College of Health Sciences

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Regulatory Requirements and Enforcement Practices for Importation of Medicines for Personal Use into Ethiopia

By

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July, 2023

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Under the supervision of;

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This is to certify that the thesis prepared by Mintwab Zellek Tilahun entitled: Regulatory Requirements and Enforcement Practices for Importation of Medicines for Personal Use in Ethiopia and submitted in partial fulfillment of the requirements for the degree of Master of Science in Regulatory Affairs (Medicine Regulation Track) complies with the regulations of the university and meets the accepted standards with respect to originality and quality.

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ABSTRACT

Background: Evidence shows that some medicines imported for personal use are poor quality and counterfeited. In Ethiopia, although travelers import medicine for their personal use, little is known what medicines, and how frequently is being imported.

Objectives: To assess importation patterns, regulatory requirements, and enforcement practice of medicine importation for personal use in Ethiopia.

Method: A sequential exploratory mixed methods design was used to assess importation pattern, regulatory requirements and enforcement practices of personal medicine importation in Ethiopia. Secondary documents analysis and one-to-one interviews were used for data collection. Quantitative and qualitative data were analyzed using Microsoft Excel and thematic analysis approach, respectively.

Results: Importing medicines for personal use have accelerated dramatically; records show that 56 travelers imported 151 medicines in 2020 and 398 travelers' imported 920 medicines in 2021. Releasing medicines without EFDA approval, gaps in the rules and regulations, shortage of some medicines and lack of coordination between key stakeholders were identified as contributing factors for the rise in the importation of personal medications.

Conclusion: Importing medicines for personal use without a prescription is a growing concern in Ethiopia. The EFDA should strengthen the regulatory system; restructure existing law enforcement operations for the importation of medicine for personal use, and engage in high-level discussions with stakeholders.

Keywords: Personal Medicine, importation, regulatory practice & requirement.

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LIST OF ABBREVIATIONS/ACRONYMS/

DACA	Drug Administration and Control Authority
ECA	Ethiopian Custom Authority
EFDA	Ethiopian Food and Drug Authority
EFY	Ethiopian Fiscal Year
ERCA	Ethiopian Revenue and Customs Authority
HHS	Health and Human Services
KIs	Key Informants
NISS	National Intelligence Security Service
NRA	National Regulatory Authority
OTC	Over the Counter
RA	Regulatory Authority
SOP	Standard Operating Procedure
WHO	World Health Organization

1. INTRODUCTION

1.1 Background

Medicine has existed for as long as people have been there, and quality ideas have gradually evolved over time. The first British regulations established pharmaceutical inspections. Following 1540, the Apothecaries Wares, Drugs, and Stuffs Act established monitoring and regulation of medicine manufacturing in England **(Rago, 2008).**

Drug regulation is the administration of drugs through regulatory bodies and international treaties. These regulations cover pharmaceutical development, approval, manufacturing, and marketing. To ensure the safety, efficacy, and quality of medications, as well as the applicability and accuracy of product information, the governing body implements a variety of legal, administrative, and technical means. Regulators work to protect and improve the public's health by focusing on two goals: ensuring drug efficacy and safety and making pharmaceuticals with medical applications more accessible **(Rägo and Santoso, 2008).**

Modern medicine regulation was established in the nineteenth century. Several of these drug-related tragedies, such as those involving sulfanilamide elixir (1937), thalidomide (1961), and clioquinol (1986), served as the primary impetus for increased control (the 1970s). Children have occasionally been victims in tragic situations. They are brought by poisonous ingredients or contaminants in medications, medications whose efficacy has not been established, medications with unknown and severe side effects, subpar preparations, or outright phony and counterfeit medications **(Lee, 1986; Suleman, 2016).**

Specialized knowledge and expertise are required for medicine production, distribution, and dispensing. There is a demand for low-cost, high-quality medication that can be given to patients when they need it, in the right setting, at the right dosage, and in the right amount. The pharmaceutical supply chain is highly complex. In the world, there are two methods for importing medicines: a personal system for individuals and a commercial system for businesses (Feder, 2004). Many participants (such as manufacturers, wholesalers, and pharmacies) are involved in the drug distribution network for legal prescription pharmaceuticals in most countries

around the world, moving pharmaceutical goods from the point of manufacture to the end consumer (Buckley, 2013).

Most developed countries have a few privately owned national wholesalers who stock and distribute a wide range of pharmaceutical products from various manufacturers to clinics, hospitals, and pharmacies. In Western Asia and Europe, a few major businesses own 90 percent of the market. In developing countries, particularly Sub-Saharan Africa, the government distributes medicines to health-care facilities via a central medical store (CMS), regional or district stores, and a government/CMS-owned transport flee (WHO, 2011).

Pharmaceutical distribution in many developing countries is insufficient to meet the healthcare needs of a large segment of the population, owing to inadequate drug delivery infrastructure. There are issues with all aspects of drug management, including ordering, receipt, storage, distribution, and resupply **(Yadav and Smith, 2014).**

Individuals are frequently prohibited from importing medicines or equipment for personal use from one country to another without the approval of the nation's regulatory authorities in order to achieve the highest level of public protection. This is because controlling individual importation is difficult. When importing drugs for personal use, safety is a major concern; however, regulating and preventing the use of dangerous, ineffective, or substandard pharmaceuticals necessitates substantial resources. Depending on the circumstances, a country's regulatory agency may allow an individual to import approved and unapproved pharmaceuticals for explicitly personal use.

Pharmaceutical regulations differ from one country to the next. The government's medical regulatory authorities have specific rules for importing medicine for personal use. Controlled substances and psychotropic drugs are completely prohibited in several countries, and even possessing a small amount of these drugs for personal use can result in arrest, jail time, and drug trafficking charges. Many commonly used prescription and over-the-counter medications are prohibited in a small number of countries and cannot be imported. Ingredients found in inhalers, cold and cough medications; allergy and sinus treatments are examples of this (Cave, 2018).

Personal medicine importation creates a gap in the "closed" system and will almost certainly increase risk because evidence suggests that oversight gaps in drug regulation and the

distribution system have been exploited. Importing personal medications increases the likelihood of illegal, unapproved, and subpar pharmaceuticals infiltrating and spreading throughout the drug distribution system **(Kleiman, 2006).**

The Ethiopian Food and Medicines Authority (EFDA) regulate Ethiopian pharmaceutical products. The EFDA was established by proclamation to ensure the safety, efficacy, and quality as well as rational use of medicine. Registration, licensing, and inspection of health professionals, pharmaceuticals, food establishments, and health institutions are among the EFDA's mandates. Human drugs, radiopharmaceuticals, traditional medicines, medical supplies, and instruments, sanitary items, cosmetics, and packaging materials are all regulated by the EFDA (fmhaca.gov.et).

There is no research in Ethiopia addressing the regulation requirement and personal medication importation practice. To assess the practice of importing pharmaceuticals for personal use into Ethiopia, the importation pattern, regulatory requirements, and enforcement method must all be studied. As a result, the goal of this research was to investigate the current state of personal medication imports.

1.2 Statement of the Problem

Individuals may import approved and unapproved pharmaceuticals for personal use, if they are clearly understood. Due to the challenges in controlling individual importation, safety is a primary concern when importing drugs for personal use, since it lacks the means to examine the content of all imports and is unable to determine the origin of certain pharmaceuticals. Quality assurance issues, substandard/falsified potential, untested substance presence, risks of unsupervised use, labeling and language issues, and lack of information are a few variables contributing to drug safety concern (Bro, 2005).

Personal importation poses concerns related to the use of fake pharmaceuticals, according to investigations carried out overseas. Personal importation is extremely risky and not recommended at all because there is no assurance of safety or control. Even regarding Canada, the country does not monitor the export of drugs, so the sheer fact that a medication originates there is hardly a guarantee that the substance is legal and part of a controlled supply chain **(Rodriguez, 2005).**

A study conducted in the USA by Shepherd, (2005) on drug quality, safety issues, and threats of drug importation, showed that products found to be improperly packaged such as, packaged in envelopes, sandwich bags, and tissue paper. Some drugs have been "cracked" or "crushed" medicines that can cause adverse interactions with other medicines have also been included. Drugs inadequately labeled for safe use or labeled in a language other than English; drugs requiring risk management (screening and monitoring programs), drugs requiring careful dosing, drugs withdrawn from the market, Potentially recalled drugs-for example, the asthma treatment drugs Serevent Diskus and Flovent Diskus are some safety issue found during the inspection.

According to studies, manufacturers who do not adhere to good manufacturing practice (GMP) standards may remain able to produce medicines for both domestic and international usage, distribution, and street sale in some countries. Many prescription medications imported into the United States today by private individuals through mail and courier services do not meet all of federal regulations information on the harmful effects of imported drugs, such as hospitalizations and fatalities related to personally imported pharmaceuticals, is scarce. To more precisely determine the risks associated with personal imported medicines, this information is required **(Shepherd, 2005)**

Prescription drug importation for personal use creates an opening in the "closed" system (manufacturers, wholesalers, pharmacies), weaknesses in the oversight of drug regulation and the distribution system , increase the opportunity for falsified and other substandard drugs to enter and be dispersed into the drug distribution system **(Kleiman, 2006)**

Access to medicines is rapidly increasing in most African countries, but the regulatory capacity to properly oversee and manage pharmaceutical centers is insufficient. The region lacks quality medicines, a prevalence of substandard/falsified medicines, and ineffective regulatory and border control system (Yadav, 2014). According to research, the distribution of fake and subpar medications has emerged as a serious hazard to public health, especially in these nations with low resources (Caudron, 2008).

There is permission in Ethiopia that still allows the import of relatively small amounts of medicines for personal use. Although some imported drugs are legal, the vast majority are not

subject to the same regulations and cannot be verified as safe and effective, regardless of whether they were purchased online, from a physical pharmacy, or while visiting another country.

As far as the knowledge of the researcher, no studies have been conducted in Ethiopia outlining the importation pattern, the regulatory requirements, enforcement practices, and strategies established by the National Regulatory Agency (NRA) to successfully deal with issues related to the import of personal medicines. Thus, the aim of this research was to look into the situation of personal medicine importation into Ethiopia, including the pattern, regulatory requirements, and enforcement methods.

1.3 Significance of the study

When a person brought personal medicine, regulating and preventing the use of dangerous, ineffective, or substandard pharmaceuticals requires many resources. This entry point, which allows people to purchase pharmaceuticals from abroad for personal use, might be used by counterfeiters to take advantage of. It is helpful to use resources to identify personal medicine importations patterns, and to strengthen the regulatory requirements and enforcement system in Ethiopia. Hence, this study might have the following significance to the following bodies.

These include; the study might have useful to custom board protection and EFDA to take a careful look at the information and investigate the potential impact of personal medicine importation before setting policy, the study also useful for Policymakers to design valuable binding rules on medicine regulatory system, and it also has due significant to EFDA to establish appropriate interventional strategies to strengthen the medicine regulation and distribution system. In addition, it also gives valuable information to all concerned bodies who are working in the health area regarding Ethiopia's present enforcement practices and the importation pattern of pharmaceuticals for personal uses, and this study also use as a reference for further study on a related issue.

2. LITERATURE REVIEW

2.1. An Overview of Medicine Importation for Personal Use: National and International Experiences.

2.1.1 Extent of Medicine Importation

The lack of particular medicines in the country, the lack of health insurance coverage, and the relatively high cost of brand-name pharmaceuticals in comparison to other countries are the main drivers for rising personal medicine importation (Sheridan et al., 2011). Because prescription medications are costly and difficult to obtain in wealthy countries, many people are importing medicine themselves, traveling across borders, and using online pharmacies. Imports of both approved and unapproved drugs for personal use are increasing (Zullo et al., 2015).

Furthermore, concerns about a lack of information about the nation's health system and a history of antibiotic overuse in their countries. Because there are differences in health care systems within and between high- and low-to-middle-income countries, new immigrants may face significant challenges when moving across healthcare systems.(Mireskandari, 2021; Babar et al., 2013). Migrants may transport medications to and from their home countries for future use (Palumbo et al., 2007; Wang and Hu, 2015).

Based on reports, the number of drug packages destined for US residents increased by 1,000% between 2003 and 2004. Every day, more than 20,000 drug-containing personal medicine packages arrive at the international mail facility from others countries such as India, Thailand, and the Philippines. It is estimated that nearly a billion dollars in drugs were shipped into the United States from Canada in 2004. The quantities of drug products per package imported from foreign sources exceed the regulatory supply limitation (Shepherd, 2005).

Based on FDA and U.S. Customs and Border Protection (CBP) assessment, about five million shipments, totaling around 12 million prescription medicine, entered the United States from Canada alone in 2003; similar quantities of prescription pharmaceuticals are entered the country from the rest of the world, through internet sales and American consumers' journey (Bate, 2019). many Latino Americans import non-prescribed antibiotics into the United States (Mainous III et al., 2005). Many prescription medications imported into the United States by private persons via

mail and courier services do not meet these entire Federal regulations standards. The types of products found to be, as unapproved versions of the cholesterol drugs atorvastatin (Lipitor and pravastatin (Pravachol), unapproved versions of phenytoin (Dilantin), levothyroxine (Synthroid) and metformin (Glucophage) unapproved drugs like human growth hormone, and the immunosuppressant alti-azathioprine; unapproved versions of FDA-approved drugs, such as Roaccutane, an unapproved version of the acne drug isotretinoin (Accutane) and taro-warfarin, an unapproved version of the anticlotting agent warfarin; are included (US Health and Services, 2004).

The growing number of online import agencies, as well as the significant and increasing number of unapproved medicine brought into Japan in 2005. In 2005, Japan imported a total of 12,196 unapproved personal medicines. Personal imports and the use of unapproved medicine are virtually unregulated in Japan. While antineoplastic drugs constituted the majority of imported drugs, medicine for a variety of non-serious diseases were also imported (Tsuji, 2008).

2.1.2 Regulatory Requirements of Medicine Importation for Personal Use.

Different countries have different medical regulations. Some medicines are permitted in one country but prohibited in another. Individuals are frequently prohibited to import medicines or equipment to personal use from one country to another without the approval of the nation's regulatory authorities in order to achieve the highest level of public protection. People search for medicines that are not available in their home country. Medicines are sometimes mailed to people in response to a prescription-like order to enable the continuation of a treatment that was started abroad. Individuals may also travel abroad for business, seminars, or medical treatment.

Personnel from the nation's medicine regulatory agency may allow the entrance of shipments when the quantity and purpose are evident for personal use and the product does not pose an undesired risk to the user. In general, each country's government regulatory bodies for medicine have specific laws for the importation of medicine for personal use (Kissane and Flaherty, 2022).

Reviewed publicly available data on medication transportation across borders for the top five countries in each continent for international tourism arrivals in 2019 showed that, 56 % of countries required a valid medical prescription at border customs. In 32% of countries, a doctor's

certificate was required to be endorsed by the traveler's national health authorities. A minority of countries (24%) required a certificate issued by the destination country's health authorities.

The majority of countries (68%) made their prohibited substances public (Kissane and Flaherty, 2022). In general, every country has the same basic rule, which they require. It is necessary to obtain a prescription from a licensed medical expert (stamped and signed through the relevant medical authority with full important points of the patient and clinical condition). All medications must adhere to strict guidelines, be in original packaging, and not be expired. Travelers seeking medical attention should only bring enough medication to last the duration of their trip. The quantity of imported non-narcotic and psychotropic medications must correspond to the duration of treatment (with a maximum of three months). According to the usage instructions, an individual may import a single course of treatment or a 90-day supply of an over-the-counter drug, whichever is less. However, narcotic and psychotropic drug import restrictions varied greatly between countries. (Kissane and Flaherty, 2022). In Ethiopia, a valid medical prescription is required; according to standard operating procedures (SOP).

2.2 Safety Issues with Personal Medicine Importation

2.2.1 The Risks to the Individual Consumers

The objective of personal importation was to allow patients to have access to drugs that were not available to them in the country either for continuation of therapy begun in another country or when there are no medicine treatments for their condition options in their home nations.

Personal medicine importation carries a risk of exposure to counterfeit (i.e., falsified, fraudulent), adulterated, and substandard drugs (Zullo, 2017). Importation and counterfeit drugs-have now become intertwined and inseparable (Gilbert, 2005). It is challenging to handle and prevent safety problems from "individual" medicine importation. A survey suggests that importing drugs for personal use from countries with looser laws on medication safety may increase the risk of taking fake (i.e., falsified or fraudulent), contaminated, or otherwise inferior drugs (Zullo, 2021, Bro, 2005). Safety is a major problem when importing prescription pharmaceuticals for personal use. Because of resource constraints, it is impossible to determine where specific drugs come from or to verify their contents for all imports (Foote, 2014).

According to a study, consumers of such products cannot be assured that good manufacturing practices have been followed or that packaging, handling, storage, and distribution procedures have been sufficient to prevent deterioration, contamination, or degradation because the quality assurance procedures of drugs produced in foreign countries cannot be verified. Even though

such substances may be acceptable and legal in the country of production, imported medications may contain ingredients that have not been studied and verified as safe and effective (Zullo et al., 2015).

When someone physically imports medicines, the most serious risks include quality assurance concerns, the presence of untested ingredients, issues related to risk management and unsupervised use, labeling, language problem, and lack of information.(Shepherd, 2005). Import blitz exams confirm that a wide variety of drug types entering the United States lack integrity in manufacturing, packaging, labeling, storage, or distribution.(Bate, 2019).

Some imported medications might be forgeries of the real thing that contain dangerous (extremely potent) or useless (sub-potent or outdated) ingredients. It is possible for highly potent medications to cause adverse consequences, some of which may be fatal. Drugs that are ineffective or out-of-date are likely to fail to provide the anticipated benefit, but a patient would not be aware that the medicine itself was the cause of the treatment's failure (Shepherd, 2005)

Drugs obtained from foreign sources could have labels written in a language other than English, keeping important details about dose and side effects unreadable. It's likely that instructions on how to handle emergencies situations are lacking, or that exaggerated claims about the drug's safety and effectiveness, or its intended or usage, are made. Even though routine checkups and follow-up exams are important risk management strategies when taking some medications, consumers who imported goods might not have access to medical supervision(Shepherd, 2005).

2.2.2 Effect on the Pharmaceutical Market

The drug distribution network for legal prescription drugs, manufacturers, wholesalers, and retailers provides multiple levels of protection. Legalized importation of medicine individually creates an opening in the “closed” system and will likely result in some increase in risk, as the evidence shows that weaknesses in the oversight of drug regulation and the distribution system

have been exploited. Doing so would increase the opportunity for falsified and other substandard drugs to enter and be dispersed into the drug distribution system (US department Health and Services, 2004)**.**

The safest drug distribution system is presently a "closed" system involving solely manufacturers, wholesalers, and pharmacies. The producing method and distribution process is tightly regulated by the regulator once the supply and therefore the channel is known. This in-depth regulation at multiple levels drastically limits the likelihood of unsafe, ineffective medication reaching consumers. This system provides multiple levels of protection against receiving unsafe, ineffective, or substandard drugs;-in some countries, manufacturers who fail to accommodate good manufacturing practice (GMP) requirements will still manufacture medicines for domestic use and for export and distribution and commercialism in marketplaces and streets counterfeiters can take advantage of this entryway (WHO, 2003).

Personal importation would open the "closed" system and indubitably raise the possibility of consumers being injured by harmful pharmaceuticals. Unsafe pharmaceuticals have an opportunity to enter the market because of questionable drug regulations in other nations and misuse of the distribution system.

In general, despite the fact that there is little literature evaluated in the subject filed, a summary of the literature review reveals that imported medicine, whether obtained online or during a journey to another country, poses risks to patient safety. There has been no research on the state of personal pharmaceutical importation in Ethiopia, therefore this study will open the way for future research in this area.

3. OBJECTIVE

3.1 General Objective

- To assess importation patterns, regulatory requirements, and enforcement practices of medicines imported for personal use in Ethiopia.

3.2 Specific Objectives

- To describe the pattern of medicine importation for personal use in Ethiopia in 2020-2021.
- To identify regulatory requirements for the importation of medicine for personal use in Ethiopia.
- To assess enforcement practice taken by Ethiopian Food and Drug Authority (EFDA) to control personal medicine importation.

4. METHODS

4.1 Study Area and Period

The study was conducted in selected regulatory authorities that are concerned with the regulation of pharmaceutical products at Bole International Airport (Terminal 1 & 2 hubs). The chosen regulatory bodies are EFDA, Ethiopian Custom Authority (ECA), and National Intelligence Security Service (NISS) which are responsible for ensuring public safety and security; protecting the environment and health; protecting consumers; collecting revenue, and maintaining trade policy (Revenues Authority, 2017). Passengers arriving from an international flight use this terminal, where they are checked under security parameters before entering the country.

While, EFDA is responsible for ensuring the quality, safety, and efficacy of pharmaceuticals, food, cosmetics, and medical devices, ECA is mandated to administer customs laws relating to the importation, export, movement, or storage of goods and collection of duties and taxes. NISS directs aviation security activities, and coordinates other aviation security stakeholders in accordance with the Ethiopian Aviation Security Declaration. The study was conducted from November 2021 to May 2022.

4.2 Study Design

The study was followed an exploratory sequential Mixed-method design. Characterized by an initial phase of qualitative data collection and analysis followed by a phase of quantitative data collection and analysis.The qualitative study followed a thematic analysis. Finally, both data were integrated.

4.3 Source and Study Population

For regulatory authority, all Ethiopian Custom Authority (ECA) in Addis Ababa, Ethiopian Food and Drug Administration (EFDA) in Addis Ababa, and all National Intelligence and Security Service (NISS) in Addis Ababa Ethiopia were used as a source population, and the study population was EFDA Addis Ababa Bole international port of entry and exit terminal($T_{1\&2}$) medicine control directorate, Addis Ababa Bole international port of entry and exit terminal($T_{1\&2}$) custom branch (ECA), and NISS Addis Ababa Bole international port of entry

and exit terminal($T_{1\&2}$). For individual participants and secondary sources of data, the source population was all professionals working at the respective institution, and all secondary data, which was collected and stored by EFDA Addis Ababa, Ethiopia. Those purposively selected individuals (key informants) having experience, role, responsibility, and understanding of the administration of customs law and import & export of pharmaceuticals regulatory rule in their respective institution, and data collected and documented for two-year (2020-2021) at EFDA Addis Ababa Bole international port of entry and exit terminal($T_{1\&2}$) medicine control directorate were used as study population. Key informants (KIs) were selected from the EFDA, ECA, and NISS authorities. Passengers were not involved in planning or conducting this study.

4.4 Sample Size, Sampling Technique, and Procedure.

For the quantitative part, secondary data (i,e. EFDA registration log book, EFDA port of entry-exit inspection result, EFDA release permits, and customs declarations for dutiable items form) collected for two years (2020 – 2021) by EFDA Addis Ababa Port of Entry medicine regulatory directorate office in terminal two were included. For the qualitative study, KIs were purposively selected from the EFDA, NISS, and ECA until the data collection process reaches saturation (the point at which the data collection process no longer offers any new or relevant data). Accordingly, saturation was reached after 31 interviews.

4.5 Data Collection and Management

For the quantitative part, secondary data were collected using data abstract form. For the qualitative study, the researcher used semi-structured interviews, which allows participants to express their thoughts. Follow-up questions were also asked as required. An interview took an average of 30 to 40 minutes, and it was conducted at their workplace by the researcher herself.

KIs were interviewed in the local language (Amharic) to give them freedom, and any ambiguity from the interviewee was cleared at the time of the interview. The interview guide consisted of questions that would address the main research objectives.

4.6 Data Analysis and Interpretation

First, qualitative data collected by note-taking was organized, and cleaned. The data collected in Amharic language was translated into the English language. Then, qualitative data were analyzed manually using themes with following the exact words from the participants. Analysis was started in which themes were generated by looking at patterns from the data set. In this approach, the researcher read through the data (texts from interviews) and allows codes to emerge. The codes were revised repetitively, and similar codes were grouped into themes. As the process continued, new themes emerged, and groups of related themes (sub-themes) were placed together under larger ones. On the other hand, Quantitative data were analyzed using Microsoft Excel (2013) and the result was mainly expressed descriptively using frequency and percentage.

4.7. Ethical Consideration

Ethical clearance was obtained from the Ethics Review Committee of the School of Pharmacy, Addis Ababa University (ERB/SOP/377/14/2021), and support letters were written from the Department of Pharmaceutics and Social Pharmacy to the respective organizations. Before data collection, permission was obtained from NISS, Addis Ababa Bole Airport Custom Branch Office and EFDA based on the letter of support and ethical clearance.

Data were collected after a clear oral presentation of the aims and importance of the study. Written informed consent was obtained from the KIs after a clear presentation of the purpose of the study and its benefit. Participants were assured about the confidentiality of their information obtained in the study by excluding any personal identifier in the data collection form and anonymization of quotes to prevent statements that could be traced back to individuals. Interviewees were assured and encouraged to talk about their views on this issue. And also, KIs were informed and assured of the right to refuse or terminate at any point in the interview. Finally, the researcher identified herself as participant of the study as members of the Ethiopian food and drug Authority (EFDA) and a Master of Science in Regulatory Affairs (Medicine Regulation Track) students at the School of Pharmacy, College of Health Sciences, Addis Ababa University.

4.8. Operational Definition

Falsified Medical Products

Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

Import/export Customs Declaration Form

A customs document on which customs officers recorded the name of the medicines; the quantity and type of the medications, the date of entry, the traveler's name, and one's passport number after determining that one traveler had already imported medicines for personal usages.

Medicines Shortages

Demand and supply imbalance or interrupted supply or the unavailability of medicines to satisfy the patient needs

Personal Use Importation

Refers to importation by an individual for his/her own use, or for a person/animal under that individual's care or guardianship, and not for further sale. It does not apply to a practitioner (Doctor, Veterinarian etc) importing drugs for patients/animals under their care.

Substandard Medical Product

Also called “out of specification”, these are authorized medical products that fail to meet either their quality standards or their specifications, or both.

4.9. Researcher’s Position and Reflectivity

The principal investigator is a woman, who permanently lives in Addis Ababa city, an Amharic speaker, and pharmacist working for EFDA as a physico-chemical analyst. In addition, the PI is doing her Master’s degree in Regulatory Affairs (Medicine regulation track). Hence, those backgrounds couldn’t carry discord sine participants were taken into consideration as knowledgeable professionals who have a minimal bachelor's degree and noble know-how of international regulatory law. Despite this, most of the participants had no prior relationship with

the researcher, so participants were unaware of the researcher's background except for those working at EFDA. As this could impact the response of a limited number of participants, the researcher has made every effort to allow participants to freely express their opinions. In addition, data collection was conducted in Amharic, the working language of the federal government, and a description of the study topic was provided during the interview session to eliminate ambiguity.

5. RESULTS

5.1. Qualitative Study

5.1. 1. Socio-demographic characteristics of Key Informants

A total of 31 KIs aged between 25 and 50 years were interviewed. Regarding their work area, 4 from NISS, 11 from EFDA inspectors, and 16 from ECA. Table 1 shows the socio-demographic characteristics of the KIs.

Table 1: **Socio-demographic characteristics of key informants (n=31)**

Characteristics	Category	N (%)
Gender	Male	15(48.6)
	Female	16 (51.4)
Age group (years)	25-30	2(6.5)
	31-40	19(61.3)
	>40	10(32.3)
Academic qualification	Diploma	2(6.5)
	Bachelor's degree	20(64.5)
	Master's degree	9(29)
Profession	Pharmacist	11(35.5)
	Accountant	12(38.7)
	Economist	2(6.5)
	Public Manager	2(6.5)
	Custom Manager	2(6.5)
	Lawyer	2(6.5)
Work experience (years)	1-5	**3(9.7)**
	5-10	13(41.9)
	10-15	8(25.8)
	15-20	7(22.6)
Work Position	NISS Inspector	2(6.5)
	NISS Manager	2(6.5)
	Custom Officers	13(41.9)
	Custom Manager	3(9.7)
	EFDA Inspectors	9(29)
	EFDA coordinator	1(3.2)
	Directorate directors (EFDA)	1(3.2)
Work area	NISS office	4
	ECA office	16
	EFDA office	11

5.1.2 Experiences and opinions of key informants on importation of medicines for personal use, regulatory requirements and enforcement practices.

The findings of this study were categorized into six themes. These are: the situation of importation of medicine for personal use in Ethiopia, Job responsibility, regulatory requirements, current law enforcement practices, factors contributing to the increased importation of medicines for personal use, and possible solutions for proper regulation. Under the six major themes, 11 sub-themes were identified and described below.

Theme 1: The situation of medicine importation for personal use in Ethiopia

During the interview, respondents provided their views about the overall personal medicine importation system and current practices. According to respondents, almost all individuals bring medicine for personal use. One interviewee said, "if there were 100 travelers, 70 of them would bring the medicine with them, especially from Turkey". The majority of respondents said that all the time, a business traveler (a person who is traveling for other businesses) brings medicine in bulk in one flight and distributes it to each traveler to minimize the size that each individual carry because they knew the restriction. The medicines were commonly brought from Turkey, Dubai, India, and China. There are three kinds of travelers who import medicine; the first one is real patients. These kinds of travelers bring a reasonable amount and have the necessary document, the second for transit purposes, from Sudan by Sudanese people.

They bring cancer medicine more than 3 times a week to transit. The third one is businessmen or women, or agents (The people who walk into their businesses on the way, purchase medicine from abroad, and bring it into Ethiopia) who bring medicines that are unpackaged and improperly stored with other items not to waste space for commercial purposes. And participants explained that nowadays there are so many personal medicine importers because Ethiopia does not apply value-added tax (VAT) or goods and services tax/general sales tax (GST) on medicines imported for personal purposes.

KIs explained about medicine importation for personal use which can be categorized under five general sub-themes, Personal medicine importation practice**,** Storage condition, Country of origin for commonly imported medicines, Kinds of imported medicine, and Characteristics of medicine importers for personal use.

a. Personal medicine importation Practice.

Findings obtained from the key informants' interviews demonstrated that it is a common practice for travelers to carry medicines with other items without a prescription for the 'purpose of their use'. They (travelers) bring medicines like any other item. This was supported by the following accounts from informants.

> "It is common for travelers to carry medicines with other items without a prescription for 'the purpose of their use'. They bring medicines like any other item. They say, 'the profit is high, I did not know about this business before." (Customs Officer 3)

> "It is common to see travelers carrying medicines without a prescription for commercial purposes. Turkey and Dubai are known for importing Galvusmet and erectile dysfunction medicines for commercial purposes, respectively. Also, in one flight you could find so many travelers carrying the same medicine. Recently, we have started collecting and detaining all the medicine from each traveler." (Custom Officer 8)

> "There is the importation of medicines by individuals daily, especially from Turkey. If there are 100 customers on those flights, 70 of them will import medicine. It is known to all customs officers, as well as EFDA inspectors." (Custom Officer 5)

> "Importing large quantities of medicines from China for purpose of personal use are also common. We do not know whether it is a medicine or not because the name of the medicine on the package is written in Chinese and most of the time, they do not have a prescription." (Customs Officer 14)

> "Importation of personal medicine increased occasionally for commercial purposes, because Ethiopia does not apply value-added tax (VAT) or goods and services tax/general sales tax (GST) on medicines." (Custom Officer 15)

b. Storage condition

Concerning storage condition of personally imported medicine the majority of KIs expressed that most of the time medicine is imported out of the original packaging (original container); to use the space they have efficiently, which result in failing to maintain the temperature of medicines (including insulin injection), and they usually try to hide in their body parts, immersed with powder soap, chocolate boxes, formula milk, and shoes. This was further explained by the following statement.

> "Individuals import medicines including insulin injection with other items in some luggage, failing to maintain the temperature of medicines (stored by inappropriate storage condition)." (Custom Officer 12)

> "All the time they separate the medicine from its original pack and put it in a bag with other items like clothing, perfume, formula food, shoes, powder soap, and so on, to use the space they have efficiently."(Custom Officer 5)

> "And some put it on a part of their body to hide because they imported medicine repeatedly, they know the restriction rule."(Custom Officer 5)

c. Country of origin for commonly imported medicines for personal use.

Participants declared that there were importations of medicine from all over the world for personal consumption purposes. But many travelers (walk-in other businessmen/women) bring medicines commonly from Turkey, China, India, and Dubai. Other groups of individuals who import medicines for personal use, are those who got treatment abroad, mostly from Thailand and India and return with their prescribed medications.

> "All the time, after completing their diagnosis and hospitalization, patients coming from India, and Thailand; import a reasonable quantity of medicines for their use. In contrast, many travelers (walk-in for other businesses) bring medicines from Turkey, China, India, and Dubai. Travelers from

> Germany, the US, and Canada bring supplements, vitamins, and OTC medicines" (Custom Officer 4)

d. Kinds of imported medicine

KIs indicated that the medicine which was imported by international travelers mostly treatment for of chronic diseases including antihypertensive, anti-cancer, anti-diabetes, treatment for baldness (treatment for hair loss), anti-pain, vitamins, supplements, antibiotics, and treatment used for erectile dysfunction (in different dosage form). And also, Chinese had brought Chinese traditional medicine (mostly Covid - 19 treatments (Remedisvir)). The KIs explain their view as follows:

> "Chinese bring medicines in bulk, which we do not know since the label is in the Chinese language. Usually these medicines are imported without a prescription, if there is a prescription; it is in the Chinese language." (Custom Officer 6)

> "Chinese commonly imports traditional medicines and medicines used for erectile dysfunction in bulk. They also import anti-pain, anti-diabetic, covid-19 treatment, and medicines that we do not know the name and types." (Custom Officer 13)

> "varieties of medicine are imported, of these antihypertensive, anti-pain, anti-cancer treatment, anti-diabetes (especially Galvus-met), the treatment used for hormones, baldness, vitamins, supplements, antibiotics, gastritis, and treatment used for erectile dysfunction (in different dosage form) are the common ones." (EFDA inspectors 4)

e. Characteristics of medicine importers for personal use

Concerning the characteristics of medicine importers, KIs described; generally real patients are relatively aged and suffer from chronic diseases, but there are also people of all age groups. As

explained by KIs; walk- in other businessmen also bring medicine, these kinds of importers are relatively adult age (both sex).

> "Most of the time real patients are relatively aged and suffer from chronic diseases like diabetes, high blood pressure, and cancers. These patients import their medicines themselves. But there are also people of all age groups." (EFDA inspector 6)

> "In most instances, travelers bring medicines for others. When asked, they say this medicine is for my relatives, friend, or acquaintance. These kinds of importers are relatively adult age (both sex), and a frequent traveler." (Custom Officer 7)

Theme 2: Job responsibility

The main theme that emerged from the qualitative analysis was the job responsibility of EFDA inspectors and ECA officers at the terminal inspection area. As clearly indicated by respondents, the permission of releasing medicine is done by customs officers in the Ethiopian airlines terminal hub. If there were personal medicine within the traveler's luggage, the designated customs officer would release it after the document (prescription).

It is custom officers' day-to-day practice. But if the imported medicine is in bulk and in different varieties, the officers seek advice to shift coordinators. Depending on the shift coordinator's advice, the medicine is released, detained, or declared and notified to EFDA inspectors.

> "Always custom officers released personally imported medicine by themselves, but if medicines come in bulk, we will ask advice from our senior staff." (Custom Officer 12)
>
> "All customs officers do the same thing when an individual comes with personal medicine; we see the prescription and passport. If the name of the medicine written on the prescription and medicine package is the same, and the amount in the prescription and the amount of medicine he or she brought

is the same, and also the name of the individual is the same as the passport and prescription, simply release the medicine. For some medicines, like paracetamol, multi-vitamins, supplements, and calcium (OTC), we released without searching on the internet." (Custom Officer 13)

"In case I did not know the medicine before, first I would interview the traveler for what purpose the medicine was brought and prescribed to him. Following this, I would search for it on Google and read about the medicine. If the information provided matches the traveler's answers, I would release the medicine, if not; I ask advice from the senior Custom Officer." (Custom Officer 1)

Many of the participants from EFDA inspectors explained that the import of Pharmaceuticals and medicines, medical supplies or instruments, baby food, food supplements, and cosmetics into Ethiopia are restricted for of the public and must be imported with the permission of responsible regulatory agencies. According to key informants from EFDA, all EFDA inspection and enforcement procedures for importing pharmaceutical products rely on coordinated action with customs. Customs officers notify EFDA inspectors of the product's entry, and the EFDA inspectors decide. Unless notified by customs officers, EFDA personnel are unaware of the entry of this product. The following statements are taken from EFDA KIs.

"The primary job responsibility of releasing medicine importation is EFDA inspectors, but the customs officers do not notify us because sometimes when we do sudden inspections at the exit, we get medicines in travelers' luggage released by customs officers." (EFDA inspector 4)

"Custom officers release more than 90 percent of medicines imported for personal use without informing EFDA inspectors, which is the responsible body for inspecting and releasing medicines." (EFDA inspector 7)

> "Custom officers declare to the EFDA inspector if they do not know the name of the medicine (brand) and if the medicines are imported in variety and in bulk. Otherwise, they do not declare and notify EFDA". (EFDA inspector 8)

As indicated by respondents, the permission to release medicine is also done by customs officers who are seated at the Ethiopian Airlines terminal one & two hubs. The participant of all custom officers gave reason for exercising beyond their mandate as follows:

> "Always, our senior staff releases medicine by themselves. They share their experience like how to read prescriptions, differentiate medicines from other goods in the x-ray machine, and so on… and make a decision." (Custom Officer 2)

> "First, medicine regulators are seated far from here (the checkpoint). If you find a traveler with medicine, it takes time to get a response from medicine regulators. Travelers also complain a lot of saying that it is wasting their time. The EFDA inspectors do nothing special, except read the medicine name with the prescription and package, which is a simple task. Secondly, we are very busy because Ethiopian airlines have many customers who come from different parts of the world, and they (travelers) do not want to go to EFDA. Even if we send the traveler to them, they release all the medicine." (Custom Officer 16)

> "EFDA inspectors do not come here (inspection area) and do the physical checking. When we send the travelers to them; they simply send release papers by seeing a custom declaration form. Secondly, they do not have a special tool for reading prescriptions and expiration dates on the package (the customs officer can do this). So, what difference do they make? Finally, drug regulators are not always available, especially at night and on weekends. They work during office hours only. However, there are travelers 24 hours

and seven days. So, customs officials have no choice other than to do the task by themselves. For this and other reasons, Customs officers get used to the job." (Custom Officer 1)

"The task is performed by ECA officers because the regulatory bodies of medicine in this terminal area have no commitment, and they are not responsible." (NISS Official 1)

Theme 3: Regulatory Requirements

Another main theme that emerged from the qualitative analysis was the regulatory requirements for personal medicine importation. All EFDA/ ECA KIs mentioned that the main regulatory requirement for permission of personal medicine importation could either be documentation required or quantity of medicines allowed.

a. Documentation Required

Few EFDA KIs described that EFDA has a standard operating procedures (SOP) that described the required document for the importation of medicine for personal use. According to their explanation, a Medical prescription (paper and electronic prescription) is the only requirement mentioned in this SOP, and all types of prescriptions from, all levels of private, government health institutions, and foreign countries are accepted to import medicine personally. This was further strengthened by the following statement.

"We have guidelines; the requirement for the importation of medicine for personal use is a medical prescription. We accept prescriptions from all types of health institutions, foreign countries, and health centers, private and government health institutions. Although most time travelers bring paper prescriptions, we also accept electronic prescriptions." (EFDA inspector 11)

In contrast, the majority of respondents from EFDA indicated that the guideline is not available in their setting.

"A committee was set up to develop SOP, but till now it was not prepared. But the only document we ask for is prescription."(EFDA inspector 11)

Also, some respondents of ECA described that there is no guideline that described the requirement of importation, doing their job by seeing and sharing experience from their senior staff.

"In the Customs office, there is no guideline, but we ask prescriptions and accepted all types of prescriptions (private, government, paper, and electronic. We are doing our job by experience.' (Custom Officer 2)

b. Amount of medicine permitted to import for personal use.

EFDA inspectors said that the quantity of medicine allowed is not indicated in the SOP, but we did this by personal judgment, usually we are releasing a 6-month-to-1-year supply. But the ECA officer said that when an individual brings a prescription drug, they release the amount as indicated on the prescription. The respondents did not know about the existence of regulations restricting the amount to be imported. This was supported by the following statements.

"We release the amount as indicated in the prescription. If the amount of medicine is higher than what is indicated on the prescription, we detain the extra. We do this always, no guideline in customs that describes this." (Custom Officer 2)

"We rely on our personal judgment to determine the amount of medicines imported for personal use. Mostly we release up to 6 months." (EFDA inspector 10)

"There is no restriction on the amount; we release the quantity sufficient for up to one year. And we also permit the amount written on the prescription. Most of the time, we release by personal judgment." (EFDA inspector 9)

Theme 4: Current enforcement practice.

Although there is an EFDA regulatory office in the terminal hub as well as established rules, there is a significant gap in the implementation of the rules and control procedures. The findings

from the interview showed that the enforcement capacity of the existing regulation of the importation of Medicine for personal use is inadequate. This was witnessed by the following accounts.

> "Our duties and responsibilities are not limited to medicines only; we see medicines like other goods. Although I do not have enough knowledge about medicine, I don't think the current practice of importing medicines is good. We see many people walking into other businesses carrying medicines saying this is for my mom, friend, or relative, and for sale." (Custom Officer 13)

> "The traveler knew about the restrictions on the importation of medicine by individuals, so they tried to hide the medicine and stored improperly. Even if I write a memo to the EFDA inspectors at the top of the declaration stating that medicines are improperly packaged and shipped, e.g., placing in their body parts, dipped in powder soap, and shoes, with chocolates, and diaper, EFDA inspectors usually release the medicines. 'I remember one traveler bringing near to expire medicine (had only 3-month expiration), without a prescription. According to the procedure, I declared and sent him to EFDA, and kept the medicine in the temporary storage area. After a long time, he brought a release paper from EFDA. By that time, the medicine was already expired, but he took it. This implies that either they did not see the declaration paper, or were not committed to inspect the medicine at the checkpoint (inspection area), do not communicate with us, or the existing regulatory bodies of medicine have no adequate enforcing capacity." (Custom Officer 8)

Theme 5: Perceived contributing factors for the growing importation of medicines for personal use

Lack of adequately qualified human resources, shortage of specific medicines, weak/no coordination between key stakeholders, and insufficient enforcement capacity of regulators

(including SOP) were the factors described by most of the Key informants as contributing factors for an increase in importation of medicines for personal use.

During the interviews, the majority of the respondents frequently mentioned, lack of qualified regulatory personnel as the major factor affecting the regulation and control of the importation of medicines for personal use. According to KIs' explanation, a sufficient number of qualified and experienced professionals are useful, especially when searching for personal baggage with X-ray machines, but there is a shortage of adequately trained and skilled professionals in this field. (Identifies drugs among other items that require experience). This was supported by the following statement.

> "There are an inadequate number of qualified and experienced professionals, especially in searching personal luggage on X-ray machines, and there is a lack of adequate numbers, properly trained and skilled expertise in the field (recognizing items such as medicine require experience and proper training). There are no trained professionals and no knowledge of the different types of medicines, especially those in lotion form. Besides, there is a workload." (Customs Officer 17)

> "Previously, we used to permit importation of drugs for treatment of erectile dysfunction in the form of a lotion; I really did not know them, but when I asked the traveler what it was, I was told that it was a skin care lotion. It was imported several times as skincare products in large quantities, and we unknowingly released it (I assume it is a regular lotion)." (Custom Officer 13)

Many KIs also suggested that the number of personal medicine importers increased when there was a shortage of a particular medicine in the country. Recently, there was a shortage of anti-diabetic drugs; during this time, many travelers started to import this drug. This was supported by the following statement:

> "The shortage of certain medicines in the country led to an increase in medicine imports for personal use. Recently, there was a shortage of antidiabetics, because

of this; there were an increased number of travelers who imports Galves-met." (EFDA inspector 8)

It was stressed that the existing weak relationships and uncoordinated communication among key stakeholders (NISS, ECA, & EFDA) are critical issues. The majority of the respondents added that there is a lack of coordination, communication, collaboration, and partnership between EFDA, NISS & ECA in Ethiopian Airlines terminal one and two hubs. This was witnessed by the following accounts.

"There is no communication and collaboration between EFDA, NISS, and ECA in Ethiopian airline terminal one & two hubs. There must be communication and information exchange between us. Sometimes we send a traveler intentionally (if the traveler imports medicine repeatedly within a few months, it was for commercial purpose; sometimes we declared and send it to EFDA inspectors). We have a system that registered their traveling history. But the EFDA inspector sends the releasing paper, this show that they have no system that registered traveler history, lack of communication with ECA officers, lack of commitment, and also maybe they did this intentionally). " (Custom Officer 1)

"Custom officers release medicine by themselves; there were so many travelers who import medicine for personal use, and no communication between us." (EFDA inspector 7)

Another key reason for the increased number of personal medicine importers is inadequate enforcing capacity of the existing regulation and *including* weak law/SOP.

"Travelers know about restrictions on the importation of medicine by individuals, which is why they tried to hide it. Most of the importers are businessmen. The existing regulatory bodies of medicine have inadequate enforcing capacity. Because the number of importers of medicine in the name of personal use has increased." (Custom Officer 13)

"There was no standard operating procedure to exercise regulatory duty; we did our job, especially in this area by personal judgment. We have no rule on amount restriction, how can one inspector perform the task without operating rule." (EFDA inspector 10)

"The current way that drug imports by individuals is one way by which the substandard and falsified products entering the country. The regulation system is also ineffective because the number of personal medicine importers has increased from time to time."(EFDA inspector 4)

Theme 6: Possible solutions for proper regulation

The recommendations suggested by KIS as a mean to curtail the importation of medicine in the name of personal use are summarized below:

1. **Strengthen the regulatory system and capacity**

All the respondents recommended that strengthen the regulatory system of current medicines importation for personal use. According to KIs policymakers and regulatory body such as EFDA and ECA should develop standard protocols to control unnecessary importation of medicine for personal use. The following illustrates this fact.

"Most of the time travelers do not have a prescription; brought the medicine without a prescription. If asked why they brought the medicine, they claimed that they would get profits out of selling those medicines. For example women usually bring sex medicine (for erectile dysfunctions) in different dosage form, and medicine for hair receding for the purpose of selling."(Custom officer 13)

"It seems that travelers knew gaps in the health system, which is why they brought medicine without a prescription. And there are also health professionals ordering the medicine behind this "Walk-in Other Business "travelers. The government must improve this weak regulatory enforcement practice. The responsible regulatory

party must develop a short and long-term plan to address the problem." (Custom Officer 18)

2. Alleviate Shortage of Particular Medicine

Improving medicines' availability in the country was mentioned as a solution to decrease volume of importation of medicines for personal use, and this was substantiated by the following account:

"The reason for an increased importation of medicine for personal use is that shortage of particular medicine in the country, and hence resolving this issue can alleviate the problem." (EFDA inspector 7)

"We have seen the stock out of medicines for a particular time in Ethiopia. During this situation, a lot of travelers imported medicine for personal use. Recently there was a shortage of anti-diabetic medication, Galvus-met. During this time, every traveler tended to bring this medicine." (EFDA inspector 2)

3. **Increasing stakeholders' coordination**

Most of the respondents added that there is a lack of coordination and communication, and cooperation between ECA officers and EFDA inspectors. Building a strong working relation between these key stakeholders is important for the benefit of the public, the regulatory body and the country at large.

"In this terminal, there is no coordination between the EFDA inspectors and the ECA officers." (EFDA inspector 10)

4. **Adequate and qualified *human resource with* continuous capacity building**

Adequate and qualified human resources, on-the-job training and continuing professional development have been suggested as the most important factors to strengthen regulation of the importation of medicines for personal use. The following quotes are taken to substantiate KIs recommendation:

"Adequate number of appropriately trained staff in finding and identifying drugs mixed with another item using X-ray machines require continuous training." (Customs Officer 15)

"Experienced and qualified experts, with commitment, are mandatory to regulate the import of medicines," (NSIS inspector 1)

"Ethiopian Airlines has plenty of customers who come from different parts of the world, and this requires skilled and sufficient staff to carry out the tasks effectively." (EFDA inspector7)

5.2. Quantitative Study

5.2.1 Status of imported medicines for personal use, through Bole International Airport

Documents such as EFDA registration book, import/export goods customs declarations for dutiable items form, EFDA port of entry- exit inspection result, and release permits were reviewed. Accordingly, as shown in Table 2 in the 2020 there have been 56 travelers who registered on the EFDA port of entry-exit inspection result form, while 78 travelers have been registered on the EFDA registration logbook.

year	Number of travelers with personal medicine registered on EFDA reg. book	Number of traveler with personal medicine registered on EFDA port of entry- exit inspection result form	Remark
2020	78	56	
2021	259	398	

Table 2: Number of traveler who brought personal medicine: 2020 – 2021

Similarly, in 2021 there were 259 and 398 travelers who brought in medicines for personal use and found recorded in the registration book and on the EFDA port of entry-exit inspection result document, respectively.

According to the EFDA's port of entry-exit inspection results, release permit, and import/export custom declaration documents of 2020 56 individuals imported 151 medicines to Ethiopia. The data showed that drugs are from those used for chronic conditions, such as anti-hypertensive (17.9%), insulin and oral antidiabetic agents (13.9%), *antineoplastic and related agents* (6.6%), *and* anti-lipemic agents (4.6%) made up the majority of the medication imported for personal use.

Only 48.2% of the travelers had prescriptions. Of the travelers with prescriptions, 19.6% were government health institution prescriptions and 25% were private health institution prescriptions. Close to 7.3% of the medicine imported by individual was labeled in a language other than English (Chinese language), thereby making it difficult to therapeutically categorize them.

Only 26.8% of the 56 travelers with documented data (import/export custom declaration documents, EFDA port of entry-exit inspection results, and release permits form) had custom declaration paper; 5.4% of the declaration was not legible to read and distinguish the type and quantity of medicine (attached white paper); 3.6% did not indicate quantity and type of medicine imported by an individual (they only wrote, four cartons/two bags/two black plastic bags of medicines.

Dermatological agents not approved for the treatment of vitiligo (Ginseng astragalusmongholicus Chinese angelic), Cardiovascular medicines:- Antihypertensive (Losartan, Carvedilol, Candesartan of hydrochlorthiazide, Telmisarta +hydrochlorotized, Blopress, anapril), Antilipemic Agent: - (Crestor)Insulin and Oral Diabetes Treatment: -(Galves Met, Acarbose, Gulcophage, Diamicron) and Preparations for Sex Hormones:-(Gonal F 900IU, Menopur, Cetrotide) are a few examples of products recorded in the port of entry-exit inspection results and import/export goods custom declaration documents in the year 2020 (Table 3).

Table 3: Therapeutic category and import quantity of medicine in 2020 - 2021

Pharmacotherapeutic classification of medicines	2020	2021
	N = 151	N = 920
1. Gastrointestinal medicines		
Antiulcer agents	2(1.3)	28(3)
Antacid	1(0.7)	5(0.5)
Antiemetics	1(0.7)	
Cathrtics and laxatives		13(1.4)
2. Cardiovascular medicines		
Antihypertensive	27(17.9)	54(5.9)
Diuretics	1(0.7)	12(1.3)
Angina/Ischemic Heart Disease	2(1.3)	
Vascular Shock	1(0.7)	3(0.3)
Antilipemic Agents	7(4.6)	24(2.6)
Heart Failure	2(0.2)	
3. Respiratory medicines		
Antitussives/expectorants		13(1.4)
Bronchodilators/Antiasthmatics		4(0.4)
4. Central nervous system medicines		
Analgesics/Antipyretics	10(6.6)	59(6.4)
Anticonvulsants	4(2.6)	15(1.6)
AntiParkinson medicines		9(0.98)
Antipsychotic medicines		9(0.98)
Medicine for attention deficit disorder		2(0.2)
5. Anesthesia		
Local Anesthesia		1(0.1)
6. Musculoskeletal and joint disease		
Medicines Used for Gout	5(3.3)	11(1.2)
Antirheumatics		4(0.4)
7. Antiinfectives		
Antibacterial	4(2.7)	32(3.5)
Antitubercusis		3(0.3)
Antivirals	2(1.5)	3(0.3)
AntiRetroviral/HIV/		14(1.5)
Other Antivirals		50(5.4)
AntiProtozoans		5(0.5)
Antihelmintic	1(0.7)	
Antimalarials	3(1.9)	2(0.2)

8. **Endocrine disorder and Contraceptives**		
Thyroid Hormones and Antithyroid Agents	4(2.6)	10(1.1)
Insulin and Oral Antidiabetic Agents	21(13.9)	171(18.6)
Female Sex Hormone Preparations	3(1.9)	25(2.7)
Corticosteroid Preparations		20(2.2)
9. Antineoplastic and related agents	10(6.6)	21(2.3)
10. Blood products and affecting the blood		
Anticoagulants	2(1.3)	42(4.6)
11. Vitamins		
Vitamins	11(7.3)	50(5.4)
Multivitamin with Minerals and/or Extracts	1(0.7)	24(2.6)
12. **Antihistamines**		
Medicines used for Allergy		11(1.2)
13. **Ophthalmic agents**		9(1)
14. Dermatological agents		
Keratolytics/Caustics and Antiacne Agents	1(0.7)	
Vitiligo Rx	1(0.7)	
Medicine for Psoriasis and Eczema		1(0.1)
Skin disinfecting agent		1(0.1)
15. Immunological preparations	6(3.97)	25(2.7)
16. Miscellaneous		
Alkalizing agent	1(0.7)	
Co-enzyme/antioxidants		4(0.4)
BPH Rx		6(0.6)
Imaging contrast		14(1.5)
Ana fissure Rx		1(0.1)
Gallstone solubilizing agent		*1(0.1)*
17. **Therapeutically not categorized**	11(7.3)	98(10.7)

In 2021 about 398 individuals imported 920 medicines into Ethiopia. Medicines for endocrine disorders and contraceptives such as insulin and oral ant-diabetic agents (18.6 %), cardiovascular medicines such as antihypertensive (5.9%), central nervous system medicines including analgesics/antipyretics (6.4 %), anti-infective including antiviral (7.2%). Only 59.3 % of travelers had prescriptions. Of these 21.6% of travelers with prescriptions from a government health care institution, 37.7% had prescriptions from a private health institution, 0.3 % had a

psychotropic substance prescription, 5% had a photocopy prescription, and 5.5 % also do not have a physician signature and seal.

Almost 10.7 % of medicine imported by individuals was labeled in a language other than English, making therapeutic categorization critical for this research. One prescription (0.3 %) of prescriptions has been transcribed into English.

It was discovered that only 51.2 % of 398 travelers documented data (import/export customs declaration and EFDA port of entry-exit inspection form) had custom declaration paper, and 3.3 % of declarations just were not legible to read and distinguish the type and quantity of medicine (attached white paper), but also 6.8 % did not indicate quantity and type of medicine imported by an individual (only they wrote phrases like four carton/two bag /two black plastic bag medicines and so on) because of the language barrier

According to the findings from the two-year data, one traveler imported three or more medicines with the same therapeutic category and different brand names at the same time. For example, different brands of anti-hypertensive medicine (Losartan 50mg, Carvedilol 6.25mg, pharmapress 10mg, Cardac 6.25mg, and Cardac 12.5mg) granted permission for a single individual to import the same therapeutic category in the different brand name. The EFDA granted permission to 94.2 % and 73.2% of travelers, respectively, to import all of the medicine they import for personal use in 2021 G.C. and 2020 G.C.

For the importation of medicine designated for personal use, the EFDA set guidelines. Any EFDA-regulated product that is imported by an individual for their personal use, usage for another person who is in their care, or use by someone they are traveling with and is not intended for sale to the general public is referred to as "personal use." As a result, the only prerequisite listed in this guideline for obtaining release permits from regulatory inspectors is a valid medical prescription. The guideline does not state how much import is suitable for personal usage.

Due to the EFDA's poor record-keeping and documentation practices, inspectors also neglected to keep the import/export customs declaration documents. The import/export custom declaration paper is a customs document on which customs officers recorded the name of the medicines, the quantity and type of the medications, the date of entry, the traveler's name, and one's passport number after determining that one traveler had already imported medicines for personal usages

and sent this document to immediately notify EFDA inspectors. A custom declaration document for imports and exports is necessary so you can see how many and what sort of medications each passenger carried.

Additionally, as a general rule, EFDA inspectors only inspected 50% of the medicines those users imported and only 50% of inspected medications were recorded in the EFDA port entry-exit inspection result document.

The port entry-exit inspection result document did not include the remaining 50% of imported medications that were not checked. As a result, there was a discrepancy between the amount of medicine listed on the import/export customs declaration and the port entry-exit inspection result document.

The number of travelers included in the registration book and port of entry-exit inspection results records for the years 2020 and 2021 was not similar, as indicated in (Table 3). due to the EFDA's poor record-keeping and documentation procedure, general rule of EFDA only 50% of medicine inspection from those user imported, and neglecting of recording the uninspected the remaining 50%.

According to the responses of the KIs, there is a massive and constant importation of drugs for the treatment of covid-19, balding, and erectile dysfunction, however, throughout the review of documents, there were few treatments for covid-19 (Remidisivir, LH24, LH36),however, no treatment for sexual dysfunction and balding has been registered.

6. DISCUSSION

This study attempted to provide insight into the situation of medicine importation for personal use in Ethiopia, including current status, regulatory requirements, and enforcement practices

According to the finding of the qualitative study, the status of personal medicine importation is very high, with nearly everyone bringing medicine for personal use into Ethiopia. It is a common practice that has recently increased rapidly. People of all ages, but adult of both sexes import medicine for personal use. Individuals commonly import medicine from Turkey (25.6 %), India (21.8%), Thailand, and China (12.3%). Similar findings have been found in other international studies, and many Latino Americans import non-prescribed antibiotics into the United States (Mainous III et al., 2005). Another study found that 32% of Chinese migrants brought medicines with them on their most recent overseas trip to Australia (Wang and Hu, 2015).

Our study indicated that medicines are imported out of their storage box (original container) to make better use of the space available, products that requires refrigeration are not properly packaged, some products had labels written in a foreign language, and trying to hide in parts of their body, immersing in powder soap, chocolate box, formula milk, and shoes. Medicine for the treatments of chronic disease such as hypertension, cancer, diabetes, and baldness, as well as anti-pain, vitamins, supplements, antibiotics, and erectile dysfunction; and Chinese's traditional medicine are commonly imported for personal use in Ethiopia. This is consistent with study conducted in November 2003 by the FDA and U.S. Customs and Border Protection at international mail facilities in Chicago, Dallas, Buffalo, and Seattle, as well as private courier hubs (Bro, 2005).

According to KIs, customs officers exceeded their power and released the medicine without being held accountable. ECA officers are not authorized to grants release permits for medicine importation for personal use, but they do grant release permits for medicine importation for personal use. Only if the medicine was imported in large quantities, in a variety of dosage form and therapeutic categories, communicated with medicine regulatory inspectors.

Certain restricted goods cannot be imported into Ethiopia without permission for environmental, health, and for other reasons. Pharmaceuticals and medical supplies or instruments, baby food, food supplements, and cosmetics are some of important restricted goods (Revenues Authority, 2017). As stated clearly in the Revenues Authority 2017 Guide, the EFDA is in charge of issuing pre-import, export, release permit, free sale certificate, and list of registered drug for import & export of drugs, medical supplies or instruments, baby food, food supplement, and cosmetics. According to custom KIs explanation, custom officers issue release permits to travelers who brings medicine for erectile dysfunction in the form of lotion under the assumption that it is skin care lotion. This is a prime example of how medical regulation necessitates expertise in the pharmaceutical field.

Since personal medicine importation regulation and entry approval were handled by these two regulatory organizations, it was challenging to determine the precise number of individuals and medicine imported into Ethiopia for personal use. Even if customs officers had performed the assignment, they did not record detailed information on the kind and volume of medicines that each person imported. Additionally, as per EFDA general rule, only 50% of medicines imported by individuals were inspected, and only those 50% inspected medicines were registered in the EFDA inspection results form. The remaining 50% of medicine were not registered and documented.

In the opinion custom KIs, observing and following senior custom officers' experiences, assumption of custom officers that the task is very simple and do not require consultation of EFDA inspectors, EFDA regulatory officers not near by the custom check point, unavailability of medicine regulatory inspectors during at night and on weekends, the overcrowding of custom officers (declaring and notifying the EFDA takes time); further more if the custom officers include a specific notice concerning the storage conditions on the top of the declaration paper but the medicine inspector rarely reads it and never detains the medicine are the main motivators for custom officers going above their mandate. This can show that there is no adequate and pertinent connection based on mutual professional trust and respect, no open communication between custom officers and medicine inspectors. Even though the level of stakeholders' involvements is mentioned in the Ethiopian custom guide, custom officers do not follow it.

Based on the study, the EFDA had a SOP outlining the legal requirements for importing medicines for personal use. To obtain a release permit to import medicine into Ethiopia for personal use, only a paper prescription from recognized healthcare facility is required. While the amount permitted is not specified in the SOP, the EFDA inspector will typically release up to a one year supply at his/her discretion. However, the majority of EFDA KIs are unaware of the existence of this SOP.

According to the KIs, the current medicine regulation in Ethiopian Airlines terminal one and two port of entry security check point is not strong. All the time, business travelers (people who travel for other reasons) bring medicine in large quantities, particularly from Turkey, Dubai and China mostly without a prescription.

Study shows that many people cannot gain access to a licensed prescriber who can write them a valid prescription; therefore, they order medications online from unsafe foreign pharmacies without a prescription. It is simple access to illegal or unapproved medications **(Mills, 2000).** This is consistent with General Accounting Office (GAO) report which indicated that it is easy to purchase prescription drugs over the internet without a prescription (Mackey, 2016).

Based on the results of this study, insufficient law enforcement capacity, lack of skilled human resources, shortage of certain pharmaceutical products and lack of coordination between key stakeholders are the most common causes of the rise in the importation of medicine for personal use in Ethiopia.

Many travelers are routinely seen bringing medicines into the country without a prescription for personal use. The medicine regulatory body has failed to act on it. The regulatory authority's role is to ensure the quality, safety, and efficacy of all medicines sold in their country. This includes the process of drug manufacturing, distribution, and promotion, as well as drug regulation and monitoring. There have been reports of a poorly functioning health regulatory system in many low and middle- income countries. According to the research study, adequate capacity for law enforcements is a critical factor influencing regulation's ability to achieve its stated goals ({Hongoro, 2000; Stenson, 1997; Kumaranayake, 2003). WHO estimated in 2004, 90% of African Medicines Regulatory Authority (MRAs) lacked capacity to carry out medicines regulatory functions, with over forty African MRAs were largely non-functional. This was due to

a lack of clear legislative framework, dispersion of regulatory responsibility, a lack of resources, a lack of experienced and qualified staff, a lack of political support, and a failure to recognize the importance of medicine regulation (Ncube, 2022).

Concerning human resources, it was identified that the CBP offices and EFDA regulatory authority lacked adequately trained personnel at the Ethiopian airlines terminal one and two security checkpoints. There is a scarcity of qualified personnel, with the necessary training, experience, and expertise, particularly when using an x-ray machine to search for passengers' personal belongings.

Identifying medicines among other item requires skilled technical personnel. A ten-country comparative study of drug regulation concludes that "the main problem faced by regulatory authorities is a shortage of qualified staff"(Ratanawijitrasin, 2002).

KIs stated that one of the drivers of an increase in the importation of medicine for personal use scarcity of medicines. According to the findings of our study, when there is a shortage of medicine in Ethiopia, there is an increase in the number of travelers who import medicine for personal use. A European study stated that medicines shortages could be expressed as demand and supply imbalance or interrupted supply or the unavailability of medicines to satisfy the patient needs **(Weerdt, 2015)**. Medicine shortages are a common global phenomenon that endangers patients' health and burdens the health care system (Bogaert, 2015). According to reports, medicine shortages occurred in the United States as a result of a disruption in raw material supply because 80% of it was imported from abroad **(Fox, 2009).**

A study participant identifies a lack of collaborative and coordination cultures among key stakeholders as one of the main reasons for the increased number of travelers who import medicine for personal use. Coordination with custom is essential for all medicine inspection and enforcement practices at port of entry. The EFDA inspector is unaware of the existence of pharmaceutical products, unless custom officers inform them.

Although it is difficult to quantify the total number of travelers and medicines imported into Ethiopia each year for personal use due to lack of recordings, based on the quantitative data 56 travelers brought 151 medicines in 2020 and 398 travelers import 920 medicines in 2021. From these, only 48.2% and 26.8% of 56 travelers in 2020 had prescription and custom declaration

forms. Similarly in 2021, only 59.2% and 51.2% of the 398 travelers had a prescription and custom declaration form, respectively. This showed that the majority of travelers brought their own medications without a prescription and that the regulatory bodies for these medications lacked effective systems for recording and documenting.

According to the review of the two years data, a single person was given permission to import three or more medications from the same therapeutic category but with different brand names at the same time, For instance a single person may import various brand of anti-hypertensive medication (Losartan 50mg, Carbidilol 6.25mg, pharmapress 10mg, Cardiac 6.25mg and Cardiac 6.25mg).

The review of the EFDA recorded document (custom declaration form, EFDA inspection result and release permits form, and EFDA registration log book) revealed that there were differences between the number of travelers who registered having personal medications and the quantity of medicine imported. For example the number traveler imported personal medicine who registered on EFDA registration log book in 2020 was 78 while, registered on EFDA inspection result form was 56. Furthermore during those two years, 18% of medicines imported for personal use had labels in language other than English. Due to the language barrier, custom officers wrote ‘four carton, two black plastic bag medicine from China ’on the declaration paper instead of the name and quantity of the medicine. As a result, estimating the exact number of travelers carrying personal medicine into Ethiopia is difficult. The average numbers, frequency, and demographic characteristics of importers, as well as the type and quantity of medicines, have not been extensively documented by the EFDA.

Solutions put forth by the majority of the participants included the government's authority to address the nation's drug shortage, to establish effective communication and coordination between ECA and EFDA and other responsible stakeholders, and also strengthen the medicine regulatory system of the country.

7. STRENGTH AND LIMITATION

7.1 Strength

This was the first research study undertaken to explore the current personal medicine importation practice and regulatory requirement in Ethiopia. This will aid policymakers and regulatory body in the development and pursuance of standard protocols to control unregulated importation of medicines through this entry way. And also this study provided a strong base for the future researchers.

7.2 Limitation

The study did not collect data from DHL-Ethiopian airlines logistics /DHL global forwarding/, and port of entry-exit cargo branch medicine regulatory offices, which may have an impact on the study's generalizability.

8. CONCLUSION

The precise number of people who import medicine for personal use in Ethiopia was difficult to estimate. The typical importer figure (a person who imports medicine for personal use, as well as the type and quantity of medicine) has not been extensively documented by the EFDA for three reasons. First, while ECA officers authorized entry, they did not record the type and quantity of medicine imported by an individual. Second, the EFDA does not have adequate record-keeping and documentation mechanisms. In the third case, the EFDA inspectors only reviewed 50% of the drugs brought in by individuals and failed to document the majority of the import and export customs declaration documents with port of entry-exit inspection data. The remaining 50% of uninspected medicine are not recorded in the import and export inspection database.

Hence, the finding implied that there is no or weak binding rule, regulation and law enforcements in the agency in relation to importation of medicines for personal use in Ethiopia. Additionally, one can also conclude the weak documentation and weak follow up of ECA officers and the EFDA staffs indicate that, the issue of import medicine for personal use in Ethiopia is the most neglected task.

Medicines for personal use are brought into Ethiopia in large quantities without prescription. From this result it can be conclude that, people in Ethiopia are found in danger in regard to personally imported medication. Because, if travelers attempt to import without a valid prescription, they may increase their likelihood of purchasing medications from an illegal pharmacy, likely confer an increased risk of exposure to substandard and falsified medications.

In the EFDA SOP, the quantity of imports suitable for personal use is not stated. Regulatory inspectors are unlikely to answer correctly in the absence of specific guidelines. It seems unthinkable that someone could smuggle such a large quantity of drugs. Even so, failure to adequately regulate these shipments makes them a potential source of substandard and falsified medicines.

Overall, according to this survey the number of travelers who imported pharmaceuticals for personal use increased overtime. Furthermore, there is an apparent gap in the regulation of imported medicine for personal use, data management system, and stakeholder cooperation.

There is a need to establish a strong regulatory system that includes the implementation of better enforcement governing personal importation of medicine, the use of a better data management system, and strengthen coordination and collaboration with stakeholders.

9. RECOMMENDATIONS

Based on the study findings, analysis of thematic contents, and the conclusions made, the following recommendations are forwarded to the EFDA, and stakeholders.

Recommendation for the EFDA regulatory authority

- Should strengthen the current regulatory enforcement strategies for importation of medicine for personal use
- EFDA should review the adequacy of existing SOP and regulations, and include
  - ✓ Quantity based on the product's direction for use.
  - ✓ Number of imports per year permitted for one individual
  - ✓ Should apply sanctions and fines either be re-exported or destroyed under the FDA's supervision, at the expense of the importer for the medicine that cannot be reasonably brought into country.
  - ✓ Prosecution of the importer in accordance with the provisions of the public health act
- Should physically inspect all personal medicine imports at the port of entry security checkpoint.
- Should hold high-level discussions with various stakeholders, including ECA, NISS, Ethiopian airlines, pharmaceutical companies, research institutions, and academia to develop appropriate and adequate relationships based on mutual professional accountability, trust, and respect.
- Should address the drug shortages in the country, and consult with legal drug importer and concerned governments body to find a solution by applying short- and long-term strategies, facilitation, incentives and regulation of manufacturers, fair pricing, additional government budget allocations and regulation of medicine distribution systems.

- Should improve the recording and retention (documentation practice) of import and export customs declaration, release permit, and import and export inspection results, and other related documents.

- Should work on the expansion of training, awareness creation campaign for public regarding Purchasing of medicine without prescription through media or other communication channels.

- EFDA should be conducted self-inspections periodically, according to an annual schedule. to monitor the implementation, compliance with and effectiveness of SOPs, as well as compliance with regulations,

Recommendation for Ethiopian Custom Authority/ECA/

- ECA clearly defines each regulatory agency's duties and responsibilities on its revenues authority guideline, 2017. The responsible regulatory agency for the import and export of drugs, medical supplies or instruments, baby food, supplements and cosmetics is EFDA. But ECA violations and offences are own rule. ECA should be accountable, responsible and follow their rule in accordance with the guidelines.
- Should collaboration between the regulatory body, governments, academia, university linkages and the medical profession is also highly recommended
- Should provide continuous training, awareness creation campaign and refresher programs to their officers. Create a system for capacity building program and experience sharing sessions especially using x-ray to differentiate medicine among other item.

Suggestion for future research

Finally the researcher highly recommends, there should be surveys with direct observational research method with larger sample size to better explore the pattern of personal medicines importation and to quantify, the exact number of personal medicine importer, type and quantity of medicine to provide continuous feedback to policy makers.

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11. ANNEXES

Annex I - Personal Information Sheet

Title of Research: Regulatory requirements and enforcement practices for importation of medicines for personal use into Ethiopia.

Institution: Health Sciences College, School of Pharmacy, Department of Social Pharmaceutical

Program: Regulatory Affairs (medicine Track), Addis Ababa University, Ethiopia.

Name of sponsor: EFDA

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Purpose: assessing regulatory requirements and enforcement practice of medicine importation for personal use.

Annex II - Participants' information sheet and consent form

Title of the project: Regulatory Requirements and Enforcement Practices for Importation of Medicines for Personal Use into Ethiopia.

Principal Investigator's Name: Mintwab Zellek **Tel:** +251911025359

My name is --------- I'm a postgraduate (MSc) student at Addis Ababa University, College of Health Sciences, School of Pharmacy, Department of Pharmaceutics, and Social Pharmacy. As part of this degree in Regulatory Affairs, I am conducting a research entitled "Regulatory Requirements and Enforcement Practices for Importation of Medicines for Personal Use into Ethiopia." If you agree to take part in this study you will be among those who will contribute towards strengthening the medicine regulatory system in the country. Your information and others participating in the study will collectively use by policymakers in strengthening the regulation system.

To obtain the necessary information, I am delivering an interview. The interview will take 25-45 minutes of your time and the interview will be held at your convenient location and time. Your participation is purely voluntary and the information you provide will be kept completely confidential. Direct quotes might be taken from your response to be used in written and verbal reports of the paper but your name will never be written and aggregate responses from different respondents will only be identified only by codes. Your honest response to the question is of paramount importance for the successful completion of the study. There is no right or wrong answer and you can have clarification for any doubt regarding the questions.

Are you willing to respond to the questions? Yes/No

Annex III – The Questionnaire

Interview Questions

Instruction: the following interview questions are intended to collect information from key informants regarding the personal medicine importation practice in Ethiopia.

1. Code no:_____
2. Date of interview:_____
3. Place of interview:_____

I. Background of respondents

1. Gender A. Male B. Female

2. Age (In year)_____

3. Profession_____

4. Academic qualification _____

5. Position_____

6. Work experience: (in years)_____

II. *General Interview Questions*

1. How do you describe medicine importation for personal use in Ethiopia?
2. How do you describe the Practical situation of personal medicine importation in Ethiopia?
3. How do you describe the pattern of personal medicine importation in Ethiopia? (increased, decreased, unknown)
4. What are the regulatory requirements for importation of medicine for personal use? (Available policies, laws, regulations, guidelines)
5. How do you describe any problems related to importation of medicine for personal use to exercise your duties?
6. How do you describe the amount of medicine one individual imported currently?
7. How do you explain the fate of illegal importation of medicine for personal use?

8. Do you explain, any regular orientation/discussion held in relation to imported medicine to carry out regulatory functions (multi-skilling)
9. How do you describe the current enforcement practice?
    - responsible regulatory body commitment,
    - feedback and communication with stakeholders
10. What are the possible contributing Factors to the increased number of personal medicine importation? In relation
    - with skilled human resources,
    - shortage of medicine in the country,
    - regulatory requirement and rule/ law
    - commitment of regulatory body of the country
    - stakeholder coordination
11. How do you think potential impact of personal medicine importation?
12. Your suggestion for the possible solutions of proper regulation.
    - role of stakeholder (CBP, NISS)
    - support of the higher level manager/policy makers
    - short of medicine
    - development of human power, training, regulatory law, operating procedures
13. Would you like to provide any additional comments or possible suggestions about the importations of medicine for personal use practice in Ethiopia?

Thank you for your cooperation!

Annex V: Data abstract form

data abstract form

Medicine imported by individual for personal use during 2020- 2021

F,Y	Passport No		Name of medicines	Therapeutic category of medicine	CBP Form	Quantity of medicines imported per person.	Requirements for importation. (fit/not fit)	rem ark
1.				Dangerous drug (Diazepam)				
2.				Antibiotic				
3.								
4.								
5.								
6.								
7.								