C. were the study population. Data were collected from customs clearing officers and custom clearing team leaders and working for government and non-government customs clearance unit in BIA, KDP and MDP branches of ECC.

4.5. Eligibility Criteria

4.5.1. Inclusion Criteria

- Being customs officers and import custom clearing team leader working in BIA, KDP and MDP ECC branches, respectively.
- Individuals who were working in CMD of EPSS.
- Technical managers or general managers, or individuals recommended by the general manager who work in pharmaceutical companies that have cleared pharmaceutical from customs stations in 2019/2020.

4.5.2. Exclusion Criteria

- Individuals who refused to give consent to the study
- Individuals who were not available at the time of data collection

4.6. Sample Size Determination and Sampling Technique

4.6.1. Quantitative Study

Due to their smaller population size, all custom clearing officers working in governmental and non-governmental import goods customs clearance (GN), food, drugs and medical equipment customs clearance, and manufacturing imported goods customs clearance (MGA) units of BIA, KDP and MDP of ECC, and all customs clearing team (10 custom clearing officers, 4 transitory

and 2 shipment follow up officers) of EPSS who were available at the time of data collection were included.

In this study, 95 (25%) PI and distributors which cleared pharmaceutical from ECC in 2019/2020 were included.

All (n=9) local pharmaceutical manufacturing companies were invited to the study. From them, seven LM participated in the study, one refused to participate, and one was closed due to the Northern Ethiopia conflict.

In addition to the pharmaceutical companies, FF companies who were providing transit service for EPSS, PI and LM that are recruited in this study were approached. One field officer from each FF companies was approached.

Table 1: Summary of sample size determination and sampling technique

Organization	**Targeted units within the selected organization**	**Participants included**	**Size all**
ECC	GN import goods customs clearance unit, Food, Drugs and Medical equipment customs clearance unit, and Manufacturing Imported Goods Customs clearance unit	All	89
EPSS	CMD	All	16
PIs	Department or unit responsible for customs clearance and shipment follow up	95	342
LM	Department or unit responsible for customs clearance and shipment follow up	All	9
FF companies	Those who are working with EPSS and pharmaceutical companies selected by sampling technique	All	105

4.6.2. Qualitative Study

For the qualitative part, customs clearing team leaders from ECC, contract management directors, and shipment follow up and custom clearing coordinator from EPSS and experts who were in charge of the customs clearance from PI and LM were purposively included as KIs. The final sample size was 3 from ECC, 2 from EPSS and based on saturation (the point at which no new or additional information was obtained from interviewee) for pharmaceutical companies. Accordingly, a saturation was reached after 23 KIs, making a total of 28 KIs.

4.7. Data Collection and Management

4.7.1. Data Collection Instrument

For the quantitative part, semi-structured questionnaire was prepared after thorough review of literatures was done on pharmaceutical customs clearance (MSH, 2011; Moïsé, Orliac and Minor, 2011; Arvis, Saslavsky, Ojala, et al., 2014). The final questionnaire has seven sections: section one contained questions regarding socio-demographic characteristics of participants. Section two included statements regarding the applicability of custom and trade facilitation standards in ECC. A 5 point Likert scale of rating strongly disagree (1 point), disagree (2 point), neutral (3 point), agree (4 point) and strongly agree (5 point) were used. Section three assessed the implementation of customs best practice in ECC. Section four asked questions regarding the efficiency of customs clearance procedure of ECC and respondent's level of response was scored as hardly ever(1), rarely(2), sometimes(3), often(4) and nearly always(5). Section five, six and seven explored source of major delays, challenges in custom department (ECC) and challenges in EFDA, respectively.

In addition to the questionnaire, two data abstraction formats were used (1) to track pharmaceutical cleared goods in 2019/2020, and (2) to measure the time taken (in days) from the moment that cargo arrives at port or airport until the moment it clears from customs, and arrives at the warehouse (USAID/DELIVER PROJECT, 2014).

For the qualitative part, the interview guide with a probing questions was prepared in English and translated to Amharic. The Amharic version was used to explore the ideas of key informants regarding the major challenges in clearance of pharmaceutical from the custom stations, presence and cause of delays, consequence of delays and means to overcome identified challenges.

4.7.2. Data Collection Procedure

Before commencing the actual data collection, a letter of support and an explanatory statement dealing with the study objective were provided to the study organization, and the heads of the respective study institutions were approached for their approval to access, and to identify appropriate professionals to participate in the study.

For the quantitative part, the questionnaires were distributed to the participant and most of them were completed and returned on the same day. For those who were not returned, the questionnaire was collected on the following day. For the qualitative part, majority of the interviews were conducted in a private environment at the respondent's office during working hours, where the procedure was unlikely to be disrupted or overheard. The remainder of the interview was performed over the phone and the conversation was recorded once the interviewee's consent was obtained. The interview lasted between 25 and 55 minutes. Data were collected from specific number of KIs from ECC and EPSS. From pharmaceutical importers and local manufactures, KI were interviewed until saturation point was reached. A total of 28 respondents were interviewed: 18 respondents from importers; 5 respondents from LM; 2 respondents from EPSS and 3 respondents ECC. An audio recorder was used to record the response of the informants for those who were willing and a note was taken for those who refused to be recorded.

The quantitative data was collected by the Principal Investigator (PI) and three data collectors (pharmacist plus MSc candidates). They were chosen because of their prior research and data collection experience. Data was collected via physical visit to the study areas and phone call. The PI collected qualitative data through face-to-face interviews and phone call with recruited interviewees using an interview guide.

4.8. Data Quality Assurance

For the quantitative part

The face validity of the study instruments was confirmed by the advisors. A pretest was conducted to ensure the validity of the study instrument. In the pretest, questions that did not actually measure participant's perception were omitted, questions that reflect similar ideas were merged and an Amharic version of the study questionnaire was prepared (for FF).

The reliability of the study instruments was checked by calculating Cronbach's alpha coefficient with SPSS, and the results are shown in the table below. A Cronbach's alpha coefficient of 0.7 or higher is commonly regarded as indicating high reliability.

Table 2: Reliability of study instruments

Constructs	**Cronbach's α**
Customs and trade facilitation standards	0.899
Efficiency of customs clearance practice	0.764
Source of major delays	0.755
Challenges at customs department	0.820
Challenges at EFDA	0.744

The data collectors were informed on the purpose of the study, on the use of questionnaires and ethical principles of confidentiality before actual commencement of data collection. Study participants were well oriented to participant in the study and fill out the questionnaire with complete attention and interest. Before data analysis for quantitative data, collected data via the respective tool was checked for completeness.

For the qualitative part

Three pilot interviews were conducted for qualitative data to ensure that the interview guide was relevant in terms of addressing the study objectives. This resulted in minor changes to the interview guide, such as the removal of vague and leading questions and the inclusion of additional probing questions.

The Amharic versions of the audio-recorded and unrecorded interview notes were both translated into English, and complete transcripts of all interviews were generated. Before coding, the interview transcript was read, re-read, and back translated to compare translation quality and accuracy with the original text and to ensure that the meaning intended by the interviewee and the equivalence of meaning between the source and target texts were maintained.

4.9. Data Entry and Analysis

The quantitative data was analyzed using Microsoft Excel (2013) and Statistical Package Software for Social Science (SPSS V.26). Descriptive statistics (frequency, percentage, mean, median, Standard deviation (SD), and Interquartile Range (IQR) (as necessary)), tables and graphs were used to describe and summarize the data whereas inferential statistics like *t*-test and ANOVA were employed to show relationship among variables. A *p*-value less than 0.05 was considered significant. For the purpose of analysis, strongly disagree, disagree and neutral were considered as disagree (mean score of <4) and agree and strongly agree were considered as agree (mean score ≥4). On the other hand, the "nearly always and "often" choices were considered as good practice or efficient (mean score≥ 4,) and other choices as negative practice or inefficient (mean score<4).

Audio-recorded Amharic versions of the interview were translated to English and complete transcripts of all interviews were prepared. The unrecorded interview notes were organized immediately after the interviews. The thematic analysis used a deductive reasoning. Analysis was started with predetermined codes to the data set and then find quotations that fit those codes from the raw data set. The themes (three themes) used in this approach were created from propositions that the researcher has developed. Quotes for the content of the theme were given: quotes were designated as "PI" for Pharmaceutical Importers, and "LM" for LM. Three major themes were identified: challenges of pharmaceutical's port clearance; Implication of challenges; and suggestions on how to improve the pharmaceutical's customs clearance procedure. The analysis was done manually.

4.10. Ethical Consideration

Ethical approval was secured from Ethics Review Committee of the School of Pharmacy, Addis Ababa University (Ref. No. ERP/SOP/201/09/2020). An official letter of support was sent and permission was obtained from ECC, EFDA, and EPSS, selected PI, local pharmaceutical manufacturers and freight forwarding companies before actual commencement of data collection. Informed verbal consent was sought from all respondents before enrolling them into the study through providing information regarding the purpose of the study, why and how they are selected and the importance of their participation in the study. During the consent process, respondents was informed that they could withdraw from the study at any time during the data collection process. Confidentiality and anonymity were maintained throughout the

study by avoiding the use of personal identifiers. The transcribed documents were kept secured only accessible to the investigator.

4.11. Operational Definition

Pharmaceutical: In this study particularly in pharmaceutical cleared from ECC section, pharmaceutical refers to medicines (drugs) and vaccines for human use.

Freight forwarder (Clearing agent): A person issued with a custom clearing agent license, including an employee of a declarant issued, by ECC, with a certificate of professional competence in respect of customs clearance (WCO, 2006).

Customs: The Government Service which is responsible for the administration of Customs law and the collection of duties and taxes and which also has the responsibility for the application of other laws and regulations relating to the importation, exportation, movement or storage of goods (WCO, 2006).

Custom clearance: The accomplishment of the Customs formalities necessary to allow goods to enter home use, to be exported or to be placed under another Customs procedure (WCO, 2006).

Customs Clearance Lead time: amount of time (in days) from the moment that cargo arrives at ECC customs station (BIA, KDP or MDP) until the moment it clears customs, and arrives at the consignee warehouse (USAID/DELIVER PROJECT, 2014).

Custom procedure: All customs operations which carried out by the persons concerned and by ECC in order to comply with customs law (WCO, 2006).

Custom station/office: Any place designated as customs office at the port of entry or exit of goods, transit routes or customs area for the control of import and export goods or for the accomplishment of customs formalities and collection of duties and taxes (WCO, 2006).

Release of goods: A procedure whereby goods under customs control are released for the purposes declared (WCO, 2006).

Restricted goods: Goods for which the importation, exportation or transit is restricted unless it is permitted by the competent authority in accordance with legal procedures (WCO, 2006).

4.12. Researchers Position and Reflexivity

Researchers need to be reflective about their role in the study. It involves researchers' reflecting on their personal experiences with the subject under study and how their experiences might shape their interpretations of the data (Cresswell, 2016). It makes the researcher's thinking about personal and theoretical commitments visible and open to critical examination of the research process (Kleinsasser, 2000).

The researcher is a pharmacist who is pursuing an MSc in health supply chain management. He is currently working at an academic institution and has no prior experience in pharmaceutical importing companies, in local manufacturing companies, ECC and EPSS. Hence, KIs were free to express their views.

At the beginning of the study, the researcher had inadequate training in qualitative research methods. He only took a research methodology course which covered introduction to qualitative study design as part of fulfilling the MSc. Program. To minimize the impact on the study, the researcher read extensively on qualitative study design including data analysis, interpretation and presentation which allowed him to get acquainted with qualitative research. Despite his effort, the researcher being novice in qualitative research designs could have affected the overall research process and output.

The researcher being an Amharic speaker created a common ground for most KIs to freely discuss in interviews. Furthermore, the direct, face-to face interaction that an interviewer maintained with an interviewee allowed the researcher to gain deeper understanding of the participants by creating an opportunity for clarification, and probing.

5. Results

The result is divided into two sections: quantitative findings and qualitative findings. The quantitative results are further divided into four sub-sections: Pharmaceutical cleared goods, pharmaceutical customs clearance practices; customs clearance lead time; pharmaceutical customs clearance challenges.

5.1. Quantitative Findings

5.1.1. Pharmaceutical Goods Cleared From ECC in 2019/2020

During 2019/20 F.Y., the ECC cleared pharmaceutical worth of $574,487,522. These pharmaceutical were imported from 53 countries mainly from Europe (57.2% by value). EPSS was the major importer (63%) followed by PI (19.7%) and LM (1.4%). Based on the mode of transportation, almost three-fourths of the pharmaceutical products by value were imported by air (73.1 %) and the rest by sea (26.8 %) (See table 3).

Table 3: Value of Pharmaceutical Cleared from ECC in 2019/20 F. Y.

Characteristics	Value in USD	% share
Category of product		
Medicines	489,712,974	85.2
Vaccines	77,096,664	13.4
Raw materials	7,677,883.65	1.3
Continent of origin		
Asia	236,654,436	41.2
Africa	2,918,734.38	0.5
North America	5,620,956.81	0.98
Europe	328,795,376	57.2
Australia	498,008.95	0.09
Imported by		
EPSS	361,901,133	63
PI	113,499,073	19.7
LM	7,932,644.25	1.4
Others	91,154,652	15.9
Mode of transport		
Air freight	420,269,564.60	73.15
Sea freight	154,217,957.80	26.85

5.1.2. Pharmaceutical Customs Clearance Practice

5.1.2.1. Background Information on Study Organizations and Socio-demographic Characteristics of Participants

In this study, ECC, EFDA, EPSS central and 91 PI and 7 LM participated in the study. The median experience of pharmaceutical importers and local pharmaceutical manufacturers in the business was 10 years (IQR=15), and 14 years (IQR=19), respectively.

A total of 281 respondents participated in the study making a response rate of 91.1%. The mean age of participants was 33.8 years (Min=18, and Max=61). Most of them were men (59.1%) and degree holders (55.2%). They had a mean experience of 4.3 and 7.9 years in their current position and in total years of experience, respectively (see Table 4).

Table 4: Socio-demographic characteristics of respondents, March 2021 (n=281)

Characteristics	Category	n	%
Age	18-30	105	37.4
	31-40	134	47.7
	41-50	29	10.3
	>50	13	4.6
Gender	Male	166	59.1
	Female	115	40.9
Organization	ECC	84	29.9
	EPSS	12	4.3
	PI	91	32.4
	LM	7	2.5
	FF companies	87	30.9
Highest educational status	2nd high school	20	7.1
	Certificate	6	2.1
	Diploma	31	11
	Degree	155	55.2
	Masters and above	69	24.6

5.1.2.2. Perception towards Applicability of Customs and Trade Facilitation Standards in ECC

With regards to the applicability of customs and trade facilitation standards in ECC branch offices, more than three-fourths of the participants agreed on the presence of a single window service at the customs station (75.4%, 3.74). Nearly sixty percent of them said that the document for import clearance is simple and clear to understand (57.3%, 3.51). On the other hand, about 57.3% of participants disagreed with the notion that electronic manuals are available to help users when a new system is implemented (57.3%, 2.65). The average time for release and clearance of goods is not published consistently on a periodic basis (50.8%, 2.81). Moreover, half of the respondents said no consultation is conducted between importers and the government when there is introduction or amendment of trade-related laws, regulations and administrative decisions of general application (43.3%, 2.84) (see Table 5).

Table 5: Perception towards the applicability of custom and trade facilitation standards in ECC branch offices, March 2021 (n=171)

Statements	Strongly disagree/disagree n (%)	Neutral n (%)	Agree/strongly agree n (%)	Mean
The document requirement for import clearance is simple and clear to understand	48(18.7)	25(14.6)	98(57.3)	3.35
The import clearance functional unit of ECC is adequately staffed with skilled personnel to deliver fast and quality services	45(26.3)	58(33.9)	68(39.8)	3.18
Customs and other border agencies accept copy of documents	27(15.8)	42(24.5)	102(59.6)	3.51
There are full operational risk management procedures in place	36(21)	36(21.1)	99(57.9)	3.43
There is a single window service at custom stations	22(12.9)	20(11.7)	129(75.4)	3.74
There is enough information on required forms, documents and import procedures for custom agencies.	62(36.3)	43(25.1)	66(38.6)	3.07
There is enough information on required forms, documents and procedures for border agencies (EFDA).	51(29.8)	50(29.2)	70(41))	3.11
Electronic manuals are available to help users when new system is implemented	98(37.2)	21(12.3)	52(30.4)	2.65

There is an appeal mechanism in place for customs matters and other related laws.	54(31.5)	49(28.7)	68(39.8)	3.11
The average time for the release and clearance of goods is published in a consistent manner on a periodic basis, for the major custom offices.	24(14)	22(12.9)	45(26.3)	2.81
There is a difference in treatment of non-health and health commodities concerning the separation of release.	45(26.3)	52(30.4)	74(43.3)	3.25
There is a difference of treatment of perishable and non-perishable goods concerning the separation of release.	49(28.7)	50(29.2)	72(42.1)	3.17
There is cooperation between various border agencies (EFDA) with clearly established roles and responsibilities.	63(36.8)	66(38.6)	42(24.6)	2.85
There is cooperation between various border agencies (EFDA) on ground on both documentary and physical control.	54(31.6)	57(33.3)	58(35.1)	3.04
There is clear information regarding custom valuation on the custom website (there are clear rules and procedures regarding classification and valuation of imported goods).	68(39.7)	43(25.1)	60(44.8)	3.00
There are consultations between importers and the government when introducing or amending trade related laws, regulations and administrative rulings of general application.	84(56.1)	45(26.3)	52(30.4)	2.84

5.1.2.3. ECC Officers and FF Perception Difference on the Applicability of Customs and Trade Facilitation Standards

An independent *t*-test was performed to test whether there was significant perception difference on the applicability of selected trade facilitation standards by ECC officers and FF. Overall, significant difference was observed between ECC officers and FF with respect the applicability of trade facilitation standards in ECC. While the FF (M=2.817, SD=0.5)) disagreed to the opinion that trade facilitation standards are being applied in customs, ECC officers (M=3.45, SD=0.7) perceived many of trade facilitation standards to be applicable in custom stations of ECC, t(169) = -6.807, p =.002, d = -0.63, 95% CI [-0.80, -0.445]. Wider ECC officers and FF perception difference were observed in the areas of "Electronic manuals are available to help users when new system is implemented" (ECC officers mean=3.34, FF mean= 1.97, p-value<0.0001); "There is clear information regarding custom valuation on the custom website" (ECC officers mean=3.6, FF mean= 2.43, p-value=0.015);" There are consultations between importers and government when introducing or amending trade related laws, regulations and administrative rulings of general application" (ECC officers mean=3.31, FF mean= 2.38, p-value<0.0001).

Other perception gaps were on "There is a difference of treatment of perishable and non-perishable goods concerning the separation of release" (ECC officers mean=3.51, FF mean= 2.85, p-value=0.003)"; The average time for the release and clearance of good is published in a consistent manner on a periodic basis, for the major custom offices (ECC officers mean=2.85, FF mean= 2.17, p-value=0.022) (see Table 6).

Table 6: ECC officer's and FF's perception difference on the applicability of trade facilitation standards, March 2021(n=171)

Statement	ECC officers		FF		*t*(df)	*p*	Cohen's d
	M	SD	*M*	SD			
The document requirement for import clearance is simple and clear to understand	3.57	1.14	3.13	0.967	0.917	0.340	0.44
The import clearance functional unit of ECC is adequately staffed with skilled personnel to deliver fast and quality services	3.26	1.17	3.12	0.75	23.723	<0.0001	0.14
Customs and other border agencies accept copy of documents with exception(based on the type of good and or agency)	3.45	1.068	3.57	0.85	3.492	0.063	-0.12
There are full operational risk management procedures in place	3.4	1.06	3.46	0.87	6.511	0.012*	-0.06
There is a single window service at custom stations	3.79	1.12	3.69	0.73	7.965	0.005	0.1
There is enough information on required forms, documents and import procedures for custom agencies.	3.45	1.1	2.71	0.98	1.77	0.184	0.74
There is enough information on required forms, documents and procedures for border agencies (E.g. EFDA).	3.25	0.857	2.73	0.946	1.013	0.316	0.52
Electronic manuals are available to help users when new system is implemented	3.34	1.27	1.97	0.82	41.55	<0.0001*	1.37
There is an appeal mechanism in place for customs matter and other related laws.	3.4	1.08	2.7	0.92	1.488	0.224	0.7
The average time for the release and clearance of good is published in a consistent manner on a periodic basis, for the major custom offices.	2.85	1.12	2.17	1.01	5.371	0.022*	0.68

There is a difference of treatment of non-health and health commodities concerning the separation of release.	3.64	1.04	2.88	0.95	3.133	0.079	0.76
There is a difference of treatment of perishable and non-perishable goods concerning the separation of release.	3.51	1.21	2.85	0.96	9.04	0.003*	0.66
There is cooperation between various border agencies (e.g. EFDA) with clearly established roles and responsibilities.	2.89	1.06	2.59	0.82	3.4	0.067	0.3
There is cooperation between varies border agencies on ground on both documentary and physical control.	2.82	0.856	2.68	1.14	10.108	0.002*	0.14
There is clear information regarding custom valuation on the custom website.(there are clear rules and procedures regarding classification and valuation of imported goods)	3.6	1.099	2.43	0.871	6.072	0.015*	1.17
There are consultations between importers and the government when introducing or amending trade related laws, regulations and administrative rulings of general application.	3.31	1.29	2.38	0.879	18.33	<0.0001*	0.5

*P-value less than 0.05 is considered significant

5.1.2.4. Perception about Customs Best Practices

As far as custom best practice is concerned, a significantly higher percentage of respondents (93%) reported that custom declarations could be submitted and processed electronically and online. Besides, nearly 85% of them were aware that customs procedures require importers to use a licensed customs broker to clear goods (84.2%). Additionally, one-thirds (29.8%) were not sure whether or not pharmaceutical shipments would be released pending final clearance against the accepted guarantee (See table 7).

Table 7: Respondents perception towards customs best practices, Addis Ababa, Ethiopia, March 2021(n=171)

Statement	Yes	No	N/A	I don't know
Customs declarations be submitted and processed electronically and on-line	159(93)	8(4.7)	1(0.6)	3(1.8)
Custom code require importers to use a licensed customs broker to clear goods	144(84.2))	27(15.8)	-	-
Customers able to choose the location of the final clearance of goods?	110(64.7)	20(11.7)	13(7.6)	31(18.1)
Pharmaceutical shipments can be released pending final clearance against an accepted guarantee	83(48.5)	23(13.4)	15(8.8)	50(29.8)

5.1.2.5. Perception towards Efficiency of Customs Clearance Procedure

Concerning efficiency of customs clearance procedure, 40% of participants indicated having transparent procedures always (36.3%, 3.03). On the other hand, the majority of them felt they were not provided adequate and timely information when the regulation was changed (37%, 2.6). Furthermore, more than one-thirds of the respondents stated imported shipments were rarely cleared from customs as scheduled (35.2%, 2.94) (See Table 8).

Table 8: Perception towards efficiency of custom clearance procedure in ECC branch offices, March 2021(n=281*)*

Statement	Hardly ever (1) n (%)	Rarely (2) n (%)	Sometimes (3) n (%)	Often (4) n (%)	Nearly always (5) n (%)	Mean(±SD)
Imported shipments are cleared and delivered as scheduled	29(10.3)	70(24.9)	91(32.4)	71(25.3)	20(7.1)	2.9(1.095)
The custom clearance procedure is transparent	35(12.5)	51(18.1)	93(33.1)	74(26.3)	28(10.0)	3.03(1.16)
The custom procedures of other border agencies (E.g. EFDA) are transparent	23(8.2)	64(22.8)	92(32.7)	77(27.4)	25(8.9)	3.06(1.089)
Received adequate and timely information when regulation changed	52(18.5)	97(18.5)	66(23.5)	43(15.3)	23(8.2)	2.6(1.1)
Importers demonstrating high level of compliance receive expedited clearance	51(18.1)	54(19.2)	84(29.9)	77(27.4)	15(5.3)	2.83(1.17)

5.1.2.6. Difference in Respondent's Perception of Efficiency of Pharmaceutical Customs Clearance Process

Generally, the study showed a lower mean score for efficiency of custom clearance process (M= 2.85) evaluating the process as inefficient. The overall mean score for efficiency of pharmaceutical custom clearance was 3.14, 2.45 and 2.97 for ECC officers, FF and Pharmaceutical importers, respectively. One way ANOVA was computed and showed a significant difference among group mean scores where ECC officers appeared to have a higher mean score as compared to FF and pharmaceutical companies (*P*-value<0.0001) (see Table 9).

Table 9: Difference in respondent's perception of efficiency of pharmaceutical customs clearance process, March 2021(n=281*)*

Variable	**Mean score(±SD)**	***F*-score**	***p*-Value**
Place of work		22.738	0.000
ECC(n=84)	3.14(0.75)		
FF(n=87)	2.45(0.657)		
PI/LM/EPSS(n=110)	2.97(0.80)		
Type of importer(n=110)		2.037	0.135
EPSS(n=12)	3.07(0.787)		
LM(n=7)	2.88(0.712)		
PI(n=91)	2.96(0.8)		

5.1.2.7. Source of Major Delays

Bureaucracy at port (60.8%) and missing or incomplete documentation (57.3%), inadequate communication with stakeholders (52.6%) were identified as the most common sources of delay in clearing pharmaceutical at port (see table 10).

Table 10: EPSS, PI and LM's experience towards source of major delays, March, 2021 (n=110)

Port clearance delays due to	Hardly ever (1) n (%)	Rarely (2) n (%)	Sometimes (3) n (%)	Often (4) n (%)	Nearly always (5) n (%)
Poor procedure by the supplier	23(20.9)	23(20.9)	43(39)	18(16.4)	3(2.7)
Bureaucratic delays at port	8(7.3)	17(15.5)	18(16.4)	43(39)	24(21.8)
Inadequate communication with stakeholders	11(10)	6(5.5)	35(31.8)	37(33.6)	21(19)
Lack of human resource at your office	38(34.5)	47(42.7)	14(12.7)	8(7.2)	3(2.7)
Missing or incomplete documentation	22(20)	13(11.8)	12(10.9)	40(36.4)	23(20.9)
Lack of fund to clear goods	50(45.5)	21(21.7)	21(21.7)	9(8.2)	3(2.7)
Compulsory warehousing	38(34.5)	39(35.5)	21(19)	8(7.3)	4(3.6)
Pre-shipment inspection	44(40)	34(30.9)	10(9.1)	8(8.2)	14(12.7)
Marine time transport	26(23.6)	22(20)	35(31.8)	17(15.5)	10(9.1)
Criminal activities	75(68.2)	22(20)	7(6.4)	3(2.7)	3(2.7)
Solicitation of informal payments in connection with logistic activities	57(51.9)	23(20.9)	13(11.8)	5(4.5)	12(10.9)

5.1.3. Customs Clearance Lead Time

Figure 4 depicts the average number of days required to clear pharmaceutical from customs. For air cargo, on average, it took 13, 7.2, and 9.6 days to clear pharmaceutical from airport for EPSS, PI and LM, respectively. On the other hand, for sea shipments, it took 49, 8.2, 13.7 day for EPSS, PI, and LM, respectively.

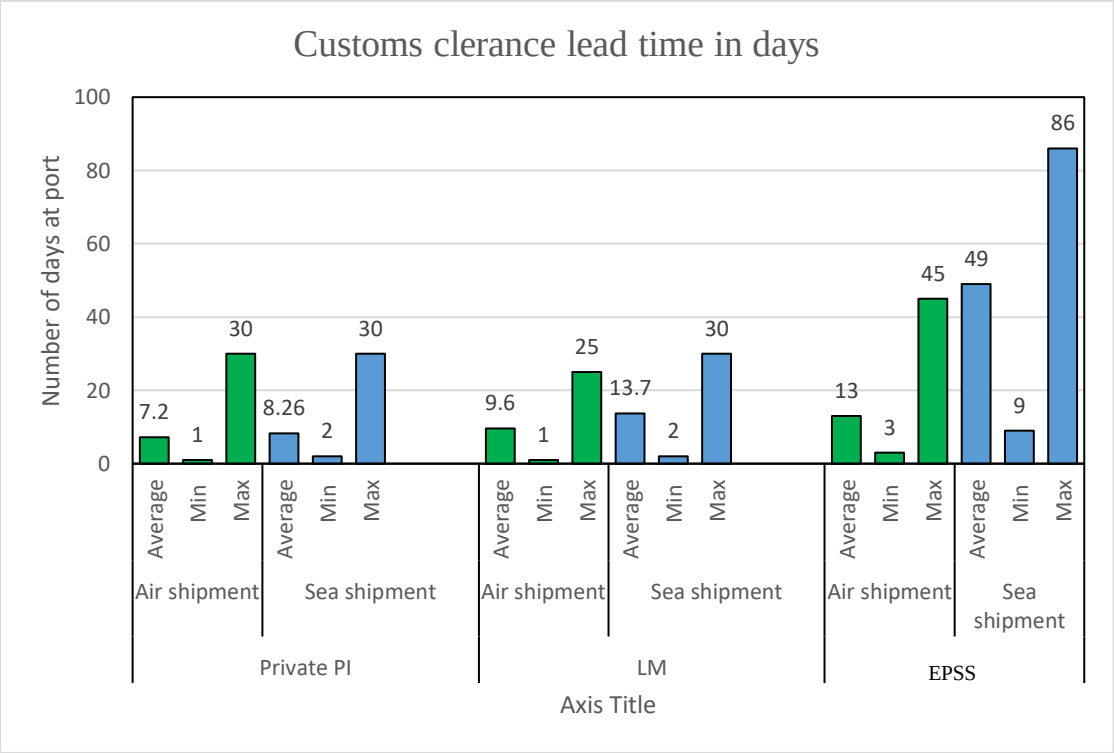

Figure 2: Lead time for the clearance of Pharmaceutical shipped via air and sea, March 2021

5.1.4. Challenges at Customs Department in ECC

In this study, majority of the respondents agreed that frequent breakdown of the electronic document lodging system (71.6%), followed by resolving issues related to valuation and tariff queries(67.5%,) were the common challenges that face the customs department. In addition, they cited not having empowered front-lines officers (67%), unprofessional attitude of customs employees (56.3%), and lack of container handling equipment (55.9%) as challenges in dealing with customs departments (see Table 11).

Table 11: Challenges of pharmaceutical's custom clearance at ECC, March 2021(n=197)

Statements	Strongly disagree (1) n (%)	Disagree (2) n (%)	Neutral (3) n (%)	Agree (4) n (%)	Strongly agree (5) n (%)
Breakdown of electronic system for document lodging	11(5.6)	14(7.1)	31(15.7)	105(53.3)	36(18.3)
Delays in processing lodged documents by custom officer.	11(5.6)	27(13.7)	44(22.3)	84(42.6)	31(15.7)
Unpredictable penalties/charges	15(7.6)	41(20.8)	73(37.1)	46(23.4)	21(10.7)
Resolving queries on valuation and tariff HS codes takes longer	5(2.5)	25(12.7)	34(17.3)	93(47.2)	40(20.3)
Lack of equipment to offload/ handle containers/cargo/	13(6.6)	36(18.3)	38(19.3)	73(37.1)	37(18.8)
Post clearance audit	27(13.7)	46(23.4)	71(36)	38(19.3)	15(7.6)
Inadequate communication with importers on changes at custom regulation	18(9.1)	31(15.7)	56(28.4)	71(36.0)	21(10.7)
Corruption	22(11.2)	36(18.3)	72(36.5)	58(29.4)	9(4.6)
Unprofessional like attitude of custom officers	13(6.6)	29(14.7)	40(20.3)	83(42.1)	32(16.2)
Disempowered frontline officer in decision making	15(7.6)	17(8.6)	33(16.8)	104(52.8)	28(14.2)
Inadequate competence of custom staff	10(5.1)	27(13.7)	65(33)	77(39.1)	18(9.1)
Incompatibility of computer system with that of stakeholders	28(14.2)	43(21.8)	63(32)	47(23.9)	16(8.1)

5.1.5. Challenges at EFDA

With regards to challenges faced at EFDA, delays in inspection and compliance testing (69.5%) was the major challenge. In contrast, taking samples bigger than the necessary (55.8%) was not a challenge (see Table 12).

Table 12*:* Challenges of pharmaceutical's customs clearance at EFDA, March 2021 (n=197)

Statement	Strongly disagree (1) n (%)	Disagree (2) n (%)	Neutral (3) n (%)	Agree (4) n (%)	Strongly agree (5) n (%)
Delays in inspection and testing for conformance to standard	3(1.5)	15(7.6)	42(21.3)	96(48.7)	41(20.8)
Inadequate competence and skills of EFDA staff	19(9.6)	53(26.9)	82(41.6)	37(18.8)	6(3)
Taking bigger samples than necessary for testing	38(19.3)	72(36.5)	47(23.9)	28(14.2)	12(6.1)
Inadequate laboratory facilities	8(4.1)	31(15.7)	101(51.3)	49(24.9)	8(4.1)

5.2. Qualitative Findings

5.2.1. Socio-demographic Characteristics of Key Informants

Twenty eight KIs (23 from pharmaceutical companies, three from ECC, and two from EPSS were interviewed. The majority of the participants were males between the age of 29 and 50 years, with 5 to 10 years of work experience (see Table 13).

Table 13: Socio-demographic characteristics of KIs, March 2021(n=28)

Characteristics	Category	N (%)
Gender	Male	20 (71.4)
	Female	8 (28.6)
Age group (in years)	25-30	6 (21.4)
	31-35	10 (35.8)
	36-40	6 (21.4)
	≥40	6 (21.4)
Work Experience (in years)	5-10	12 (42.9)
	11-15	10 (35.7)
	≥16	6 (21.4)
Work area	Pharmaceutical companies(PI and LM)	23 (82.1)
	EPSS	2 (7.2)
	ECC	3 (10.7)

5.2.2. Key Informants Opinion on the Challenges of Pharmaceutical Customs Clearance

For the analysis and interpretation of KI's opinion, a manual thematic analysis using a deductive approach was followed under three major themes. The three major themes were challenges of pharmaceutical's port clearance; Implication of challenges; and suggestions on how to improve the pharmaceutical's customs clearance procedure.

Theme 1: Challenges Related to Pharmaceutical's Port Clearance

Participants attributed the cause of prolonged custom clearance procedures to several challenges related to ECC and EFDA. The most common challenges from ECC were identified as competency gaps in customs employees, system interruption, valuation issues, poor pharmaceutical handling, and a shortage of handling equipment at the port. From the EFDA's perspective, the challenges were inspection delays, bureaucracy, and poor professional mix. Specific challenges substantiated with KIs quotation is presented below.

Challenges Related to ECC

Participants reported that customs employees lack the required technical knowledge, competencies and skills about the items they handle.

> "*The professionals assigned to the position are social science (management or accounting or marketing) graduates, who do not have enough knowledge about pharmaceutical. For example, they do not differentiate pharmaceutical based on their strength, dosage form, brand, or generic nature, or even between manufacturer and license holder. It's obvious that you will suffer if your case is being processed by someone who doesn't have the know-how." (Male, 14 years of experience, LM)*

Another respondent added

> *"Because the pharmaceutical and medical equipment custom clearance unit is not being led by professional who is knowledgeable about them, the agency is facing a huge challenge. I don't expect individual working in the ECC who have a background of banking and insurance or accounting to have detail knowledge about pharmaceutical. Instead, why not assign pharmacists or laboratory scientists to the position?"(Male. 15 years of experience, EPSS)*

They also pointed out that customs officers lack how to handle customers.

> *"They always see us (customers) like a thief or cheater. They treat us " skeptically"" (Male, 10 years of experience, PI)*

Respondents also explained that pharmaceutical are being treated like any other good, they hardly get priority.

"Although they say priority is given for pharmaceutical, we haven't seen priority on board" (Male, 8 years of experience, PI)

Almost all participants faced system (Ethiopian Custom Valuation System [ECVS]) related challenges such as interruption, and delay.

" There is a problem with the so-called 'system.' Even in the event of an emergency, customs officers say that your document is trapped by the system (Male, 5 years of experience, EPSS).

Custom officers also witnessed that

"*The biggest and most significant challenge is system interruption and power outage."(F, 24 years of experience, ECC)*

Many participants stated that there is a problem with the custom valuation system. The tax levied is not based on the invoice submitted by the supplier. In addition, it lacks consistency between similar medicines imported from the same country and the same supplier.

"Although we submit a commercial invoice that we have received directly from the manufacturer, we are taxed on the basis of the Google reference price. The reference price and the supplier price are completely different, not even comparable."(Female, 8 years of experience, LM).

One respondent said

"Customs officers take the highest price from the Custom Database (CD) when they levy tax on a particular medicine even though it has a different country of origin from the reference. The dispute starts here, which could take up to six months and cause a huge delay" (Male, 14 years of experience, PI)

One respondent added

"*Two or three importers may import products from a single supplier. While others are taxed based on an invoice, I might be asked to pay extra. There is a variation depending on the custom officer positioned there. If they are not well-experienced and especially*

newly assigned, to protect themselves from under-invoicing suspicion, they shall levy the highest tax." (Male, 20 years of experience, PI)

One respondent from local manufacturer claimed that

"The exempt tax is irrelevant; it does not take into account the sector and the overhead costs that we incur". (Male, 15 years of experience, LM)

Customs officers responded that the electronic system (ECVS) managed at the head office level is the primary source of data and pricing, on which they rely. They agreed that the levied tax could vary depending on customs officer expertise and personal judgment.

"Because we have one data source, the ECVS, a centralized system managed at the head office level, the valuation method used at all custom stations is similar. It has a consolidated price for all products, which we all use as a reference. The issue with importers is that they do not submit true invoices."(Female, 13 years of experience, ECC)

Another customs officer replied

"We compare the invoice price with ours in the database. In the case of products with multiple prices from a single country of origin, we may accept or reject the invoice price. This varies depending on one's understanding; here, experience plays a crucial role in making a better decision. If you are unsure of what to do, you may charge a higher duty." (Male, 14 years of experience, ECC)

Participants highlighted another major challenge, which is poor handling of imported pharmaceutical shipments at port in terms of non-compliance with storage requirements and exposure to direct sunlight and rain, which compromises the quality and effectiveness of pharmaceutical.

"I don't think there is a well roofed and enough storage area at the port. There were incidents in which our consignment was exposed to rain and spoiled." (Male, 14 years of experience, PI)

One respondent added

> *"Temperature sensitive biological products are not stored as per their specific requirements. After being unloaded from the cargo, they are left on the port street for 2 to 3 days without being refrigerated. You can judge how much potency or efficiency it will have when it reaches the hands of the public." (Male, 15 years of experience, EPSS)*

In addition, respondents noted that locating the shipments (the shipment may not be found at that given location) from the airport cargo takes days. This will result in delay in inspection.

> *"EFDA inspectors say they have not been able to locate the pharmaceutical shipment in the specified place at the Airport cargo and leave without inspecting it. This prolong the custom clearance process." (Male, 5 years of experience, EPSS)*

Participants reported there is poor collaboration between ECC and EFDA.

> "*There is poor cooperation between EFDA and ECC. For example, sometimes customs officers request the import permit as new that we obtained from EFDA after going through the necessary steps. Due to such reasons, there have been incidents that we have gone back and forth between the two offices due to miscommunication between them. Female, 10 years of experience, PI)*

Respondents also pointed out shortage and frequent out-of-service of loading and unloading cranes and forklifts for sea transport. This causes delay in the custom clearance process.

> "*There are a limited number of container lift cranes in Modjo dry port, and they are sometimes out of service. Because of this, there will be a delay." (Male, 12 years of experience, PI)*

Challenges Related to EFDA

Participants indicated that the EFDA port officers are bureaucratic and often serve through informal means of communication.

> *"There is a technical incompetence. Besides they are bureaucratic, for example, while they could access Certificate of Registration (COR), Market Authorization Certificate (MAC) and Purchase Order (PO) online, they ask you to bring those documents for every import transaction. They're still on the manual system, they haven't moved to the online system.*

This could lead to a delay of 4-5 days in the clearance of imported shipments." (Male, 8 years of experience, PI)

One respondent added

"At port the work is done through informal way of doing business like personal connection, friendship and other means" (Male, 14 years of experience, LM)

Some participants argued that there is a high turnover of experienced EFDA officers and substitution with less experienced officers.

"Every time there's turnover of staff at EFDA port offices. New officers replace experienced professionals. Since the new officers have no work experience, they must read every directive and every law and try to implement it as much as they can. The customs clearance activity requires flexibility, subjective judgment based on the procedure and previous experience. If not, it's going to be impossible to run business." (Male, 12 years of experience, PI)

Most of the participants agreed that there would be a delay in the inspection of the imported shipment and the release of the port clearance permit. They also stressed the loss of import documents submitted to the EFDA Port Offices as a request for inspection. "

"EFDA has been conducting consignment tests for the last two to three year (sample will be taken from each batch of imported pharmaceutical and tested to the standard). This process takes a long time, sometimes up to six months. Unless and until the test results are received, the agency will be unable to distribute the pharmaceutical. This raises the issue of shelf life and lead time (to reach the patient)." (Male 15 years of experience, EPSS)

One respondent added

"*The document may be lost during inspection. In this case, the document must be re-collected and re-submitted. This will prolong the custom clearance process and expose you to demurrage costs." (Male, 5 years of experience, EPSS)*

Some participants argued that there is a poor professional mix in the EFDA port offices indicating absence of multi-disciplinary work.

"There is a problem with the professional mix that fails to consider the nature of the product (laboratory reagent and medical equipment). Most of the positions are filled by pharmacists; it's rare to meet a lab technician or a biomedical engineer." (Male, 24 years of experience, PI)

Another respondent added

"We're having trouble availing spare parts for previously imported medical equipment. This is because the positioned professionals lack the specific knowledge and capacity required." (Male, 20 years of experience, PI)

Theme 2: Implication of Challenges in PI/LM and EPSS Operation

Participants reported disruption of supplies and losing market as a result of delayed customs clearance procedure. They explained that another importer who imports the same product will take the market share.

"*You lose market opportunities, in particular for products that have been missing from the market for a while. Another importer brings the product and take advantage of the market share." (Male, 5 years of experience, PI)*

Another responded added

"*The patient is expecting the medicine! You must complete the customs clearance process and deliver it as soon as possible. The longer the pharmaceutical shipment is held up in customs, the less likely the patient will receive the medication and be cured." (Male, 10 years of work experience, PI)*

Incurring additional costs in the form of demurrage and penalty payments are another implication of challenges faced at ECC and or EFDA.

"*As the customs clearance is delayed, importers are exposed to demurrage which is an additional expense to the landing cost of medicine, resulting higher price than the market price. This ultimately affects your competitiveness with other pharmaceutical importers." (Male, 5 years of experience, PI)*

Another respondent added

"There is no doubt that the agency incurs significant costs in terms of demurrage, transportation and container rent, and that most of these costs are added to the product price, making it expensive. Sometimes the price of the private market outbids us." (Male, 15 years of experience, EPSS)

Some of the participants claimed that, whenever there is a dispute over the valuation of imported shipments, the customs clearance procedure will be delayed. This will impact the profitability of the company as it relates to working capital.

"*When high taxes are levied on your shipment, you need the courage to deal with the customs office and win the case. Until then, a lot of money will be tied up. This results in a serious shortage of working capital." (Male, 14 years of experience, PI)*

Participants from the local pharmaceutical manufacturer also explained that the challenges faced by customs clearance will cause disruption and congestion in the production plan. This will result in delays in production and loss of waiting customers.

"Arranged plans will be affected by prolonged customs clearance. There will be delays in work activities and failure to move according to the plan. You're not going to achieve a monthly target that ultimately causes a huge loss. (Male, 14 years of experience, LM)

Another respondent added

"Failure to deliver the medicine to EPSS and the private market on time." (Male, 11 years of experience, LM)

Theme 3: Suggestions on How to Improve Pharmaceutical Customs Clearance Procedure

Participants provided various suggestions to improve the pharmaceutical customs clearance process. They suggested that ECC must hire professionals who are relevant to the sector, taking into account the distinctive nature of imported shipments. In addition, the on-going capacity-building mechanism for professionals must be established through training, guidance and experience sharing, especially for newly appointed officers.

"Since there would be a lot of disputes, competent staff must be hired and their competence must be continually enhanced. It would also be better if there were follow-up from the higher official." (Male, 14 years of experience, PI)

One respondent added

"*EFDA, in collaboration with ECC, must provide training to customs officers on the pharmaceutical nature, such as strength, dosage form and proprietary." (Female, 10 years of experience, PI)*

They indicate that professionals working in ECC and or EFDA has to do their job professionally by being accountable and responsible. In addition, participants stressed that it's better if they show friendly approach and create smooth working environment.

"It would be better if the professional could fulfill his/her responsibilities. In addition, they must provide service as per the procedure in which everyone is equally served by avoiding partiality. (Female, 8years of experience, LM)

They also underlined the importance of consultation between ECC, EFDA and the importers or agents prior to the new regulation or law coming to an effect. They also proposed guidelines/directives to be flexible for amendment.

"It would be better if they could ask for our opinion and concern, share the draft and prepare a panel for discussion before the adoption and implementation of new rules and procedures." (Male, 24 years of experience, PI)

Most of the participants stressed the valuation technique used by customs to charge tax and other customs duties on the basis of the invoice submitted by the manufacturer/supplier. They also emphasized that the customs office to update the prices in the Customs Database (CD) more frequently.

"Customs CD (price) should be updated on a regular basis. If that is the case, there will be no price fluctuations and there will be no unnecessary disputes." (Female, 10 years of experience, PI)

Respondents underlined increasing the number of handling equipment (cranes and forklifts) and providing timely service. They also suggested ECC to consider outsourcing (partially or fully) the loading and unloading service to the private sector.

> *"Planned Preventive Maintenance (PPM) and timely service for container lift cranes must be provided. It will keep the equipment operational and reduce down time. (Male, 12 years of experience, PI)*

6. Discussion

This study attempted to characterize pharmaceutical goods cleared from ECC in 2019/2020 G.C. It also assessed the applicability of trade facilitation standards, best practices in customs, and the efficiency of the customs clearance processes. Furthermore, the present study tried to identify challenges faced by EPSS, PI, and LM in dealing with pharmaceutical's customs clearance.

In this study, medicines accounts for a significant percentage of the total import value followed by raw materials. A similar finding was observed in a Tanzanian study, where medicinal products accounted for 91% of the imported value and raw materials accounted for <1% (Wande *et al.*, 2019). This figure demonstrates that Ethiopia heavily rely on import for its pharmaceutical need (MOI and MOH, 2015)

More than half of the imported pharmaceutical by value were sourced from European countries (53%). In other studies, conducted in African countries like Uganda, Kenya and Tanzania, a higher percentage of medicine were imported from Asian countries (India and China) (UNIDO, 2009a, 2009b; 2011; Wande *et al.*, 2019). In the present study, the presence of vaccines could explain a higher percentage of pharmaceutical imports from Europe, as they account for 10% of total import value and are primarily imported from European countries.

In the present study, EPSS is the biggest importer of pharmaceutical followed by private PI and other sector importers. On the other hand, in Tanzania private sector is the major importer of pharmaceutical (Wande *et al.*, 2019). In this study, the largest share being taken by EPSS could be seen as a greater opportunity for sustainable supply of essential pharmaceutical to public health institutions, resulting in improved availability.

Concerning the applicability of customs and trade facilitation standards, the majority of participants indicated the implementation of electronic single window service in customs stations of ECC. A COMESA report showed that the electronic Single window service has been operational in eight member states (COMESA, 2017). The implementation of a single window service could be viewed as a great initiative because it contributes significantly to lower customs operation costs, faster clearance times, and overall simplicity (European Commission, 2015).

On the other hand, lack of cooperation between national i.e. EFDA and ECC and cross border agencies in both documentary and physical control. This is supported by the study's qualitative

findings, in which participants from PI claimed poor collaboration between EFDA and ECC. Other studies in Ethiopia also revealed similar results, indicating a lack of proper cooperation among border agencies (Bireda, 2018; Lemma, 2018; Muktar, 2019; Yigletu, 2020). This not only causes delay of clearance time delays (COMESA, 2017) but also leads to duplication of effort and an increased costs of imported pharmaceutical (Ojala and Celebi, 2015; Yigletu, 2020).

In addition, electronic manuals are not available whenever a new system is implemented. A similar finding was reported in Nigeria, Ghana, and Morocco, making import and export methodology time-consuming (Dare *et al.*, 2019).

Unlike ECC officers, the majority of FF participants in this study disagree that consultations between importers and government occur when new or amended trade-related laws and regulations are enacted. This is consistent with a previous study conducted in Ethiopia of importers and customs clearing agents, which showed that half of the respondents were dissatisfied with the availability of a proper consultation and awareness creation forum (Minwagaw, 2016; Muktar, 2019). Preparing discussion platforms between importers/ their agents and the government prior to the implementation of new customs or trade-related legislations may encourage voluntary compliance and improve trade facilitation efforts (Kassahun, 2014).

Submitting and processing customs declarations electronically and on-line, and enforcing importers to use a licensed customs broker to clear goods, are considered as best practices. This is obviously due to the fact that Ethiopia has implemented an electronic single window service since April 2020, and declarations are now made electronically and online (Ethiopian Single Window for Trader, 2020). Second, Ethiopian customs regulations necessitate the use of a customs clearing agent to have import items cleared (ERCA, 2017).

In terms of the efficiency of the customs clearance procedure, the majority of participants rated that the customs clearance procedure was often or nearly always transparent. In line with the current finding, the LPI 2018 report revealed that the majority of respondents (60%) from Sub-Saharan Africa stated that customs clearance was frequently or nearly always transparent (Arvis *et al.*, 2018a). This could be viewed positively as transparency entitles importers to fully comprehend the condition of imports and their constraints, as well as to gain an accurate picture of potential costs (WCO, 2016)

In addition, imported shipments are rarely or hardly ever cleared and delivered as scheduled. This is consistent with Modjo dry port's findings (Dare *et al.*, 2019). This implies as pharmaceutical shipments are delayed in reaching health facilities and, ultimately, patients. More to that, the longer they remain in the customs station, the greater the risk of damage and quality compromise as a result of exposure to extreme temperatures and mishandling (Lemma, 2018).

Importers and LM hardly ever receive adequate and timely information when regulation is changed as reported in the previous study conducted in Ethiopia (Muktar, 2019; Mekonnen, 2020). Similarly, a Myanmar trade survey report found that only 13% of importers said they nearly always receive adequate information (Asian Development bank, 2017). This may have a negative implication because a sudden change in regulations on clearance of consignment that importers or their agents are unaware of can seriously erode predictability and negatively impact importers' transactions (WCO, 2016).

In terms of lead time, this study showed that it took 7.6 days for PI to complete the customs clearance process of a pharmaceutical consignment, while it took 9.6 days and 13 days for LM and EPSS when the consignment was imported via airfreight, respectively. For imports transported through sea freight, the number of days in cargo were an average of 8.2, 13.6 and 49 days for PI, LM and EPSS, respectively. This average clearance time is longer than neighboring countries such as Kenya, where it was 4 hours and 29 minutes, and Djibouti, where it was 14 hours and 27 minutes (COMESA, 2017). In this study, the longer clearance time could be due to lack of coordination among regulatory agencies, and duplication of efforts among them (Yigletu, 2020). The longer clearance period observed in EPSS could be due to EPSS's in-house issues, such as a shortage of warehouse space to store imported consignments and the existence of unsettled unpaid payments to ECC by EPSS (ECC holds up subsequent shipments before the outstanding fees are settled)(EPSS and R4D, 2021). The implication of longer clearance times could be in terms of additional cost (demurrage costs, penalty payments) and increased import lead time affecting timely arrival of goods.

When it comes to the challenges of pharmaceutical customs clearance at ECC, a breakdown of the electronic system for document lodging is identified as the main issue which is supported by the qualitative findings and a study conducted in Modjo dry port (Temesgen, 2020).

Another issue that the majority of respondents in the current study agreed on was the length of time it takes to resolve valuation and tariff issues. Furthermore, the qualitative findings revealed that there is a problem with the ECC valuation system, indicating that the tax and duty levied are not invoice-based and lacks consistency. The majority of the interviewee complained that custom officers by default choose the highest price when they levy tax. This result is in line with almost all studies conducted in Ethiopia, which identified customs valuation as the most difficult area and a major source of delay (Minwagaw, 2016; Bireda, 2018; Lemma, 2018; Dawit, 2019; Muktar, 2019; Temesgen, 2020). In this study, pharmaceutical importers were clear that any cost incurred during the process is considered an expense and will be added to the landing cost of the medicine. This scenario has the potential to significantly increase the price of imported medicines before they begin their journey down the distribution chain, jeopardizing the product's affordability (Banic and Stevens, 2015). This means that patients will have to face an additional financial burden on the cost of imports (Dawit, 2019).

Another challenge faced in dealing with port clearance was a lack of adequate cargo handling equipment such as loading and unloading cranes and forklifts in Modjo dry port causing longer waiting times and delay in custom clearance process. This result is in line with a previous study in Ethiopia, which found lower customer satisfaction with the adequacy and modernization of loading and unloading equipment in Modjo dry port (Seid, 2014). Similar findings have been reported in other countries (COMESA, 2017; Elferjani, 2017; Shanmugam, 2020). Adequate number of handling equipment coupled with advanced technologies like Radio Frequency Identification (RFID) should be used to improve efficiency of handling activities (Politecnico *et al.*, 2007) and lower waiting times, minimize risk of damage and loss of cargo as well as decrease port congestion (Shanmugam, 2020).

Aside from the challenges discussed in the quantitative section of the finding, participants who were interviewed raised additional concerns. According to the interviewee, poor handling of pharmaceutical consignments and exposure to unnecessary storage condition was also mentioned as another challenge while dealing with customs clearance. Another study conducted in Ethiopia among private importers discovered that pharmaceutical are being exposed to less than required storage conditions due to a lack of adequate equipment and facilities such as cold storage. According to the same study, importers contribute to the mentioned challenge by importing

temperature sensitive pharmaceutical in a standard container rather than an insulated one (Teklu, 2019). This has serious implications because it compromises the quality and efficacy of pharmaceutical, especially vaccines and other temperature sensitive products (MSH, 2011). Additional costs may be incurred to test the potency of the items and dispose of damaged or obsolete products (MSH, 2011). In addition to shipping temperature sensitive pharmaceutical in insulated containers, importers can overcome these bottlenecks by strictly following and enacting customs procedures and proving their customs control and procedures are efficient and compliant as Authorized Economic Operators (AEO) to gain faster access to certain simplified procedures and, in some cases, the right to fast-track shipments through customs. Importers could also build bonded warehouse to keep pharmaceutical goods with duty or import VAT payments suspended, allowing them to maintain the essential handling and storage conditions the pharmaceutical items require. .

With regard to challenges related to EFDA, more than two-thirds of participants (69.5%) agreed on the presence of delay in inspection. Similar findings were also highlighted in the qualitative findings. This finding is consistent with recent study conducted in EPSS which identified EFDA's slow inspection process as the primary challenge delaying the subsequent clearance process (EPSS and R4D, 2021). The finding is also consistent with a study conducted in Saudi Arabia, which found that the inspection process was delayed and was dependent on the mood of the inspector (Al-Haddad, Chuman and Kouki, 2021). This would add to the other challenges of custom clearance and contribute to longer lead times and affect timely arrival of pharmaceutical consignments.

6.1.Limitation of the study

The respondents were interviewed or filled the questionnaire (ECC officers) in the setup of the facility. Therefore, the findings of the study could suffer from social desirability bias. This study partly used a secondary data source and therefore, it may have suffered from the disadvantages associated with such sources. This study used phone calls to interview some of the respondents (due to the COVID 19 protocol at the time of data collection), which may have influenced the data collection process (had it been a face-to-face interview, probing, maintaining an eye contact, and clarifying questions could have been done better).

7. Summary of study findings

- Pharmaceutical worth of $574,487,522 are cleared from ECC in 2019/2020 physical year. Majority of pharmaceutical were sourced from European countries by EPSS via airfreight.
- The overall mean score for customs and trade facilitation standards was 3.13(±0.6). An independent t-test was performed and showed as significant perception difference respondents where FF (M=2.817±0.5) perceived that most of trade facilitation standards are not being applied on contrary to ECC officers (M=3.45±0.7).
- The overall means score for efficiency of pharmaceutical customs clearance was 3.14, 2.45, and 2.97 for ECC officers, FF and PI, respectively. The computed mean score was found to be 2.85, evaluating the clearance process as having low efficiency. One-way ANNOVA was computed and showed that ECC officers had a higher mean score as compared to FF and pharmaceutical importers.
- For importers from all sectors (PI, LM, and EPSS), it took an average of 10 days to clear pharmaceutical consignments transported via air freight, and 23 days for sea freight.
- Respondents cited various ECC and EFDA challenges as the cause of the prolonged customs clearance process. Some of the challenges in ECC custom station include gaps in ECC employee competency, system interruption (eCMS and ECVS), gaps in valuation system (not invoice based and inconsistent), and poor pharmaceutical handling. EFDA's challenges were inspection delays, bureaucracy, and a poor professional mix (lack of adequate laboratory technologists and Biomedical Engineer).

8. Conclusion

Generally, participants perceived that most of customs and trade facilitation standards are not being applied in ECC custom stations and that the customs clearance procedure for pharmaceutical was inefficient. According to the findings, ECC officers have shown positive perception towards the pharmaceutical customs clearance practice in ECC customs station as compared to FF, EPSS and pharmaceutical companies. This study also identified that EPSS, PI, and LM face delays and additional cost as a result of interruptions in the electronic system (ECVS), issues with valuation techniques, gaps in competence of front-line customs officers, and delays in inspection, and testing for conformance to standard and that their operations are being negatively affected. Consequently, patients are forced to bear unnecessary costs incurred due to the system inefficiency.

9. Recommendations

The following recommendations are forwarded based on the findings of this study:

To ECC

- Should adopt and implement upcoming customs and trade facilitation standards timely to simplify, modernize and enhance efficiency of the customs clearance process.
- In collaboration with EFDA, it should provide on-the-job training for newly assigned customs officers on the dynamics of pharmaceutical nature such as generic and branded formulations, strengths, dosage forms, and packaging. Additionally, on-going capacity-building mechanism for professionals must be established through training, guidance and experience sharing, especially for newly appointed officers.
- There is a need to complete and update the ECVS towards a rich and diverse standard. It should be developed according to the categories (country of origin, strength, and dosage forms), at both the domestic and international levels, taking into account the nature of imported goods, their value, and the number of importers and manufacturers. It is also suggested that the customs office to update the prices in the Customs Database (CD) more frequently.
- Should consider rewarding and encouraging importers and stakeholders producing accurate value declarations putting them in the enterprise priority custom clearance and providing certificates of appreciation to motivate and educate them.
- ECC should provide consultation platforms and an appropriate time period for pharmaceutical importers, manufacturers, and other interested parties to comment on proposed new or amended laws and regulations governing the clearance and release of goods. Importers should also be notified in advance before such changes take effect.
- ECC, in collaboration with airport agencies and the EFDA, must ensure that imported pharmaceutical consignments are stored and handled in accordance with storage requirements, particularly for those requiring special storage conditions.

To EFDA

- EFDA officers shall add reasonable flexibility to their work and provide a timely inspection and conformance to standard tests to facilitate fast clearance and release of pharmaceutical consignments.

To EPSS, PI and LM

- Should strictly adhere to and implement customs procedures, as well as continuously check their customs control and procedures are efficient and compliant in order to gain faster access to certain simplified procedures and the right to expedite shipments through customs.
- Should use insulated containers, when importing temperature-sensitive pharmaceutical i.e. Using such containers ensures that the required storage conditions are maintained during shipping and even during their stay at the customs station.

To future researchers

- A similar study on pharmaceutical customs clearance practices using a prospective study design would provide a complete picture of the situation.

Reference

Adeniji, T. et al (2021) *Brooking Africa Growth Initiative Foresight Africa 2021*.

Al-Haddad, B., Chuman, M. and Kouki, R. (2021) "Clearance Process and Its Effect on The Supply Chain Performance in Jeddah Port-Palarch's," *Journal of Archaeology of Egypt/Egyptology*, 18(12), p. 31.

Ariekot, C. And Persson, M. (2016) *Trade Facilitation in Land Locked Countries*. Lund University.

Arvis, J.-F. et al. (2018a) *Connecting To Compete 2018: Trade Logistics in the Global Economy: The Logistic Performance Index And Its Indicators*. Washington, DC.

Arvis, J.-F.et al. (2018b) *Connecting to Compete 2018: Trade Logistics in the Global Economy 'The Logistic Performance Index and Its Indicators'*. New York.

Arvis, J. et al. (2014) *Trade Logistic in Global Economy: The Logistic Performance Index and its Indicators*. New York.

Asian Development Bank (2017) *Second Survey of Trade-related Private Sector in Myanmar*.

Besley, T. and Persson, T. (2014) "Why do developing countries tax so little?" *Journal of Economic Perspectives*, 28(4), pp. 99–120. Available at: https://doi.org/10.1257/jep.28.4.99.

Bireda, M. (2018) *Assessment of the Challenges Customs Import Clearance: The Case of Addis Ababa Kality Customs Branch Office*. Addis Ababa University.

Chauhan, B. S. *et al.* (2013) 'An Approach Based on Advantages Over Conventional System', *Journal of Biomedical and Pharmaceutical Research*, 2(1), Pp. 41–51.

Chinnapareddy, V. K. R. (2019) 'Assessment of the Challenges of Customs Import Clearance Procedures in The Case of Addis Ababa Airport Customs Branch Of ERCA, Ethiopia', *European Journal Of Accounting, Finance And Business*, Ix/2019(February).

COMESA (2017) *Common Market for Easter and Southern Africa (COMESA): Inclusive and Sustainable Industrialization, 2017-2016 Biennial Report*. Available At: Https://Www.Undp.Org/Content/Dam/Pakistan/Docs/Developmentpolicy/InclusiveandSustainab

leDevelopment.Pdf.

Cresswell, J.W. (2016) *30 Essential Skills for the Qualitative Researcher*. Edited by O. Weber-Stenis. California: SAGE Publications.

Dare, T. O. *et al.* (2019) *The Maritime Commons : Digital Repository of the World Maritime Analyzing , Evaluating And Improving The Logistics Performance Index (LPI) of A Country ' S Economy : Case Study : Nigeria , Ghana And Morocco Analyzing , Evaluating And Improving the Logistic*.

Dawit, H. (2019) *Challenges of PI and Distributers in Ethiopia: An Exploratory Study*. Addis Ababa University.

Durgavich, J. (2009) *Customs Clearance Issues Related to the Import Of Goods for Public Health Programs*. Arlington.

ECC (2019) 'Customs Amendment Proclamation No.1160/2019', *Federal Negarit Gazette*, 30 September.

ECC (2020) *No Title, About Us*.

Economic Commission for Africa (ECA) (2013) *Trade Facilitation from an African Perspective, ERD Working Paper Series*. Addis Ababa, Ethiopia. Doi: 10.2307/J.Ctvk3gndb.16.

EFDA (2020a) *No Title, About Us*.

EEFDA2020b) *Top Import Permit Applicants Report, 13th January, 2010*. Addis Ababa, Ethiopia.

Elena, D. And Aziza, K. (2016) 'Risk Management in Customs Control', *Economy of Region*, 13(2), Pp. 551–558. Doi: 10.17059/2017-2-19.

Elferjani, I. (2017) 'Enhancing the Performance of Libya' S Ports : An Investigation of Local Stakeholders' Experience', Pp. 1–19.

EPSA (2018) *Ethiopian Pharmaceutical Supply Agency Annual Report*. Addis Ababa, Ethiopia.

EPSA (2019) *No Title*. Available At: Https://EPSS.Gov.Et (Accessed: 14 November 2019).

EPSA and R4D (2021) *Comprehensive Market Shortcomings Assessment*. Addis Ababa, Ethiopia.

ERCA (2002) ‘ቅድሚያ ተሰጥቷቸው የጉምሩክ ሥነ - ሥርዓት የሚፈፀምባቸውን E ቃዎች ለመወሰን የወጣ መመሪያ’, February, Pp. 0–4.

ERCA (2017) ‘Ethiopian Customs Guide’, (March).

ERCA (2019) *Ethiopian Revenue and Custom Authority/About Us*. Available At: Http://Www.Mor.Gov.Et (Accessed: 14 November 2019).

Ethiopian Single Window for Trader (2020) *Launching of Electronic Single Window Service*.

European Commission (2015) *Evaluation of the Electronic Customs Implementation in the EU*.

Federal Negarit Gazeta (2009) *Customs Proclamation*. 27.

Getahun, R. (2020) *Factors Affecting unimodal Custom Clearance Efficiency, The Case Of Addis Ababa Kality customs Branch Office*. Addis Ababa University.

Gobie, Y.G. (2020) *Contract Management Performance of Ethiopian Pharmaceuticals Supply Agency*.

Heijmann, F. *et al.* (2020) “The changing role of Customs: Customs aligning with supply chain and information management,” *World Customs Journal*, 14(2), pp. 131–142.

Jones, V.C. and Seghetti, L. (2015) *U.S. Customs and Border Protection: Trade Facilitation, Enforcement, and Security*. Available at: www.crs.gov.

Institute Of Medicine (2013) *Countering the Problem of Falsified and Substandard Drugs*. Edited By G. J. Buckley And L. O. Gostin. Washington, Dc: National Academic Press (Us).

Juma, C. (2012) *Perceived Challenges of Importation through the Port Of Mombasa Faced By Countries in the Great Lakes Region By : Caroline Tunu Juma a Research Project Submitted in Partial Fulfillment of the requirements for the Award of the Degree of Master of Business*. University Of Nairobi.

Kabui, B. N. And Gakobo, T. (2019) ‘Effect Of Single Window System Procedures on Cargo Clearance Efficiency in Kenya : A Case for Mombasa Port’, 11(24), Pp. 94–108. Doi: 10.7176/Ejbm.

Kassahun, T. E. (2014) ‘Trade Facilitation in Ethiopia : The Role of WTO Accession in Domestic

Reform', *Mizan Law Review*, 8(1), Pp. 145–190. Doi: Http://Dx.Doi.Org/10.4314/Mlr.V8il5.

Kleinsasser, A.M. (2000) "Researchers, Reflexivity, and Good Data: Writing to unlearn," *Theory into Practice*, 39(3), pp. 155–162. Doi: 10.1207/s15430421tip3903_6.

Le, D. H., Nayyar, A. And Rots, N. L. (2018) 'Implementation of the WTO Agreement n Customs Valuation In Vietnam : Trade Integration And Local Compliance At Da Nang Port', (September). Doi: 10.17010/Ijf/2018/V12i7/129970.

Lemma, M. (2018) 'Analysis Of Challenges In The Private Sector Pharmaceutical Import And Distribution Channel In Ethiopia', 6(4).

Management Science for Health (MSH) (2011) *Managing Access to Medicine and Other Health Technologies: Importation and Port Clearing*. Arlington, VA.

Mashiri, E. And Sebele-Mpofu, F. Y. (2015) 'Illicit Trade, Economic Growth and the Role of Customs: A Literature Review', *World Customs Journal*, 9(2), Pp. 38–50.

Matsuda, S. (2012) 'The Time Release Study as A Performance Measurement Tool for A Supply Chain and an International Corridor', *World Customs Journal*, 6(1), Pp. 79–92.

Mekonnen, W. (2020) *The Effect Of Customs Regulations And Customs Clearance Process On Company Performance : The Case Of Nestle Waters Ethiopia S. Co.* Addis Ababa University.

Minwagaw, E. (2016) *Challenges of Import Customs Clearance in Ethiopian Revenue and Customs Authority Advisor*.

MOI And MOH (2015) *National Strategy And Plan Of Action For Pharmaceutical Manufacturing Development In Ethiopia (2015 – 2025), Federal Democratic Republic Of Ethiopia(Ministry Of Health And Ministry Of Investment), World Health Organization*. Addis Ababa, Ethiopia.

Moïsé, E., Orliac, T. And Minor, P. (2011) *'Trade Facilitation Indicators: The Impact on Trade Costs', OECD Trade Policy Working Papers*. 118. Doi: Http://Dx.Doi.Org/10.1787/5kg6nk654hmr-En OECD.

Muktar, B. (2019) *Challenges of Customs Clearing and Their Implication on International Trade in Ethiopia*. Adids Ababa University.

Ojala, L. And Celebi, D. (2015) *the World Bank' S Logistics Performance Index (LPI) and Drivers*

of Logistics Performance. Turkey.

Onogwu, D. J. (2018) 'Corruption and the Efficiency of Customs Clearance Process In Selected Countries', 6(3). Doi: 10.4172/2315-7844.1000257.

Peterson, J. (2017) "An Overview of Customs Reforms to Facilitate Trade," *Journal of International Commerce and Economics* [Preprint]. Available at: https://www.usitc.gov/journals.

PFSA (2014) *Standard Operating Procedures (Sop) Manual for the Integrated Pharmaceuticals Logistics System*. Addis Ababa, Ethiopia.

Politecnico, G.M. *et al.* (2007) *RFID technology in a container port: an activity-based model to assess costs and benefits Intelligent Transportation Systems (ITS) supporting Intermodal Freight Transport*. Available at: https://www.researchgate.net/publication/228436043.

Seid, M. A. (2014) *Assessment of Customer Service Quality in Mojo Dry Port of Ethiopian Shipping and Logistics Service Enterprise*. Saint Merry University.

Senthil, V. *Et Al.* (2015) 'Regulatory Process for Import and Export of Drugs in India', *International Journal of Pharmaceutical Science and Research*, 6(12), Pp. 4989–4999. Doi: 10.13040/Ijpsr.0975-8232.6 (12).4989-99.

Shanmugam, V. (2020) 'Challenges Of Handling Bulk Cargoes At Discharging Port', (October 2018).

Shepa, C. M. (2013) *Assessment Of The Challenges Behind The Ineffective Customs Clearance Of Goods At Sea Port: The Case Study Of Medical Stores Department Darussalam*. Open University Of Tanzania.

Sheridan, J. *Et Al.* (2011) 'Importation of Prescription Medicines into New Zealand: A Snapshot of Intercepted Products', *International Journal of Clinical Pharmacy*, 33(1), Pp. 80–87. Doi: 10.1007/S11096-010-9457-Y.

Sisay, M. *et al.* (2021) "Availability, pricing and affordability of essential medicines in Eastern Ethiopia: a comprehensive analysis using WHO/HAI methodology," *Journal of Pharmaceutical Policy and Practice*, 14(1). Available at: https://doi.org/10.1186/s40545-021-00339-2.

Siwadenti, M. (2013) *An Assessment Of The Challenges Facing The Customs*.

Solomon, G. (2014) *Assessment of Opportunities and Challenges of Pharmaceutical Marketing in Ethiopia: The Case of PI*. Saint Merry University.

Teklu, D. (2019) *Assessment of Challenges of Multinational Pharmaceutical Companies in Ethiopia*. Saint Merry University.

Temesgen, E. (2020) *the Impact of Customs Clearance Process On Logistics Efficiency : The Case of Modjo Customs Branch Office*. Addis Ababa University.

The Health Strategies Consultancy LLC (2005) *Follow the pill: Understanding the US CommercialPpharmaceutical-Supply-Chain.* Menlo Park CA.

The World Bank (2018) *Aggregated LPI 2012-2018*.

UNCTAD (2006) *Trade Facilitation Handbook Part Ii: Technical Notes on Essential Trade Facilitation Measures*. New York and Geneva.

UNIDO (2009a) *Pharmaceutical Sector Profile : Uganda*. Vienna.

UNIDO (2009b) *Pharmaceutical Sector Profile Of Kenya*. Vienna.

USAID/Deliver Project (2009) *Quantification of Health Commodities : A Guide to Forecasting and Supply Planning For Procurement*. Task Order 1. Arlington, Va.

USAID/Deliver Project, T. O. 4 (2014) *Guidelines for Warehousing Health Commodities.* Task Order 4. Arlington, Va.

Wande, D. P. *Et Al.* (2019) 'Pharmaceuticals Imports in Tanzania: Overview of Private Sector Market Size, Share, Growth and Projected Trends to 2021', *PLOS One*, 14(8), Pp. 1–17. Doi: 10.1371/Journal.Pone.0220701.

World Customs Organization (WCO) (2008) *Enhancing Growth and Development through Trade Facilitation and Border Security*.

WCO (2008) *Revised Kyoto Convention (RKC): Supporting documents*. Available at: https://tfig.unece.org/contents/supporting-documents.htm (Accessed: February 27, 2022).

WCO (2016) *Transparency and Predictability Guidelines*.

WCO (2018) *Guide To Measure The Time Required For The Release Of Goods*. Available At:

Http://Www.Wcoomd.Org/En/Topics/Facilitation/Instrument-And-Tools/Tools/Time-Release-Study.Aspx.

WHO and HAI (2008) *Measuring medicine prices, availability, affordability and price components 2ND EDITION*. Switzerland.

Widdowson, D. (2007) 'the Changing Role of Customs : Evolution or Revolution ?' *World Customs Journal*, (May).

Wiedenmayer, K. (2004) 'Access to Medicines Medicine Supply: Lessons Learnt In Tanzania and Mozambique', *Swiss Agency for Development and Cooperation (SDC)*.

World Bank (2014) *Strengthening Export Performance through Improved Competitiveness in Ethiopia*.

World Custom Organization (2006) *Revised Kyoto Convention*. Chapter 2.

World Custom Organization (2008) *International Convention on the Simplification and Harmonization of Custom Procedures*.

Yigletu, F. (2020) *Factors Affecting The Customs Clearance Of Pharmaceuticals At Bole Airport: The Case Of Private Importers In Addis Ababa*. Addis Ababa University.

ANNEX'S: Data Collection Instruments

Annex I: Questionnaire for ECC Officers

Questionnaire

Addis Ababa University

College of Health Sciences

Department of Pharmaceutics and Social Pharmacy

Dear respondents, I'm a graduate student at Addis Ababa University, College of Medicine and Health science. Currently, I'm conducting a research entitled " ***Pharmaceutical's custom clearance practice at ECC''*** as a partial requirement for the award of Masters of science degree in Health supply chain management. The purpose of this questionnaire is to gather data for the proposed study, and hence you are kindly requested to assist the successful completion of the study by providing the necessary information. Your participation is entirely voluntary and the questionnaire is completely anonymous. I confirm you that the information you share will stay confidential and only used for the aforementioned academic purpose, thus will not affect you in any way. So, your genuine, frank and timely response is vital for the success of the study. I want to thank you in advance for your kind cooperation and dedication of your precious time to fill this questionnaire.

Sincerely Yours, Kaleab Taye

P.№= 0912941953

Email address: teezysam@gmail.com

Section I: Socio-demographic characteristics of respondents

1. Age (in years)_____
2. Sex

   □ Male □ Female
3. Educational status

   □ Diploma □ Degree □ Masters and above
4. Profession_____
5. Place of work

□ ECC Bole airport Branch □ ECC Modjo dry port branch

5. Current position

□ ECC custom clearing officer

□ Import custom clearing coordinator

6. Work experience in current position (in years)_____

7. Total work experience (in years)_____

Section II: **Applicability of international standards in custom clearance procedure of ECC**

*Please read and respond to the following statements by ticking on one that best describes the evel of your agreement, using the numbers 1-5 where **1** is **strongly disagree** and **5** is **Strongly agree***

Statements	**Strongly Disagree(1)**	**Disagree (2)**	**Neutral (3)**	**Agree (4)**	**Strongly agree (5)**
The document requirement for import clearance is simple and clear to understand					
The import clearance functional unit of ECC is adequately staffed with skilled personnel to deliver fast and quality services					
Customs and other border agencies accept copy of documents with exception(based on the type of good and or agency)					
There are full operational risk management procedures in place					
There is a single window service at custom stations					
There is enough information on required forms, documents and					

import procedures for custom agencies.					
There is enough information on required forms, documents and procedures for border agencies (E.g. EFDA).					
Electronic manuals are available to help users when new system is implemented					
There is an appeal mechanism in place for customs matter and other related laws.					
The average time for the release and clearance of good is published in a consistent manner on a periodic basis, for the major custom offices.					
There is a difference of treatment of non-health and health commodities concerning the separation of release.					
There is a difference of treatment of perishable and non-perishable goods concerning the separation of release.					
There is cooperation between various border agencies (e.g. EFDA) with clearly established roles and responsibilities.					
There is cooperation between varies border agencies on ground on both documentary and physical control.					
There is clear information regarding custom valuation on the custom website.(there are clear rules and procedures regarding					

classification and valuation of imported goods)					
There are consultations between importers and government when introducing or amending trade related laws, regulations and administrative rulings of general application.					

Section IV: Efficiency of custom clearance procedures

*Please read and respond to the following statements according to your experience , using the numbers 1-5 where **1** is **hardly ever, 2** is **rarely, 3** is **sometimes, 4** is **often** and **5** is **nearly always.***

Statements	**Hardly ever(1)**	**Rarely (2)**	**Sometimes (3)**	**Often (4)**	**Nearly always(5)**
Are imported shipments cleared and delivered as scheduled?					
Is the custom clearance procedure transparent?					
Is the custom procedures of other border agencies (e.g. EFDA) transparent?					
Do you receive adequate and timely information when regulation change?					
Do importers demonstrating high level of compliance receive expedited clearance?					

Section V: Please evaluate the following statements regarding customs

Statement	Yes	No	N/A	Do not know
Can customs declarations be submitted and processed electronically and on-line?				
Does custom code require importers to use a licensed customs broker to clear goods?				
Are customers able to choose the location of the final clearance of goods?				
Can pharmaceutical shipments be released pending final clearance against an accepted guarantee?				

Annex II: Questionnaire for Freight forwarders

Addis Ababa University

College of Health Sciences

Department of Pharmaceutics and Social Pharmacy

Dear respondents, I'm a graduate student at Addis Ababa University, College of Medicine and Health science. Currently, I'm conducting a research entitled " ***Pharmaceutical's custom clearance practice at Ethiopian Customs Commission''*** as a partial requirement for the award of Masters of science degree in Health supply chain management. The objective of the study is to evaluate the pharmaceutical's custom clearance practice in Ethiopian Customs Commission (ECC), and explore enabling factors and challenges associated with custom clearance. The purpose of this questionnaire is to gather data for the proposed study, and hence you are kindly requested to assist the successful completion of the study by providing the necessary information. Your participation is entirely voluntary and the questionnaire is completely anonymous. I confirm you that the information you share will stay confidential and only used for the aforementioned academic purpose, thus will not affect you in any way. So, your genuine, frank and timely response is vital for the success of the study. I want to thank you in advance for your kind cooperation and dedication of your precious time to fill this questionnaire.

Sincerely Yours, Kaleab Taye

P.№= 0912941953

Email address: teezysam@gmail.com

Section I: Socio-demographic characteristics of respondents

Age (in years)_____

Sex

☐ Male ☐ Female

Educational status

☐ Certificate ☐ Diploma ☐ Degree ☐ Masters and above

Current position

☐ Private pharmaceutical import transitor

☐ Local pharmaceutical manufacturer transitor

☐ Freight forwarder

Work experience in current position (in years)_____

Total work experience (in years)_____

Section II: **Applicability of international standards in custom clearance procedure of ECC**

*Please read and respond to the following statements by ticking on one that best describes the level of your agreement, using the numbers 1-5 where **1** is **strongly disagree** and **5** is **Strongly agree***

Statements	Strongly Disagree(1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly agree (5)
The document requirement for import clearance is simple and clear to understand					
The import clearance functional unit of ECC is adequately staffed with skilled personnel to deliver fast and quality services					
Customs and other border agencies accept copy of documents with exception(based on the type of good and or agency)					
There are full operational risk management procedures in place					
There is a single window service at custom stations					
There is enough information on required forms, documents and import procedures for custom agencies.					
There is enough information on required forms, documents and procedures for border agencies (E.g. EFDA).					
Electronic manuals are available to help users when new system is implemented					
There is an appeal mechanism in place for customs matter and other related laws.					
The average time for the release and clearance of good is published in a consistent manner on a periodic basis, for the major custom offices.					
There is a difference of treatment of non-health and health commodities concerning the separation of release.					

There is a difference of treatment of perishable and non-perishable goods concerning the separation of release.					
There is cooperation between various border agencies (e.g. EFDA) with clearly established roles and responsibilities.					
There is cooperation between varies border agencies on ground on both documentary and physical control.					
There is clear information regarding custom valuation on the custom website.(there are clear rules and procedures regarding classification and valuation of imported goods)					
There are consultations between importers and government when introducing or amending trade related laws, regulations and administrative rulings of general application.					

Section III: Efficiency of custom clearance procedures

*Please read and respond to the following statements according to your experience , using the numbers 1-5 where **1** is **hardly ever, 2** is **rarely, 3** is **sometimes, 4** is **often** and **5** is **nearly always.***

Statements	**Hardly ever(1)**	**Rarely (2)**	**Sometimes (3)**	**Often (4)**	**Nearly always(5)**
Are imported shipments cleared and delivered as scheduled?					
Is the custom clearance procedure transparent?					
Is the custom procedures of other border agencies (e.g. EFDA) transparent?					
Do you receive adequate and timely information when regulation change?					
Do importers demonstrating high level of compliance receive expedited clearance?					

Section IV: Please evaluate the following statements regarding customs

Statement	Yes	No	N/A	Do not know
Can customs declarations be submitted and processed electronically and on-line?				
Does custom code require importers to use a licensed customs broker to clear goods?				
Are customers able to choose the location of the final clearance of goods?				
Can pharmaceutical shipments be released pending final clearance against an accepted guarantee?				

Section V. Challenges at custom department

Which of the following challenges do you face while dealing with custom department? Please read and indicate your level of agreement to the following statements according to your experience , using the numbers 1-5 where 1 is strongly disagree, 2 is disagree, 3 is neutral, 4 is agree and 5 is strongly agree.

Statement	Strongly disagree(1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly agree (5)
Breakdown of electronic system for document lodging					
Delays in processing lodged documents by custom officer.					
Unpredictable penalties/charges					
Resolving queries on valuation and tariff HS codes takes longer					
Lack of equipment to offload/ handle containers/cargo					
Delays in bond cancellation					
Post clearance audit					
100% verification of goods					
Inadequate communication with importers on changes at custom regulation					
Corruption					
Un-business like attitude of custom officers					
Disempowered frontline officer in decision making					
Inadequate competence of custom staff					
Incompatibility of computer system with that of stakeholders					

Please mention if there are any other challenges in custom clearance of pharmaceutical _____
_____

Section VI. Challenges at Ethiopian Food and Medicine Authority (EFDA)

*Which of the following challenges do you face while dealing with EFDA? Please read and indicate your level of agreement to the following statements according to your experience , using the numbers 1-5 where **1** is **strongly disagree, 2** is **disagree, 3** is **neutral, 4** is **agree** and **5** is **strongly agree.***

Statement	**Strongly disagree(1)**	**Disagree (2)**	**Neutral (3)**	**Agree (4)**	**Strongly agree (5)**
Delays in inspection and testing for conformance to standard					
Inadequate competence and skills of EFDA staff					
Taking bigger samples than necessary for testing					
Inadequate laboratory facilities					

Please mention if there are any other challenges in custom clearance of pharmaceutical

_____

_____

Questionnaire for Freight forwarders (Amharic Version)

አዲስ አበባ ዩኒቨርሲቲ

ሕክምና ጤና ሳይንስ ኮሌጅ

ፋርማሲዩቲክሰ ኣና ሶሻል ሳይንስ ትምህርት ክፍል

ውድ ተሳታፊዎች፣ እኔ በአዲስ አበባ ዩኒቨርሲቲ ፣ በሕክምና ኮሌጅ እና በጤና ሳይንስ እና ፋርማሲዩቲክሰ ኣና ሶሻል ሳይንስ ትምህርት ክፍል የድህረቃ ተመራቂ ተማሪ ነኝ ። በአሁኑ ወቅት በጤና አቅርቦት ሰንሰለት አስተዳደር " *Pharmaceutical's custom clearance practice at Ethiopian Customs Commission''* በሚል ርዕስ የማሙያ ጥናት አደርጋለሁ ። የጥናቱ ዓላማ በኢትዮጵያ የጉምሩክ ኮሚሽን (ECC) ውስጥ የመድኃኒት አወጣጥ ልምድን መገምገም እና ኣሱ ጋር ተያይዘው የሚመጡ ሁኔታዎችን እና ተግዳሮቶችን መመርመር ነው ። የዚህ መጠይቅ ዓላማ ለታሰበው ጥናት መረጃ መሰብሰብ ነው ስለሆነም አስፈላጊ መረጃዎችን በመስጠት ጥናቱ በተሳካ ሁኔታ እንዲጠናቀቅ እንዲረዱ በትህትና ተጠይቀዋል ። የእርስዎ ተሳትፎ ሙሉ በሙሉ በፈቃደኝነት ነው እናም መጠይቁ ሙሉ ሚስጥራዊነቱ የተጠበቀ ነው።የሚያጋሯቸው መረጃዎች በሚስጥር የሚቆዩ እና ለተጠቀሰው የትምህርት ዓላማ ብቻ የሚያገለግሉ ስለሆኑ በምንም መንገድ እርስዎ ላይ ተጽዕኖ አያሳርፉም ። ስለዚህ ፣ ትክክለኛ ፣ ግልፅ እና ወቅታዊ ምላሽ ለጥናቱ ስኬት አስፈላጊ ነው ። ይህንን መጠይቅ ለመሙላት ስለ ውድ ጊዜዎ ስለ ደግ ትብብርዎ እና ስለ መሰጠዎ አስቀድሜ ላመሰግናችሁ እፈልጋለሁ ።

ከሰላምታ ጋር

ቃልአብ ታዬ

P.№= 0912941953

ኢሜል= teezysam@gmail.com

ክፍል 1: የተሳታፊዎች ማህበራዊ እና ስነ-ህዝባዊ ባህሪያት

1. እድሜ (በአመት)_____

2. ፆታ፡ ☐ ወንድ ☐ ሴት

3. የትምህርት ደረጃ

☐ርተፍኬት ዲፕ☐ማ ዲግ☐ ማስ☐ስ እና ከዛ በላይ

4. የስራ ድርሻ

☐የግል መድሀኒት አስመጪ አስተላላፊ

☐የመድሀኒት ፋብሪካ አስተላላፊ

☐የጉምሩክ አስተላላፊ

5. የስራ ልምድ አሁን ባሎት የስራ ድርሻ (በአመት)_____

6. አጠቃላይ የስራ ልምድ (በአመት)_____

ክፍል፡ የመድሀኒቶች ገቢ እቃ አወጣና ስነስርዓት ከአለም አቀፍ ደረጃዎች አንጻር ሲፈተሽ እባኮትን የሚከተሉትን አርፍተ ነገር አንብበው የእርሶን አመለካከት የተሻለ የሚገልጸውን ያስቀምጡ።።

1. **1 ማለት** በፍፁም አልስማማም 2. አልስማማም 3. ገለልተኛ 4. እስማማለሁ 5. በሚገባ አስማማለው

ተ.ቁ	መግለጫ	በፍፁም አልስማማም	አልስማማም	እስማማለሁ	በሚገባ እስማማለሁ
1.	ለገቢ እቃ አወጣጥ የሚጠየቀው ሰነድ ቀላል እና ለመረዳት ግልፅ ነው።።				
2.	የኢትዮጵያ ጉምሩክ ኮሚሽን(ኢጉኮ) የገቢ እቃ አወጣጥ ክፍል በቂ ክህሎት ባላቸው በቂ ባለሙያዎች የተሞላ ነው ፈጣን እና ጥራት ያለው አገልግሎት ለመስጠት				
3.	ጉምሩክ እና የድንበር ኤጀንሲዎች ኮፒ ሰነዶችን ይቀበላሉ።።				

4.	ሙሉ በሙሉ ተግባራዊ የሆነ የስጋት አጣጣል አሰራር (risk management procedure) በኢጉኮ አለ።				
5.	ከኢጉኤኮ የአንድ መስኮት አገልግሎት አለ።				
6.	ኢጉኮ በሚያስፈልጉ ፎርሞች፣ ሰነዶች እንዲሁም በገቢ እቃ አወጣጥ ስነስርአት ላይ በቂ መረጃ አለ።				
7.	አዲስ አሰራር ሲዘረጋ ተጠቃሚውን የሚረዳ (የሚያግዝ) ኤሌክትሮኒክ ማኑዋሎች (electronic manuals) አሉ።				
8.	በጉምሩክ እና በተመሳሳይ ሀጎች ላይ ቅሬታ ሲኖር ይግባኝ መጠየቅ የሚያስችል አሰራር አለ።				
9.	የገቡ መድሀኒቶችን ለማውጣት እና ለማስለቀቅ በአማካይ የሚፈጀውን ሰዓት በየጊዜው በግልፅ ተቀምጧል።				
10.	የጤና እና ጤና-ነክ ያልሆኑ ገቢ እቃዎች አወጣጥ ስነስርአት ላይ ልዩነት አሉ።				
11.	በቀላሉ ሊበላሹ የሚችሉ እቃዎች ከሌሎች እቃዎች የተለየ የገቢ እቃ አወጣጥ ስነስርዓት አለ።				
12.	በተለያዩ የድንበር ኤጀንሲዎች (ምሳሌ፡- የኢትዮጵያ መድሂኒት ቁጥጥር ባለስልጣን) መካከል በግልፅ በተቀመጠ ሚና እና ሃላፊነታቸው ትብብር አለ።				
13.	በተለያዩ የድንበር ኤጄንሲዎች በተግባር ላይ የዋለ በሰነድ እና በአካላዊ ቁጥጥር ላይ ትብብር አለ።				
14.	የጉምሩክን ዋጋ አጣጣል በተመለከተ ግልፅ መረጃ በኢጉኮ ድህረ-ገፅ ላይ ተቀምጧል (የገቢ እቃዎችን				

	ምደባ እና የዋጋ አጣጣል በተመለከተ ግልፅ ህጎች እና አሰራሮች ተቀምጠዋል)				
15.	አዳዲስ ህጎች እና አሰራሮች ሲተገበሩ ወይም የነበሩት ሲሻሻሉ በመንግስት፣ በአስመጪዎች ወይም በተወካዮቻቸው መካከል የምክክር መድረክ ይዘጋጃል።				

ክፍል 2 የገቢ እቃ አወጣጥ ስነ-ስርዓት ውጤታነት(Efficiency)

እባኮትን የሚከተሉትን አርፍተ ነገር አንብበው የእርሶን አመለካከት ከስራ ልምዶት አንፃር ያስቀምጡ።።

1. ማለት መቼም፤ 2 ማለት አልፎ አልፎ፤ 3 ማለት አንዳንድ ጊዜ፤ 4 ማለት ብዙውን ጊዜ፤ 5 ማለት ሁልጊዜ

ተ.ቁ	መግለጫ	መቼም	አልፎ አልፎ	አንዳንድ ጊዜ	ብዙውን ጊዜ	ሁልጊዜ
1.	ገቢ እቃዎች የሚወጡት እና የሚለቀቁት በተቀመጠላቸው ጊዜ መሰረት ነው					
2.	የገቢ እቃ አወጣጥ አሰራር ግልፅ ነው					
3.	የድንበር ኤጀንሲዎች ገቢ እቃ አወጣጥ ስነስርዓት ግልፅ ነው					
4.	የጉምሩክ አሰራሮች ሲቀየሩ በቂ እና ጊዜያዊ መረጃ ታገኛለህ/ሽ?					
5.	ለጉምሩክ አሰራር ከፍተኛ ተገዥነትን ያሳዩ አስመጪዎች የተፋጠነ የገቢ እቃ አወጣጥ ስነስርዓት ይመቻችላቸዋል?					

ክፍል እባኮትን የጉምሩክን የተሻለ አሰራር (Customs best pratice በተመለከተ የሚከተሉትን መግለጫዎች ይገምግሙ

ተ.ቁ	መግለጫ	አዎ	አይደለም	ተግባራዊ አይደለም	አላውቅም
1.	የጉምሩክ መግለጫዎች በኤሌክትሮኒክ እና አንላይን (on-line) ሊቀርብ እና ሊሰሩ ይችላሉ?				
2.	የኢጉኮ አሰራር አስመጪዎች ገቢ እቃዎችን ለማስለቀቅ ፈቃድ ያለው የጉምሩክ አስተላላፊ እንዲጠቀሙ ያስገድዳል?				

3.	ደንበኞች የገባ እቃ መጫረሻ ላይ የሚለቀቅበትን ቦታ (መወሰን) መምረጥ ይችላሉ?				
4.	ተገቢውን ዋስትና ካስያዙ የመጫረሻ ማጣሪያያ እስኪደረግ ድረስ የመድሀኒት ጭነት ሊለቀቅ ይችላል?				

ክፍል፡ በኢጉኮ ሊያጋጥሙ የሚችሉ ተግዳሮቶች

ከኢጉኮ በሚሰሩበት ጊዜ ከሚከተሉት ተግዳሮቶች ውስጥ የትኛው ያጋጥሙዎታል።፡

5. በፍፁም አልስማማም 2. አልስማማም 3. ገለልተኛ 4. እስማማለሁ 5. በሚገባ አስማማለው

ተ.ቁ	**መግለጫ**	**በፍፁም አልስማማም**	**አልስማማም**	**ገለልተኛ**	**እስማማለሁ**	**በሚገባ እስማማለሁ**
1.	ሰነድ ወደ ኤሌክትሮኒክ ስይስተም (electronic system) በሚገባበት ጊዜ የሲይስተም (system) መቆራረጥ					
2.	ወደ ሲስተም(system) የገቡ ሰነዶች ለመመርመር እና ለማስተናገድ የጉምሩክ ባለሙያ መዘግየት					
3.	ያልተጠበቁ ቅጣቶች/ ክፍያዎች					
4.	በዋጋ አሰጣጥ እና ኤችኤስ ኮድ (HS Code) ታሪፍ ላይ ጥያቄዎችን መፍታት ረዘም ያለ ጊዜ ይወስዳል					
5.	ኮንቴይነሮችን/ ጭነትን ለመጫን ለማውረድ/ የሚያስፈልጉ መሳሪዎች እጥረት					
6.	የቦንድ ስረዛ መዘግየት					

7.	እቃዎች ከተላቀቁ በኃላ የማጣራት ሂደት (Post-Clearance audit)					
8.	እቃዎችን ሙሉ በሙሉ መፈተሻ					
9.	በጉምሩክ ደንቦች ላይ ለውጥ ሲኖር ከአስመጪዎች ጋር በቂ የሆነ ግንኙነት አለመኖር					
10.	ሙስና					
11.	የጉምሩክ					
12.	በውሳኔ አሰጣጥ የተዳከመ የጉምሩክ መኮንን					
13.	የጉምሩክ ባለሙያዎች ብቃት ማነስ					
14.	አገልግሎት ላይ የዋለው ሲይስተም (system) ከባለ ድርሻ አካላት ጋር አለመጣጣም					

እባኮትን የመድሃትን ገቢ እቃ አወጣጥ በተመለከተ ሌሎች ተግዳሮቶች ካሉ ይጥቀሱ-

_____

_____

_____

ክፍል፡ በኢትዮጵያ ምግብና መድሃኒት ባለስልጣን (EFDA) ያሉ ተግዳሮቶች

ከ EFDA ጋር በሚሰሩበት ጊዜ ከሚከተሉት ተግዳሮቶች ውስጥ የትኛው አጋጥመዎታል።

1. በፍፁም አልስማማም፤ 2. አልስማማም 3. ገለልተኛ 4. እስማማለሁ 5. በሚገባ እስማማለሁ

ተ.ቁ	መግለጫ	በፍጹም አልስማማም	አልስማማም	ገለልተኛ	እስማማለሁ	በሚገባ እስመማለሁ
1.	ገቢ እቃዎችን መፈተሽ እና ከደረጃ (s አንፃር መመርመር መዘግየት					
2.	የEFDA ሰራተኞች ብቃት እና ክህሎት ማነስ					
3.	ለሙከራ አስፈላጊ ከሆኑ ና በላይ ናሙናዎችን መውሰድ					
4.	በቂ ያልሆነ የናሙና መመርመሪያ (ላብራቶሪ) ተቋማ					

እባኮትን የመድሀኒትን ገቢ እቃ አወጣጥ በተመለከተ ሌሎች ተግዳሮቶች ካሉ ይጥቀሱ_____

Annex III: Questionnaires for Importers, LM and EPSS

Questionnaire

Addis Ababa University

College of Health Sciences

Department of Pharmaceutics and Social Pharmacy

Dear respondents, I'm a graduate student at Addis Ababa University, College of Medicine and Health science. Currently, I'm conducting a research entitled '***Pharmaceutical's custom clearance practice at Ethiopian Customs Commission'*** as a partial requirement for the award of Masters of Science degree in Health supply chain management. The purpose of this questionnaire is to gather data for the proposed study, and hence you are kindly requested to assist the successful completion of the study by providing the necessary information. Your participation is entirely voluntary and the questionnaire is completely anonymous. I confirm you that the information you share will stay confidential and only used for the aforementioned academic purpose, thus will not affect you in any way. So, your genuine, frank and timely response is vital for the success of the study. I want to thank you in advance for your kind cooperation and dedication of your precious time to fill this questionnaire.

Sincerely Yours

Kaleab Taye

P.№= 0912941953

Email address: teezysam@gmail.com

Section I: Socio-Demographic Characteristics Of Respondents

1. Age(in years)_____
2. Sex ☐ Male ☐ Female
3. Educational status
   ☐ Diploma ☐ Degree ☐ Masters and above
4. Profession
   ☐ Druggist ☐ Pharmacist ☐ Others, Please specify_____
5. Place of work
   ☐ EPSS central ☐ Private pharmaceutical import ☐ Local pharmaceutical manufacturer

6. Current position

- ☐ General Manager
- ☐ Technical manager
- ☐ Medical sales representative
- ☐ Supply chain manager
- ☐ Others please specify_____

7. Work experience in current position(in years)_____
8. Total work experience(in years)_____

Section III: Source of major delays in port clearance

*Please read and respond to the following statements according to your experience , using the numbers 1-5 where **1** is **hardly ever, 2** is **rarely, 3** is **sometimes, 4** is **often** and **5** is **nearly always.***

How often do you experience delays due to	Hardly ever (1)	Rarely (2)	Sometimes (3)	Often (4)	Nearly always (5)
Poor procedure by the supplier					
Bureaucratic delays at port					
Inadequate communication with stakeholders					
Lack of human resource at your office					
Missing or incomplete documentation					
Lack of fund to clear goods					
Compulsory warehousing					
Pre-shipment inspection					
Marine time transport					
Criminal activities					
Solicitation of informal payments in connection with logistic activities					

Section IV: Efficiency of custom clearance procedure

*Please read and respond to the following statements according to your experience , using the numbers 1-5 where **1** is **hardly ever, 2** is **rarely, 3** is **sometimes, 4** is **often** and **5** is **nearly always.***

Statements	Hardly ever(1)	Rarely (2)	Sometimes (3)	Often (4)	Nearly always(5)
Are imported shipments cleared and delivered as scheduled?					
Is the custom clearance procedure transparent?					
Is the custom procedures of other border agencies (E.g. EFDA) transparent?					
Do you receive adequate and timely information when regulation change?					
Do importers demonstrating high level of compliance receive expedited clearance?					

Please mention if there are any other source of clearance delays _____

_____

Section V. Challenges at custom department

*Which of the following challenges do you face while dealing with custom department? Please read and indicate your level of agreement to the following statements according to your experience , using the numbers 1-5 where **1** is **strongly disagree**, **2** is **disagree, 3** is **neutral**, **4** is **agree** and **5** is **strongly agree**.*

Statement	Strongly disagree(1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly agree (5)
Breakdown of electronic system for document lodging					
Delays in processing lodged documents by custom officer.					
Unpredictable penalties/charges					

Resolving queries on valuation and tariff HS codes takes longer					
Lack of equipment to offload/ handle containers/cargo/					
Delays in bond cancellation					
Post clearance audit					
100% verification of goods					
Inadequate communication with importers on changes at custom regulation					
Corruption					
Unprofessional attitude of custom officers					
Disempowered frontline officer in decision making					
Inadequate competence of custom staff					
Incompatibility of computer system with that of stakeholders					

Please mention if there are any other source of clearance delays_____
_____

Section VI. Challenges at Ethiopian Food and Medicine Authority (EFDA)

*Which of the following challenges do you face while dealing with Ethiopian Food and Drug Authority (EFDA)? Please read and indicate your level of agreement to the following statements according to your experience , using the numbers 1-5 where **1** is **strongly disagree, 2** is **disagree, 3** is **neutral, 4** is **agree** and **5** is **strongly agree.***

Statement	**Strongly disagree(1)**	**Disagree (2)**	**Neutral (3)**	**Agree (4)**	**Strongly agree (5)**
Delays in inspection and testing for conformance to standard					
Inadequate competence and skills of EFDA staff					
Taking bigger samples than necessary for testing					
Inadequate laboratory facilities					

Please mention if there are any other challenges_____
_____

Annex IV: Data Abstraction Format

1. Country of origin (manufacturer):_____
2. Value of Import_____
3. Import route
   - ☐ Sea shipment ☐ Air shipment
4. Importer
   - ☐ EPSS ☐ Private Pharmaceutical's importers ☐ LMS

Annex V: Custom Clearance Cycle

Custom clearance cycle is measures the amount of time from the moment cargo arrives in the port or airport until the moment that it clears customs and arrives at the warehouse, and it is ready to be put away.

Cargo arrival date at port/airport	Cargo arrival date at the warehouse

Annex VI: Interview Guide

I would like to thank you for taking the time to meet with me today. My name is Kaleab Taye, a prospective post graduate student in Health supply chain management at School of Pharmacy, Addis Ababa University. Currently I am conducting a study entitled ***'Pharmaceutical's custom clearance practice at ECC'***. The objective of the study is to evaluate the pharmaceutical's custom clearance practice in Ethiopian Customs Commission (ECC), and explore enabling factors and challenges associated with custom clearance time

To achieve the objective of the study, your participation in the study by responding to the question listed below is invaluable. Hence, you are kindly requested to participate in this study. All of your responses, your identity as well as that of your company will be kept confidential and anonymous during reporting of study findings. This means you and your company will not be identified as respondents of this study. The interview should take 30 min to an hour. I Will be audio-recording the session to capture all the information. Although I will be taking some notes during the session, I can't possibly write fast enough to get it all down. Because we're on tape, please be sure to speak up so that I don't miss your ideas/opinions. Remember, you don't have to talk about anything if you don't want to and you may end the interview at any time.

Are you willing to participate in the interview? Yes……. No……..

If yes the interview will continue.

Date of Interview:

Venue:

Socio-demographic characteristics

1. Age_____
2. Sex_____
3. Educational status_____
4. Profession_____
5. Current occupation and position_____
6. Years of service in current position_____
7. Total years of experience_____

Guiding questions for EPSS/ Private Importers/LM

1. Please introduce yourself?
2. Can you please tell me about your company profile?(Private importers and local pharmaceutical manufacturers only)

1. Year of establishment
2. Product range
3. Human resource (number of employees…)
4. Performance(number of import per year, volume)

5. How do you see custom clearance process of pharmaceutical /API? (in terms of valuation and item handling)
6. What do you think the cause of prolonged custom clearance procedures are?
7. From your experience, do you think EPSS's/ Private importers/LM operation is affected by prolonged deliveries from port?
8. What are the implication of problems in custom clearance in EPSS's/ private importer's/local pharmaceutical manufacturers operation? (Lost business, incurred cost, damaged products…)
9. Your recommendations to improve the custom clearance process?

Guiding questions for ECC

1. Can you tell me the reason for prolonged custom clearance procedure?

1. Internal challenges (HR, system, cooperation with other departments/working units)
2. External challenges (Importer/agent, EFDA……)

3. How do you describe the availability of required professional in ECC?

1. In terms of number and type (pharmacist….)
2. In terms of level of training and experience

3. How do you describe the transparency of custom clearance operation in ECC? Are there mechanism to maintain transparency?

Thank you for your time

Interview Guide (Amharic version)

አዲስ አበባ ዩኒቨርሲቲ

ፋርማሲ ትምህርት ቤት

የፋርማሲዩቲክስ እና ሶሻል ፋርማሲ ትምህርት ክፍል

የቃለ-መጠይቅ ፎርም

ዛሬ ከእኔ ጋር ለመገናኘት ጊዜ በመውሰድህ/ሽ አመሰግናለሁ። ስሜ ቃልአብ ታዬ ይባላል፤ በአዲስ አበባ ዩኒቨርስቲ በፋርማሲ ትምህርት ቤት በጤና አቅርቦት ሰንሰለት አስተዳደር ውስጥ የድህረ ምረቃ ተመራቂ ተማሪ ነኝ። በአሁኑ ወቅት **"Pharmaceutical's custom clearance practice in Ethiopian Customs Commission"**. የሚል ጥናት እያጠናሁ እገኛለሁ። የጥናቱ ዓላማ በኢትዮጵያ ጉምሩክ ኮሚሽን ውስጥ ያለውን የመድኃኒት እቃ አወጣት ልምድን መገምገም እና ከእሱ ጋር ተያይዘው የሚመጡ ሁኔታዎችን እና ተግዳሮቶችን መመርመር ነው ።

የዚህን ጥናት አላማ ከግብ ለማድረስ የሚከተሉን ጥያቄዎች በመመለስ የእርስዎ ተሳትፎ ትልቅ አስተዋፅኦ ይኖረዋል። ጥያቄዎቹን ለመመለስ በአማካኝ ከ30-60 ደቂቃ ሊፈጅብዎት ይችላል። በጥናቱ ወቅትም ሆነ ጥናቱ በሚቀርብበት ጊዜ የእርስዎም ሆነ የካምፓኒው ማንነት ተጋላጭ እንደማይሆን አረጋግጥልዎታለሁ። በቃለ መጠይቅ ወቅት የሚኖሩትን መረጃዎች ለመሰብሰብ ሲባል የድምፅ መቅረጫ እጠቀማለሁ ሆኖም ግን መረጃዎቹ ሌላ ሰው በማያገኝበት ይቀመጣሉ። ጥያቄዎቹን ሙሉ በሙሉ እንዲመልሱ ይበረታታሉ፤ ቢሆንም በጥናቱ ውስጥ መሳተፍ ካልፈለጉ ምርጫዎ ይጠበቃል።

ስለጊዜዎ አመሰግናለሁ!

በቃለ-መጠይቁ ለመሳተፍ ፈቃደኛ ኖት? አዎ አይደለሁም

ክፍል 1:- ሥነ-ማህበራዊ እና ሥነ-ህዝባዊ መረጃዎች

1. ፆታ፡ _____
2. እድሜ፡ _____
3. የት/ደረጃ፡ _____
4. የሙያ ዓይነት፡ _____

5. የስራ መደብ _____

6. በዚህ የስራ መደብ ለምን ያህል ጊዜ ቆይተዋል፡ _____

7. ጠቅላላ የስራ ልምድ፡ _____

ክፍል 2፡ የኢትዮጲያ መዲሃኒት አቅርቦት ኤጀንሲ (EPSS)/የመዲሃኒት አስመጪዎች/የመድሃኒት አምራቾች ገቢ እቃ አወጣጥን በተመለከት የሚያጋጥማቸው ችግሮች

1. እባኮትን እራሶትን ያስተዋውቁ
2. እባክዎን ስለ ኩባንያዎ መገለጫ ሊነግሩኝ ይችላሉ
   ሀ. መቼ ተመሰረተ

   ለ. ስለ ሰው ሃብት አስተዳደር

   ሐ. ምን ያህል መድሐኒቶች ያስመጣሉ

   መ. የድርጅቱን የስራ አፈፃፀም

3. በመዲሐኒት ማስመጣት ላይ የገቢ መድሐኒቶች/ጥሬ ግብዐቶች/ አወጣጥ ሂደት እንዴት ታየዋለህ/ትገመግመዋለህ (ከመድሃኒቶች አያያዝ አንጻር፤ ከዋጋ አጣጣል አንጻር……..)
4. የገቢ መድሐኒቶች/ጥሬ ግብዐቶች/ አወጣጥ ሂደት ምን ችግሮች ያጋጥማሉ(እያጋጠሙ ነው)
   ሀ. በካምፓኒው ውስጥ ያለውን ችግር አስመልክቶ

   ለ. በካምፓኒው ውጭ ያለውን ችግር አስመልክቶ(ከኢጉኮ፤ ኢመምቁባ፤ ጉሙሩክ አስትላላፊዎች፤ አቅራቢዎች…)

5. ከላይ የጠቀስካቸው/ሻቸው ችግሮች ለዘገየ(ረዘም ላለ) የገቢ እቃ አወጣጥ ሊዳርግ ይችላል ብለህ/ሽ ታምናለህ/ኛለሽ? ሀ. አዎ ለ. አላምንም

6. ለጥያቄ 5 አዎ ከሆነ መልሶት፤ ከእርሶ ተሞክሮ በመሳት፡ የድርጅቶ ስራ በዘገየ (ረዘም ባለ) የገቢ እቃ አወጣጥ ስነ-ስርዐት ሊስታጉጎል (ሊጎዳ) ይችላል? አዎ ከሆነ መልሶት አንድምታው ምነድነው?(ያመለጠ የንግድ አጋጣሚ፤ የወጣ ተጨማሪ ወጪ፤የተበላሹ መድሐኒቶች/ግብዐቶች)

7. የገቢ መድሐኒቶች/ጥሬ ግብዐቶች/ አወጣጥ ሂደት የተሸለ ያደርጋሉ የሚሉቸውን ምክሮች ቢጠቅሱልን?

ክፍል 3፡ የኢትዮጵያ ጉሙሩክ ኮሚሽን(ኢጉኮ)

1. የገቢ መድሐኒቶች/ጥሬ ግብዐቶች/ በተመለከተ በአሁኑ ጊዜ ምን ዓይነት የዋጋ አሰጣጥ ዘዴዎች ጥቅም ላይ ይውላሉ?
2. ከላይ የተቀስካቸው/ሻቸው የዋጋ አሰጣጥ ዘዴዎች በሁሉም ኢጉኮ ቅርንጫፎች ወጥነት አላቸው? አዎ ከሆነ መልሱ፤ እንዴት ነው ወጥነቱ የሚረጋገጠው?
3. ኢጉኮ ለስራው አስፈላጊው ባለሙያ መኖሩን እንዴት ይገልጹታል?

ሀ. ከቁጥር እና ከዓይነት አንጻር (Professional mix)

ለ. በቂ ሥልጠና ከማግኘት እና ከስራ ልምድ አንጻር

4. ለዘገየ ገቢ መድሓኒቶች/ጥሬ ግብዐቶች/ አወጣጥ ሊዳርጉ ይችላሉ የሚሉትውን ምክንያቶች ሊጠቅሱልን ይችላሉ?

ሀ. ውስጣዊ ችግሮች (የሰው ሐይል ፣ ስርዓት (system)፣ ከሌሎች የስራ ክፍሎች ጋር ትብብር)

ለ. ውስጣዊ ችግሮች(የአስመጪዎች፣መድሃኒት አምራቾች፣ጉሙሩክ አስተላላፊዎች፣ ሌሎች የድንበር ተቋማት)

Annex VII: Ethical Clearance Letter

በ ፋርማሲ ት/ቤት
የኢቲካል ሪቪው ቦርድ

አዲስ አበባ ዩኒቨርሲቲ
Addis Ababa University

School of Pharmacy
Ethical Review Board

ቀን Date: September 15, 2020

ቁጥር Ref. No.: ERB/SOP/201/09/2020

To: Kaleab Taye
School of Pharmacy

Re: Ethical Clearance

It is to be recalled that you submitted a study proposal entitled ***"Pharmaceuticals custom clearance practice in Ethiopian Customs Commission"*** for ethical approval by the School's Ethical Review Board (ERB). The Board thoroughly reviewed the proposal based on its operational guidelines and found it to fulfill all ethical requirements stipulated in the guidelines. This is, therefore, to inform you that the proposal is ethically approved for implementation.

With best regards,

Arebu Issa
Chairperson, ERB

☎ 00251156 02 12 ✉ 1176 ቴሌክስ Telex: 21205 ፋክስ Fax: 00251(11)1558566 ቴሌግራም Cable: AAUNIV