Assessment on Import Status of Registered Medicines in Ethiopia and its Associated Factors: Pharmaceutical Importers' Perspective

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Assessment on Import Status of Registered Medicines in Ethiopia and its Associated Factors: Pharmaceutical Importers' Perspective

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This is to Certify that the thesis prepared by Abebaw Gessesse Minikes, entitled "Assessment on Import Status of Registered Medicines in Ethiopia and its Associated Factors: Pharmaceutical Importers' Perspective" and submitted in partial fulfillment of the requirements for the degree of Master of Pharmacy in medicine regulatory affairs complies with the regulations of the university and meets the accepted standard with respect to originality and quality.

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Abstract

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Introduction: Studies show that many registered medicines are not marketed in a number of countries due to various reasons. In Ethiopia, the extent of the importation and associated factors for not importing registered medicines was not studied. Therefore, the aim of the study was to assess the import status of registered medicines and identify associated factors at the pharmaceutical importers level, in Ethiopia

Methods: Parallel mixed methods were used in the study. The quantitative part involved the one-year imported medicines (January 9, 2018-January 8, 2019) at the port of entries /2804/ and the qualitative part used semi-structured interviews. All registered medicines in the study period were included in the study and their importation status was checked at the port of entry by using a registry template. Ten pharmaceutical importers which registered 53% of the medicines were interviewed. The quantitative data were coded, entered into a data entry template on Microsoft excel, and relevant descriptive statistics was done whereas the inductive thematic analysis method was used to analyze the qualitative data.

Results: Of registered medicines (n=2,804) by the regulatory authority between January 9, 2018- January 8, 2019, only 1,061 (37.7%) medicines were imported. Major factors for

the non-importation of registered medicines were: marketing-related, foreign currency-related, manufacturing-related, and government-related factors.

Conclusions and recommendations: Most of the registered medicines are not imported. Establishing an organized imported medicines database, establishing a national notification system for medicine shortages, creating a conducive environment for the importation of the registered medicines, and improving currency allocation are recommended.

Keywords:-medicines, import status, registered medicines, mixed methods, Ethiopia.

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My special thanks go to Ethiopian Food and Drug Authority (EFDA) inspectors working at Ethiopian Airlines cargo, Kality, and Modjo dry port for their collaboration in collecting data on imported medicine. Also, I'm grateful to private pharmaceutical importers for being willing to participate in the study and responding to my questions.

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Acronyms and abbreviations

CIRS	Centre for Innovation in Regulatory Science
CoC	Certificate of Competency
EFDA	Ethiopian Food and Drug Authority
EFMHACA	Ethiopian Food, Medicine and Healthcare Administration and Control Authority
EFPIA	European Federation of Pharmaceutical Industries and Associations
EPSA	Ethiopian Pharmaceutical Supply Agency
eRIS	Electronic Regulatory Information System
EU	European Union
FDRE	Federal Democratic Republic of Ethiopia
FIP	International Pharmaceutical Federation
GFF	Global Financing Facility
GMP	Good Manufacturing Practice
HSTP	Health Sector Transformational Plan
L/C	Letter of Credit

MoH	Ministry of Health
MoI	Ministry of Industry
NDP	National Drug Policy
NME	New Molecular Entities
PFSA	Pharmaceutical Fund and Supply Agency
SDGs	Sustainable Development Goals
SRA	Stringent Regulatory Authority
TGE	Transitional Government of Ethiopia
UHC	Universal Health Coverage
WHO	World Health Organization
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organization

1. Introduction

1.1. Background

Medicines are one of the vital components of a healthcare system that plays a major role in the health and well-being of individuals and populations when used appropriately (Wagner et al, 2014). Access to medicines is a universal right. However, the low availability of medicines is a barrier for a significant proportion of the world population who do not enjoy this right (Dabare et al, 2014).

According to world health organization estimates, nearly two billion people around the globe have no access to basic medicines. This is becoming a cause for the death of millions of children from diseases that could have been prevented or cured by existing medicines (WHO, 2017). It also hampers the capability of national healthcare systems in ensuring the continuity of care, causing a potentially profound impact on human health (Musazzi et al, 2020). When the unavailability of medicines relates to medication for life-threatening diseases or involving children and where there are no therapeutic alternatives it may result in serious consequences. Besides, it may compromise or delay medical procedures, lead to medication errors, and to the use of less desirable, often more expensive, alternative medicines (European Healthcare Distribution Association, 2018 & EFPIA, 2020).

The root causes for the non-availability of registered medicines are diverse and multi-dimensional. While some are related to supply-related factors (e.g., manufacturing issues, regulatory issues, logistics, and distribution), the others are related to demand-related

factors (e.g., fluctuating drug demand, parallel market, tendering, price, and reimbursement policies) (Musazzi et al, 2020).

In 1993, Ethiopia developed a National Drug Policy (NDP) with the aim of, among others, ensuring consistent availability of quality, safe, and efficacious essential medicines at an affordable price to all citizens (TGE, 1993). As per this policy, Food and Drug Authority was established, among others, to ensure the safety, efficacy, and quality of all medicines before being distributed to the public (FDRE, 2019). Due to the limited capacity of local pharmaceutical manufacturers in satisfying the public demand for medicines, the health sector heavily depends on imports which account for 80% of the total supply (MoH and MoI, 2015).

Previous studies on the availability of medicines in Ethiopia have been conducted in limited geographical areas and on a limited number of selected medicines at the health facility level and none of these studies indicated about import status of the registered medicines in the country (PFSA, 2018; Ewen et al. 2017; Sado & Sufa, 2016). Thus a national survey was needed to ascertain the import status of all registered medicines and their associated factors to provide a better understanding of the situation. This survey was therefore conducted to assess the import status of all registered medicines and their associated factors at the importer's level. To the best of the researcher’s knowledge, this is the first survey in Ethiopia.

1.2. Statement of the problem

Access to medicines and universal health coverage depend on a continuous supply of quality medicines to all health facilities and patients (WHO, 2017& WHO, 2016). However, Non availability of medicines has become an increasing problem in recent years. Some of the reasons for this are unsuccessful pricing negotiations between manufacturer and buyer, limited or absent demand, high medicines price and quality problems are also the other reasons (Ferrario et al., 2014; EC, 2012; PFSA & EFMHACA, 2017).

Non-importation of medicines may adversely affect therapy and cause poorer treatment outcomes, compromise or delay medical procedures, lead to medication errors, and the use of less desirable, often more expensive, alternative medicinal products. In addition, it can lead prescribers or dispensers to switch patients to unapproved treatment regimens or force patients to seek medicines from informal and unregulated markets where medicines quality may be poor. For those drugs which have no therapeutic alternative, unavailability of the drug may lead to poor patient outcomes (Morrison, 2011; European Healthcare Distribution Association, 2013; EC, 2012).

Although the Ethiopian government has taken several measures to ensure continuous supply of quality medicines at an affordable price to the public, there is still a huge gap in achieving this target (PFSA, 2018).

Both public and private importers are under performing. They were able to supply only 44.7% of hospital requests which shows the need to work hard to ensure the continuous availability of pharmaceuticals (MOH, 2015). Recently due to the recurring of foreign

currency shortage and other reasons, manufacturers and importers have not been able to import medicines as needed and patients with critical illnesses are finding themselves in serious condition and forced to turn to unregulated black-market sources to find life-saving medicines (Endale, 2018).

In addition, all previous studies conducted regarding availability of medicines in Ethiopia were focused only on limited number of medicines at health facility level (Ewen et al. 2017; Sado & Sufa, 2016). To the researcher's knowledge, there is no research showing import status of registered medicines and no study attempted to understand the underlying reasons for the non-importation of medicines after securing market authorization approval. Therefore, it is very important to determine import status of the registered medicines and identify factors associated with non-availability of medicines in Ethiopia, which will enable to solve the problems in the supply system.

1.3. Significance of the study

This study assessed the import status of registered medicines and their associated factors at the pharmaceutical importers level in Ethiopia. Therefore this study will show a clear image of the import status of registered medicines and also contribute towards a better understanding of factors affecting importation. In addition, it will show for policymakers for the establishment of a new system to maintain a continuous supply of medicines. Furthermore, it will also be a basis for further research.

2. Literature review

2.1. Pharmaceutical regulatory and supply chain system in Ethiopia

Every imported medicine to the country should receive a marketing authorization certificate from the authority which has a validity period of five years. Unless the certificate is renewed, the product will be canceled (FDRE, 2019). EFDA issues import release permits for all registered products after the arrival of the consignment by conducting the necessary documentary and physical inspection at customs. It is also an input for customs clearance (EFMHACA, 2013 & EFMHACA, 2014).

There are more than 384 private importers and one state-owned supplier namely the Ethiopian Pharmaceutical Supply Agency (EPSA) (MOH & GFF, 2019). Ethiopian Pharmaceuticals Supply Agency (EPSA) was established in 2007 to overcome the problems and assure uninterrupted supply of pharmaceuticals to the public at an affordable price (PFSA, 2007). EPSA procures registered medicines on a tender basis. When a product is not registered by EFDA, prior to procurement EPSA checks whether the product is registered either by a stringent regulatory agency, prequalified by WHO, or manufactured by EFDA GMP inspected manufacturers. However, private importers are allowed to import after their products got registered by EFDA (PFSA & EFMHACA, 2017).

2.2. Import status of registered medicines

Every patient has the right to get equitable access to medicines. Currently, 30% of the world population has not been able to access essential medicines and this situation is

worst in the poorest countries in Africa and Asia which accounts for around 50% (Cameron et al., 2009 & Liberti, 2017).

It is common that before medicine is marketed or accessed to the public it should be quality assured and registered in the respective countries. A study conducted in the Republic of Moldova by (Ferrario et al., 2014) revealed that on average, about 70% to 80% of the registered medicines by the national regulatory authority were imported (Figure 1). In 2012, of 47 amlodipine 5 mg and of 42 amlodipine 10mg registered by foreign manufacturers, only (20, 42%) and (21, 50%), respectively, were imported. Similarly, of 16 metformin 500 mg and of 15 metformin 850 mg products registered by foreign manufacturers, only (5, 31%) and (5, 33%) of them, respectively, were imported. In most cases, medicine registered by more than one foreign manufacturer, even if not all strengths were available, at least one strength was imported and on the other hand, mostly cancer medicines, and strength for a particular product was not available in the market after they got market authorization.

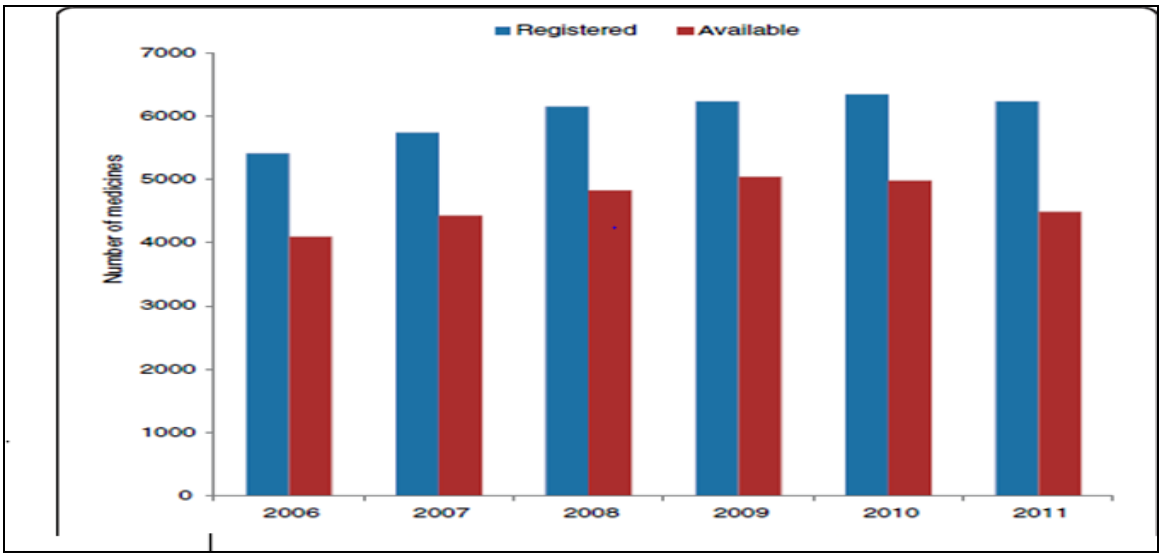


Figure 1: Number of medicines registered by foreign manufacturers vs. available ones.

In Estonia from centrally authorized medicines 74% (1540 from 2092) and from nationally authorized medicines 10% (155 from 1494) were not sold on the Estonian market in the past three years which shows that market authorization of medicine does not mean it is available on the market (Ferrario et al., 2016).

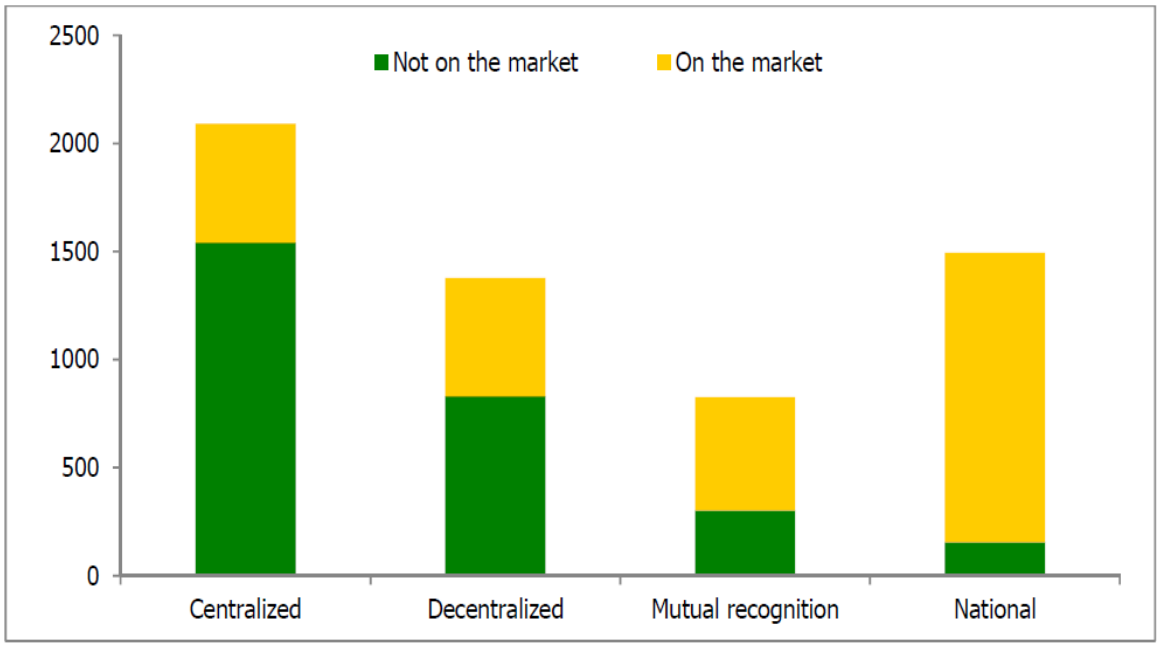


Figure 2: Number of licensed medicines in Estonia in March 2015, by authorization procedure and marketing status in the previous three years[a].

[a]Different strengths and formulations of the same active ingredient are counted separately, as are different source of data: state Agency of Medicines.

Among 703 new molecular entities, FDA approved from 1980 to 2008 71.8% (506) of all medicines were marketed during the study period. Of the approved medicines, 5 (0.7%)

medicines never entered the market after securing FDA's approval, while (100, 14.4%) were discontinued from the market (Qureshi et al., 2009).

A study conducted in South Africa by Leng et al. (2015) revealed that only 54% of all registered generic brands were being marketed and from which 80% or more of the market value was covered by two to five of particular medicines and the remaining 70% of the marketed generic medicines have less than 5% market share. In contrast, 40% of the registered medicines are not marketed because of market saturation.

As Ewen et al. (2017) report shows, the average availability of medicines in public sector outlets in Ethiopia was 64% from which local products cover (48%) and imported one (19%) and in the private sector its mean availability for the imported and locally produced medicines was 73% and the availability for imported and locally produced medicines was 54% and 35%, respectively.

A cross-sectional study conducted in the east Wollega zone, the western part of Ethiopia by (Sado & Sufa, 2016) revealed that the mean availability of essential medicines for children was 43% and 42.8% in public and private sectors, respectively. Another study conducted in five health centers in rural Ethiopia showed that the availability of essential medicines at the health facilities was 91% based on selected medicines and 84% based a study on prescriptions filled assessment (Carasso et al., 2009). A national survey conducted in Ethiopia showed that the availability of essential medicines at public health facilities, regional drug stores, and private drug retail outlets was 70%, 85%, and 91 % respectively and the average stock out period in the respective public health facilities and regional drug stores were 99.2 days, and 99 days (FMOH & WHO, 2003).

2.3. Factors associated with non-importation of medicines

Registered medicines could be unavailable in the market because of various reasons. In Moldova, unsuccessful pricing negotiations, and limited or absent demand as a result of irrational prescribing, heavy promotion of other medicines, and limited promotion of essential medicines were identified as reasons (Ferrario et al., 2014).

Multiple and complex reasons for medicine shortages were indicated by the stakeholders on different levels of a supply chain. On manufacturer level, medicine shortages were found related to raw material, import issues, availability issues, pricing and quota allocation for controlled raw material, planning and forecasting gap, poor inventory management, and procurement procedure, budget constraints and delayed quality control testing, low price and low demand were cited as reasons of shortage of medicines. However, intermittent or inadequate supply of products from the manufacturer's side and biased distribution of shortage products were identified as the main reasons (Atif et al., 2019).

One final availability issue noted by wholesalers and also some of the National Competent Authorities (e.g. in the UK) relates to quotas imposed on wholesalers by the producers. If the quotas are exhausted, the wholesalers will not be supplied with further stocks of the product. The level of quotas differs between producers and the Member States and in some cases may not be communicated to the wholesaler, affecting the wholesaler's ability to plan the supply of the product in advance (EC, 2012).

2.4. Countries experience to encourage importation

The role of regulatory authorities in terms of creating access to essential medicines to patients is immense but in most cases, their inefficiency seems to be a barrier to access to safe, effective, and quality medicine (EFPIA, 2017). Patients demand to have timely access to essential medicines and the pharmaceutical industries interest to register their products in the respective countries national regulatory authorities to get into the market enforced regulatory authorities to accelerate their registration process and create a conducive environment for the availability of safe, effective, and quality medicines in the health system (Eshetu & Sauwakon, 2002; EFMHACA, 2017; CIRS, 2017).

In Europe, market authorization holders for products marketed in European Union members give two-month notification to regulatory authorities when market access to a product will be temporarily or permanently interrupted and also invalidating market authorization if a product has not been placed on the market within three years of authorization (Birgli, 2013 & EC, 2012). On the other hand, FDA Drug Shortage Program enforces manufacturers to give early notification to the Authority when there is an expectation that leads to medicine shortage (Morrison, 2011).

Including Ethiopia many countries around the world, implemented accelerated registration procedures to increase the rate of medicines Market Authorization, thereby curbing duplication and burden of regulatory review and to make sure access of essential medicines to the public promptly. These accelerated procedures are used as an alternative to the standard registration process which enables regulatory authorities to maximize the use of their limited resources (EFPIA, 2017; EFMHACA, 2017; CIRS, 2017).

Article 81 of Directive 2001/83/EC (as amended by Directive 2004/27/EC) also enforced market authorization holders for medicinal products and their distributors to ensure appropriate and continued supplies of their products (EC, 2012).

3. Conceptual framework

Based on the available literature, the following conceptual framework has been developed (Birgli, 2013; FDA, 2013; FIP, 2013; Markowski, 2012; Morrison, 2011; Atif et al., 2019; Heiskanen et al., 2017; Schwartzberg et al., 2017; Qureshi et al., 2009; The Multi-Stakeholder Steering Committee on Drug Shortages in Canada, 2017; European HealthcareDistributionAssociation,2013).

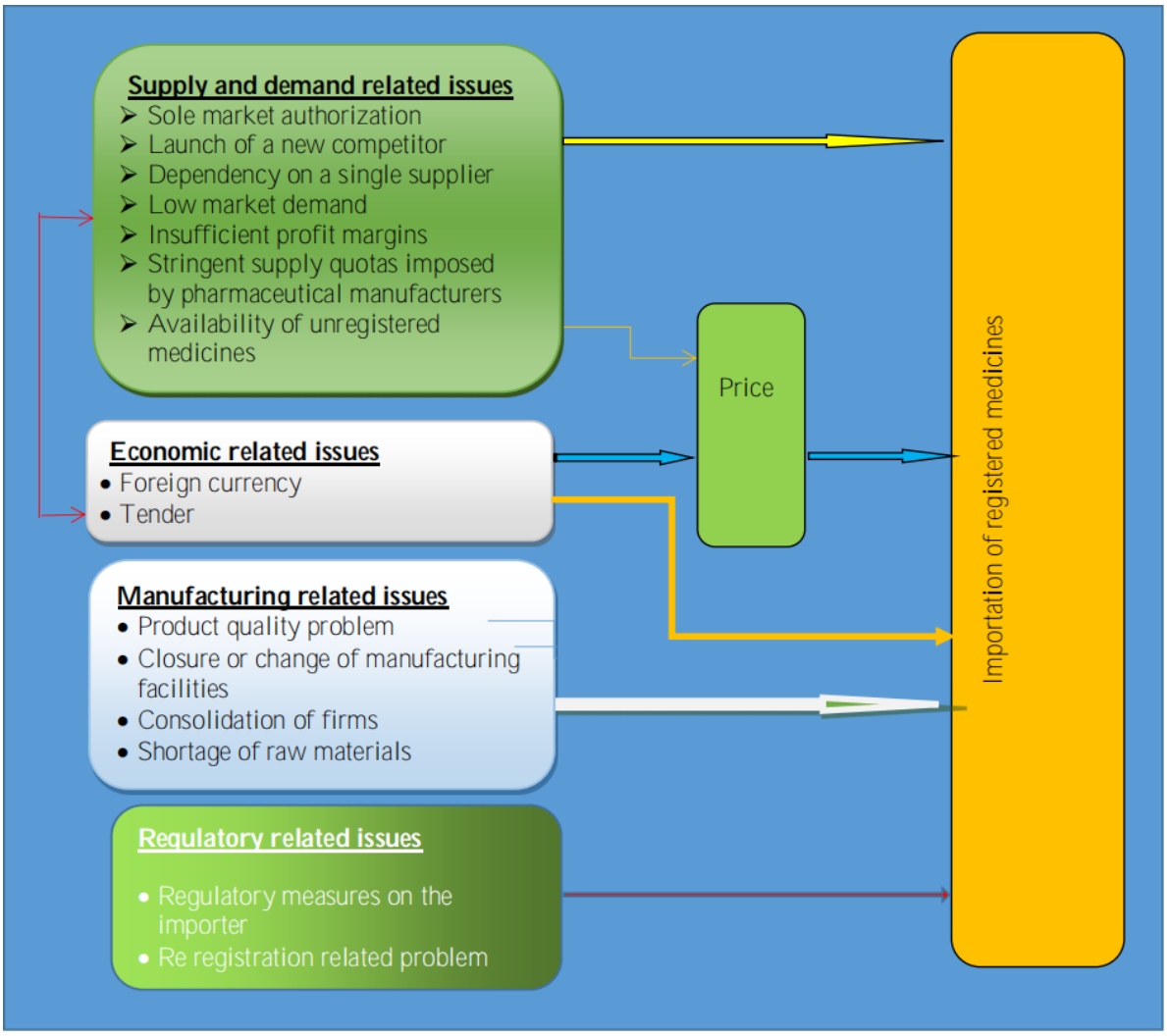


Figure 3: Conceptual framework of the different factors for unavailability of medicines.

4. Objectives of the study

4.1. General objective

The general objective of this study was to assess the import status of registered medicines and identify associated factors from the pharmaceutical importers' perspective

4.2. Specific objectives

- To assess import status of registered medicines.
- To assess factors influencing the import status of registered medicines.

5. Method

5.1. Study area

Ethiopia is the second most populated country in Africa with a population of around 112 million (United Nations, 2019). The country is landlocked and located in the North-Eastern part of Africa and bordered by Eritrea, Djibouti, Somalia, Kenya, South Sudan, and Sudan with a total area of 1.1 million square kilometers (MOH, 2015).

The health system, which consists of a mixture of public, private, and non-governmental healthcare sectors, is guided by the national health policy developed in 1993 (TGE, 1993). At the national level, the Federal Ministry of Health (FMOH) is responsible for health policymaking, strategic planning, coordination, and harmonization of all health actors and stakeholders (MOH, 2019).

As part of health policy, the pharmaceutical sector is guided by a national drug policy (NDP), which was developed in 1993 G.C (TGE, 1993). Food and Drug Authority (FDA) Proclamation No 1112/2019 have been promulgated to implement the health regulatory sector at the federal and regional state and city administration level (FDRE, 2019). The authority was organized by nineteen directorates, six branch offices, and seventeen ports of entry. The Ethiopian Airlines Cargo and three dry ports, which are Mojo, Kality, and Adama dry ports, are the major ports of entry authorized for the import of pharmaceutical products (Lemma & Abera, 2018).

The study was conducted in the Ethiopian Food and Drug Authority head office in Addis Ababa, Ethiopia, and selected pharmaceutical importers and distributors. From January 9, 2018-January 8, 2019, there were 2,804 registered medicines with an active registration

certificate and imported by 81 importing companies in Ethiopia. All importing companies were licensed by Food and Drug Authority (FDA) and located in Addis Ababa.

5.2. Study period and design

The data collection for this study was conducted from May 5, 2019 – July 2, 2019.

The study combined both retrospective quantitative and qualitative methods and was conducted concurrently. Recording of imported medicines from January 9, 2018-January 8, 2019 at the port of entries was compared with the recording of registered medicines on the eRIS to know their import status. In order to explore the main reasons for not importing registered medicines, a semi-structured interview was held with ten purposively selected pharmaceutical importers, which registered 93 and above number of medicines and accounts for 53% of the total registered medicines at the time of the study.

5.3. Study Participants and sampling procedure

For the quantitative part, all registered medicines (N=2804) between January 9, 2018, and January 8, 2019, were included from eRIS and checked for their importation status at the port of entries by extracting from import documents (commercial invoice, registration certificate). Inclusion and exclusion criteria

Inclusion criteria: All medicines registered by foreign manufacturers/suppliers within the study period were included for the analysis.

Exclusion criteria

- Medicines with invalid registration certificate within the study period

- locally manufactured medicines were not included in the study

For the qualitative part, the purposive sampling method was applied to select ten medicine importers who registered more than 93 medicines and accounting for 53% of the total registered medicines considering that they could provide the information needed for the study topic. From among these importers, a key informant who was running the import process in the company was purposely selected.

5.4. Operational definitions

Registered medicines: these are medicines, which have got market authorization from EFDA after proper dossier assessment.

Valid registration certificate: A medicine registration certificate, that is within the 4-years validity time

Imported medicine: when the studied medicine is imported from countries outside Ethiopia by the pharmaceutical importers during the study period.

5.5. Quantitative and qualitative data collection procedures

The quantitative data were collected using the imported medicines data registry template on Microsoft Excel prepared by the principal investigator. Information collected by the template include brand name, generic name, imported date, imported quantity, importer name, and manufacturer name and country of origin were included. The registered medicines within the study period were extracted from the regulatory eRIS system. Data entry of the imported medicines was conducted at the port of entry. Finally, the imported

medicines were categorized therapeutically and became ready for comparison with the registered medicines.

The qualitative data were collected by interviewing medicine importers as key informants. The key informant interviews were conducted face to face by a trained investigator who was a clinical pharmacy MSc holder by using a semi-structured interview guide with probing questions. The interview was done until saturation of data occurred. The information given by the key informants was more or less similar after the seventh interviewee and just for certainty data was collected from the remaining three key informants. The topic of discussions were focusing on the effect of local production, government policies and regulations, having more than one local agent, and other factors having an impact on the non-importation of registered medicines. The interview took on average 25 minutes.

5.6. Data processing and analysis

Quantitative Processing and Analysis: The collected data using Microsoft excel were coded, edited, and cleaned manually before final analysis. Descriptive statistics were done to describe variables in the study and the percentile of the imported medicines in comparison with the registered medicines was calculated.

Qualitative Processing and Analysis: The interview was done in Amharic and interviews were audio-recorded. Translation and transcribed verbatim were done by a professional translator & transcriber. The transcribed scripts were read repeatedly to identify key themes and the data were analyzed using inductive thematic analysis and the analysis was done manually by the investigator. Keywords, phrases, and sentences relevant to the

study objectives were marked, and themes and subthemes were created based on differences and similarities. To increase the credibility of data, transcripts, codes, and categories were intensively reviewed by one external researcher, who was not involved in the present study. Beyond the external researcher, the supervisors checked the coding and participated in the analysis process.

5.7. Quality assurance

For the quantitative part, eight experienced pharmacy professionals working at the regulatory authority were recruited and trained for one day. The collected data were checked for their consistency and completeness before coding and analysis. Each dosage form and strength was counted as separate. Finally, the imported medicines were categorized therapeutically and became ready for comparison with the registered medicines.

For the qualitative part, key informants who had experience and responsibility on pharmaceuticals importing process in the importing company were selected. The interview guide was piloted in a similar setting before being used for the study. The interviews were audio-recorded and notes were taken properly. Furthermore, the principal investigator has applied the concept of reflexivity while the institutions and key informants were carefully selected and their characteristics described.

5.8. Ethical consideration

The ethical approval to conduct the study was granted by Addis Ababa University, College of Health Sciences, School of Pharmacy, Research and Ethics Committee

(R.No.ERB/SOP/89/04/2019). In addition, before data collection permission was obtained from EFDA and importers selected for this study.

For the qualitative part participation in the study was voluntary based and the autonomy of participants was respected. This study had no risk/negative consequence for study participants. Written consent was taken from the key informants after briefing them on the objective of the study. Confidentiality of participant's related data was maintained by avoiding possible identifiers such as by replacing interviewee identity with a code. The semi-structured interview guide, audio recorded data, and notes of key informant interviews were kept safe throughout the whole process of the research work.

5.9. Positionality and reflexivity statement

I was working at the Ethiopian Food and Drug Authority as an inspector and as a director for the Central Ethiopia Branch office for more than 7 years and I got a lot of experience in the import and export of medicines, foods, and cosmetics. My research focuses on the import status of registered medicines in Ethiopia and their associated factors: pharmaceutical importers' perspective and participants in this study were importers. Due to my position in the regulatory authority, I had a relation with research participants for a long time. My identity as regulatory personnel was a major consideration in the roles I played in this study. Being a director greatly facilitated getting import data and knowing the country's supply chain. Beyond the benefits being a staff to the regulatory authority had an impact on the process of data collection and interpretation of the data. Due to the anticipated reaction of research participants to me as a "government official" I did not interview study participants and directly ask them personal questions. Instead, my roles

were behind the scenes helping to draft the interview guide, recruiting trained data collectors, and data transcriber.

6. Results

6.1. Import status of registered products

6.1.1. Number of medicinal products authorized

Table1. Number of registered medicines (N=2804) by therapeutic category (January 9, 2018 to January 8, 2019)

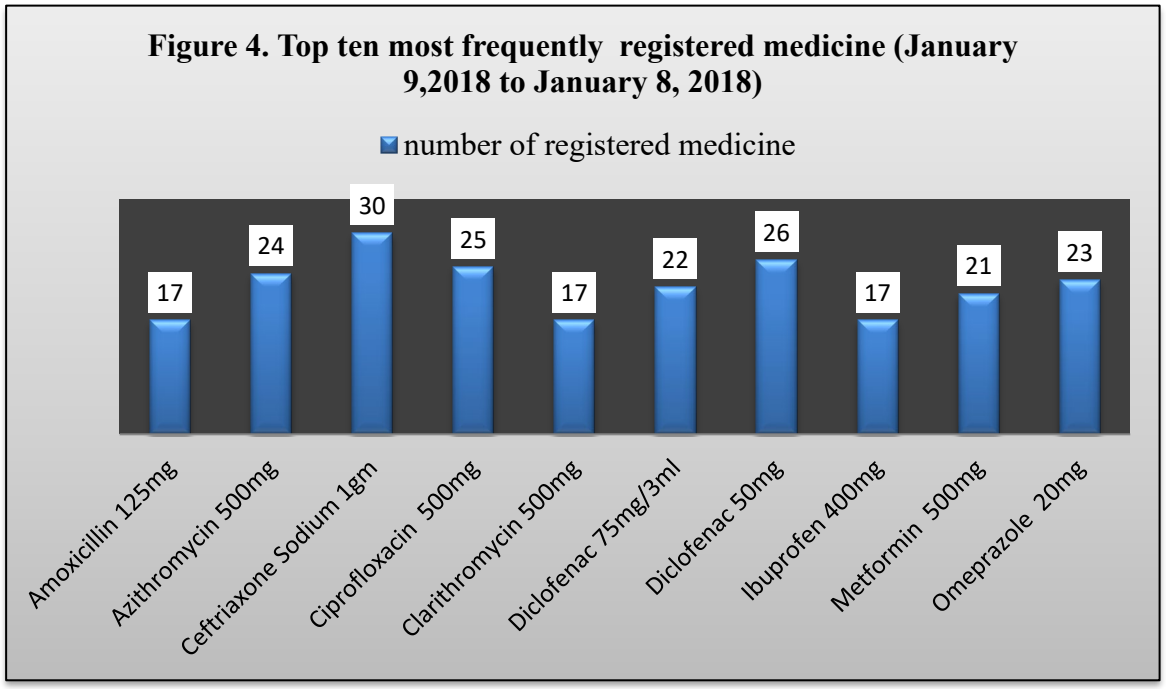
Therapeutic category	N	(%)
Anti-infectives	820	26.7
Cardiovascular	369	12
Central nervous system	290	9.5
Endocrine disorders & contraceptives	239	7.8
Gastrointestinal	220	7
Dermatological agents	178	5.8
Antineoplastic & adjuvants	145	4.7
Musculo-skeletal & joint diseases	140	4.6
Ophthalmic agents	126	4
Respiratory medicines	104	3.4
Obstetric & gynaecological	62	2
Vitamins	60	1.9
Antihistamins & antiallergics	60	1.9
Blood products & medicines affecting the blood	54	1.7
Immunologial preparations	52	1.7
Medicines for correcting water, electrolyte & acid- base disturbances	46	1.5
Anaesthesia	34	1
Ear, nose & throat preparations	26	0.8
Miscellaneous	24	0.8
Urological and related	9	0.3
Antidotes & other substances used in poisoning	5	0.1

From January 9, 2018-January 8, 2019 there were a total of 2804 registered medicines of different dosage forms and strengths from foreign manufacturing companies.

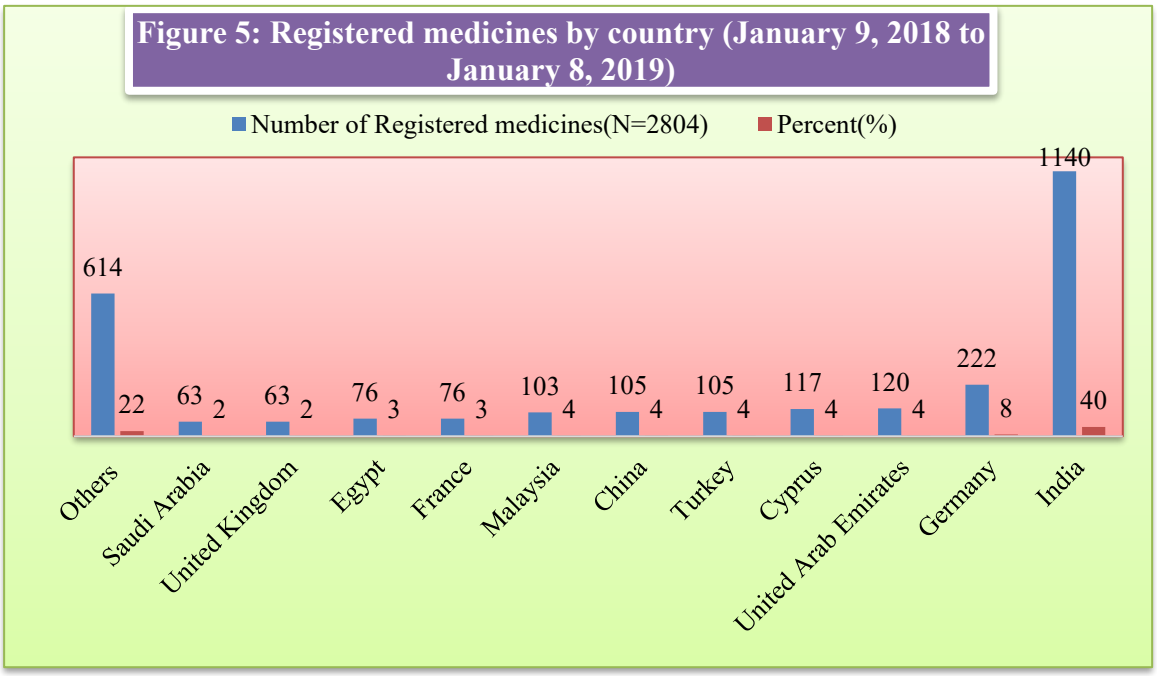
As we can see from table 1, anti-infective (26.7%) were the most frequently registered medicines followed by cardiovascular (12%), central nervous (9.5%), and endocrine therapeutic (7.8%).

As we can see from figure 4 depicting the top ten most frequently registered medicines, ceftriaxone was registered by 30 companies, diclofenac 50mg by 26 companies, and amoxicillin 125mg by 17 companies of the same strength and formulation.

Figure 4. Top ten most frequently registered medicine (January 9,2018 to January 8, 2018)



By country of origin, as we can see from figure 5, the medicines were registered from 47 countries. Of these, India accounts for 40% of the total registered medicines.



6.1.2. Registered medicines versus imported medicine

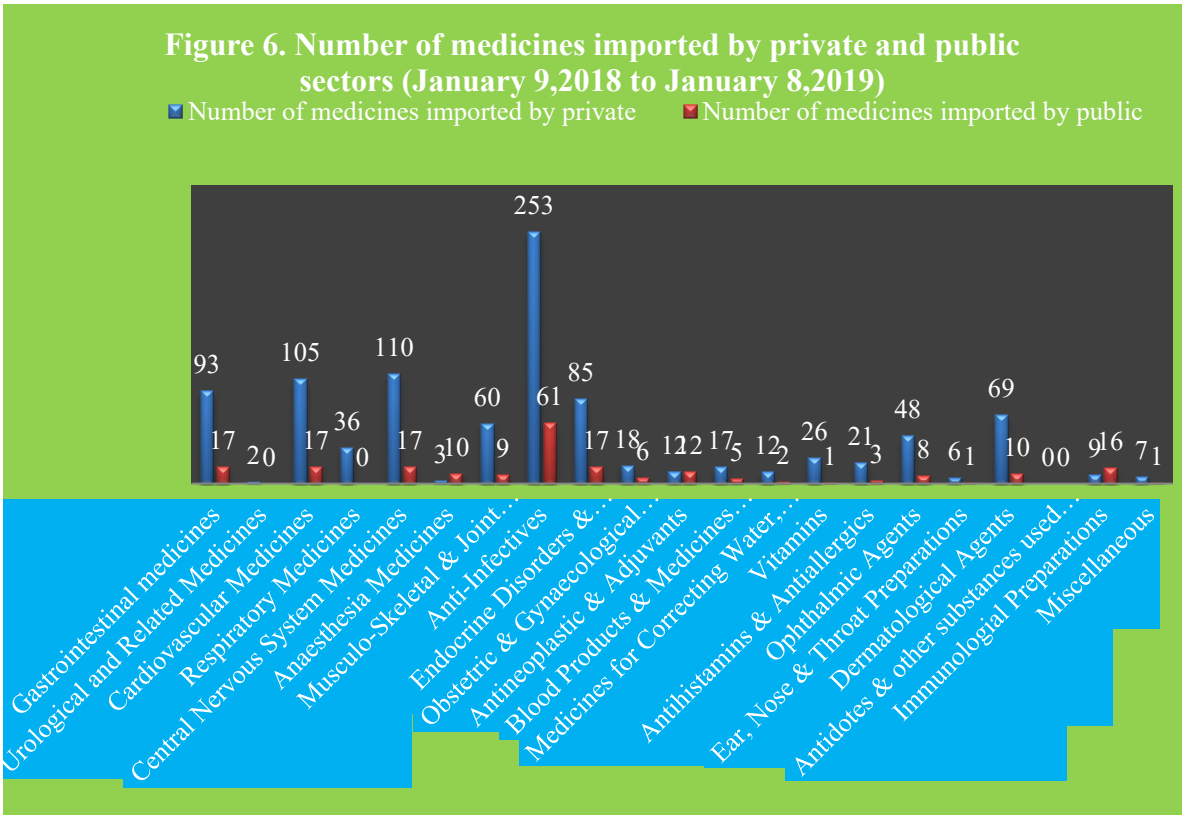
Within the study period, a total of 2804 medicines of different dosage forms were registered. However, the fact that a medicine is registered does not mean it is available on the market. For instance, as we can see from table 2, as of January 8, 2019, only 1061 (37.7%) medicines were imported in the previous year. A higher proportion of medicines were imported from musculoskeletal & joint diseases medicines (47%) group followed by gastrointestinal medicines (46.8%), and immunological preparations (46%). On the contrary, the lowest numbers of medicines were from antineoplastic & adjuvants (15%) and antidotes & other substances used in poisoning (0%) therapeutic groups.

Table 2: Number of registered medicines (N=2804) versus imported medicines (n=1061) (from January 9, 2018 to January 8, 2019)

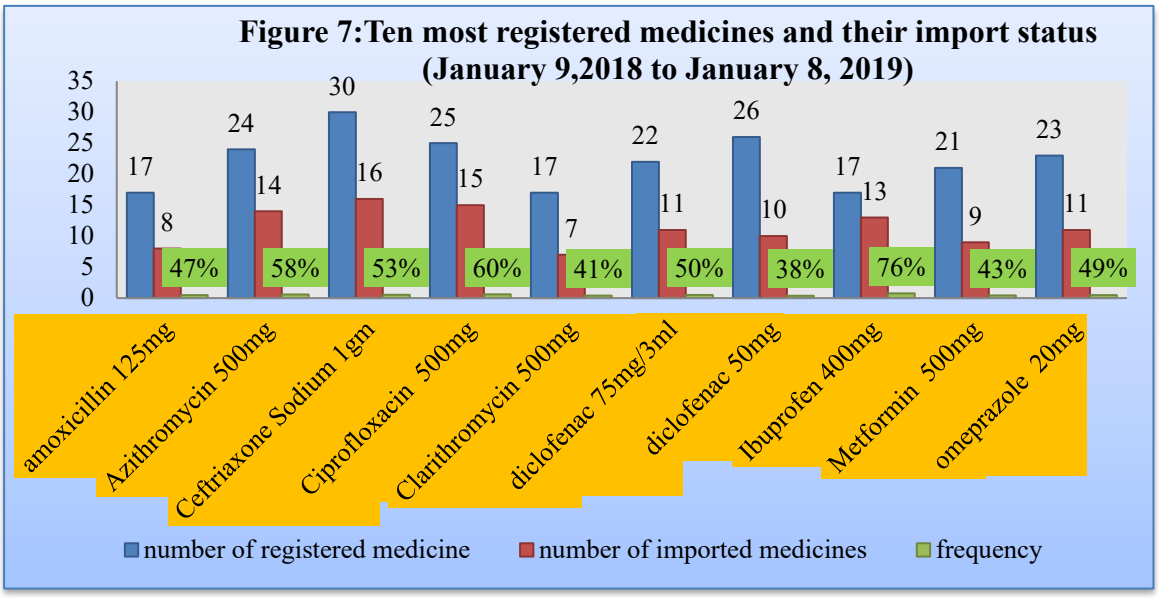
Therapeutic category	Registered medicines (N)	Imported medicines (n)	Percent Difference (%)
Musculo-skeletal & joint diseases medicines	140	66	47
Gastrointestinal medicines	220	103	46.8
Immunologial preparations	52	24	46
Vitamins	60	27	45
Dermatological agents	178	77	43
Ophthalmic agents	126	53	42
Endocrine disorders &contraceptives medicines	239	98	41
Central nervous system medicines	290	115	39.6
Anti-infectives	820	306	37
Antihistamins & antiallergics	60	22	36.6
Respiratory medicines	104	36	34.6
Obstetric & gynaecological medications	62	21	33.8
Blood Products & medicines affecting the blood	54	18	33
Miscellaneous	24	8	33
Anaesthesia medicines	34	11	32
Cardiovascular medicines	369	118	31.9
Medicines for correcting water, electrolyte & acid- base disturbances	46	13	28
Ear, nose & throat preparations	26	6	23
Urological and related Medicines	9	2	22
Antineoplastic & adjuvants	145	22	15
Antidotes & other substances used in poisoning	5	0	0

As figure 6 shows, 86.5% of medicines (by frequency) were imported by the private importers and the remaining 18.58% were imported by EPSA. Surprisingly, more than

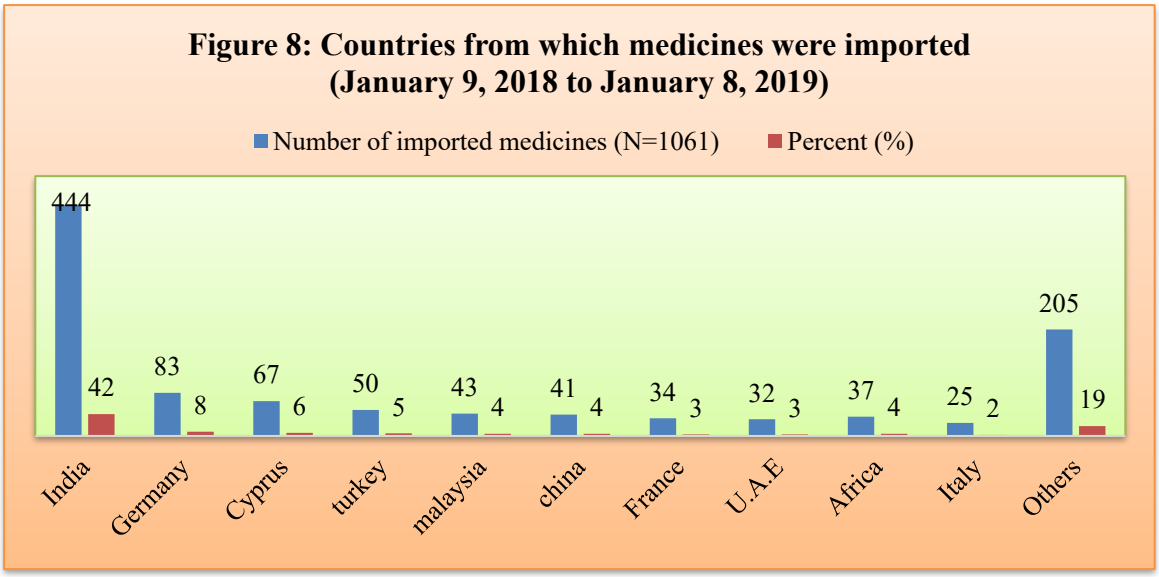
half (57%) of medicines imported by EPSA were not registered by the regulatory authority. Some classes of medicines such as medicines used for digestants, urinary incontinence, sclerosing agents, psoriasis and eczema, antidotes & other substances used in the poisoning were not imported totally.



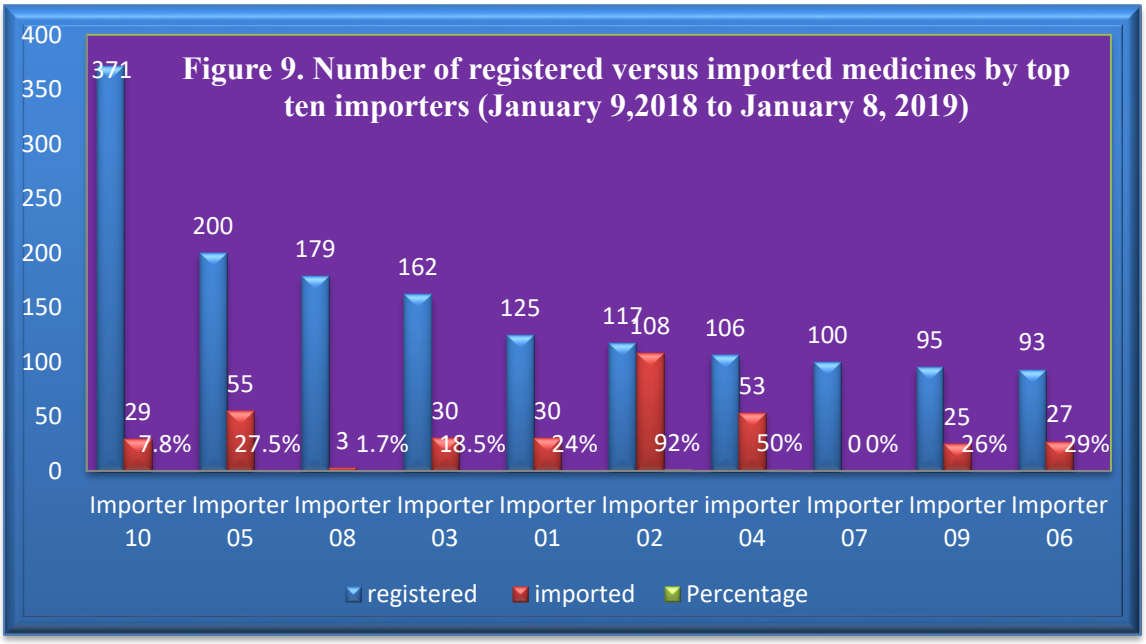
Analysis of the number of registered and imported products for different formulations suggests that registering a product does not mean that it is available in the market. For instance, ceftriaxone is the most frequently registered (n=30) medicine. However, only 53% of these registered medicines were imported (Fig 7).



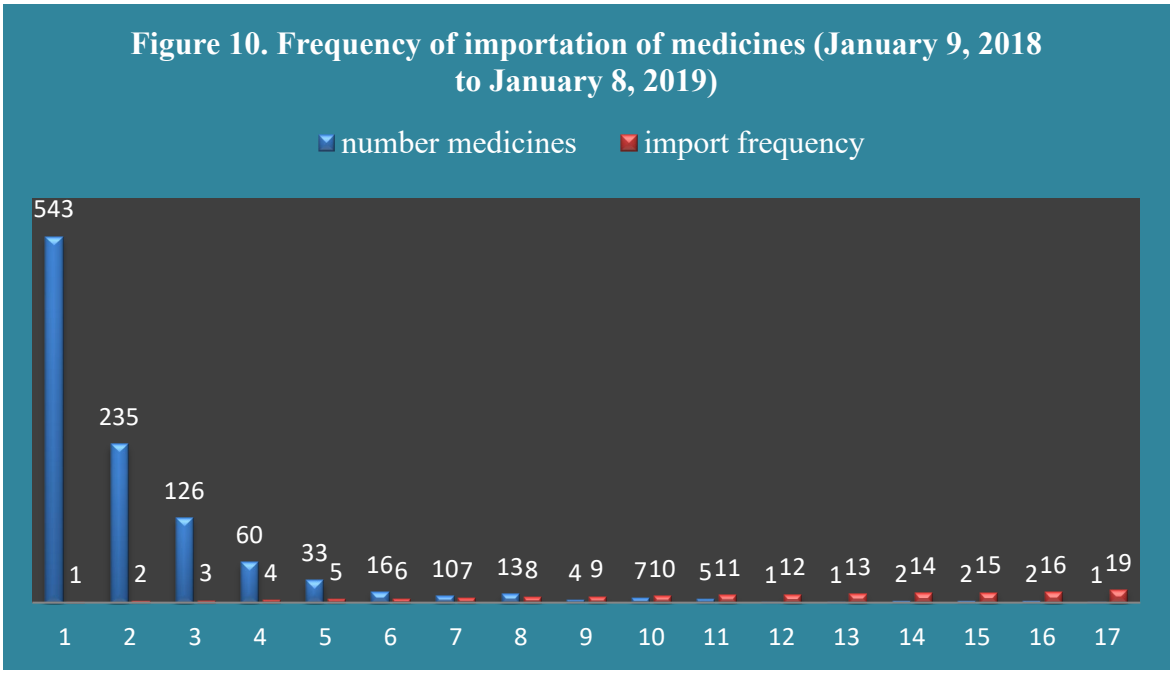
Generally, medicines were imported from 41 countries and nearly half the number of these (42%) were imported from India, 4% from African countries and the remaining from other countries (figure 8).



55% of medicines were registered by 10 importers and these companies imported on average 23% (min=0%, and Max=92%) of the registered medicines (figure 9).



As we can see from figure 10 from the total imported medicines 51% of them were imported once only, 22% two times, 11.8% three times, and 0.09% nineteen times within the study period.



6.2. Background characteristics of the interviewees and importers

In-depth interviews were done with ten key informants from selected pharmaceutical importers and distributors. As Table 3 shows all importers had more than 20 years of experience in the pharmaceutical import business, each registered 93 or more registered products and representing five and more manufacturers.

Table 3 Baseline characteristics of the company

Company name coded	Manufacturers representing	Trade houses representing	Registered medicines	Imported medicines (n) from January 9,2018-January 8, 2019
Importer 01	5	0	125	30
Importer 02	20	0	117	108
Importer 03	14	1	162	30
Importer 04	12	1	106	53
Importer 05	14	0	200	55
Importer 06	10	0	93	27
Importer 07	6	0	100	0
Importer 08	13	2	179	3
Importer 09	11	0	95	25
Importer 10	23	9	371	29

All the interviewees were pharmacists and majority of them were male (9, 90%), with more than 5 years of work experience related to medicine import and were aged more than 30 years (table 4).

Table 4: Background Characteristics of key informants (n=10)

Participant Characteristics	n
Gender	
Male	9
Female	1
Age	
31-40 years	3
41-50 years	4
>50 years	3
Year of experience in the pharmaceutical sector	
5-9 year	3
10-14 years	3
>15 years	4

6.3. Perceived reasons for non-importation of market authorized medicines

The information given by the key informants was more or less similar after the seventh interviewee and just for certainty data was collected from the remaining three key informants. The key informants shared their perspectives on the factors for the non-importation of registered medicines in Ethiopia. From the information compiled, four major themes were extracted: marketing-related, foreign currency-related, manufacturing-related, and government-related factors for non-importation of registered medicines. The themes were then subdivided into thirteen sub-themes. The most important common reasons were described here below.

6.3.1. Marketing related

Registration of products by imposition from suppliers: Registration of products by imposition from suppliers was mentioned as one of the reasons for non-importing of market authorized medicines as depicted by the quote from one key informant.

> *"We have registered valsartan for chronic condition but no doctors are prescribing it. Still suppliers push us to have products registered they hope will be put to use in some 3 to 4 years." (Importer 10)*

Promotion-related: The promotion of pharmaceuticals has a key role in the introduction of new medicines into the market. Most decision-making of buying medicines lies in the hand of prescribers rather than the final consumer. Some key informants believe that promotion is a priority before importing newly registered medicines.

> *"We recently had reproductive health products registered but we couldn't import them so we had to hold off. Because when you introduce new type of molecules such as these you need to hire a promotional team to penetrate market and import a large amount to cover your costs & for market penetration". (Importer 05)*

Price-related: the private business is related to profit beyond social role and so the import of registered medicines is highly sensitive to the price of the products. Some key informants believe that price competition and low-profit margin of their products affected continuous importation of registered medicines as depicted by the following quotes.

> *"There was FDA approved Amoxicillin 250 mg we used to import which also didn't match prices with locally produced Amoxicillin. The FDA approved*

product price was high as compared to GMP approved Amoxicillin product which will not be profitable in the market". (Importer 04)

"You try out a product and since the private sector is business oriented, products could be dropped if they're non-profitable. The other is price competition or price war. There are common products that companies' battle over which eventually lead to molecule over stock in the market and decreased profit margin leading to wastage and product expiry as well as product shift by patients." (Importer 08)

Demand-Related: low or high demand for any product in the market may contribute to the shrinking supply-sustainability of certain markets. Some key informants believe that low demand contributed to the non-importing of market authorized medicines as illustrated by the quote below.

"One company has been sold because it couldn't manage to survive in the Ethiopian market. Even though they have dedicated plenty of resources here they weren't able to generate a satisfactory market. They had intended to work on chronic conditions, and the percentage of consumers with chronic conditions and the percentage of consumers who need these products are limited to Addis Ababa, and a target group of only a 100 million for such a vast investment wasn't enough." (Importer 10)

Presence of government tender: One key informant stated that they were registering products only for the tender process and they were not importing by themselves.

"We import some 15 generic products but we mainly work on tender with TB and HIV medications provided for free by the government." (Importer 07)

Presence of multiple local agents for a manufacturer: Different key informants have different arguments on the presence of multiple local agents for manufacture as a cause for disruption of importation of registered medicines. Some respondents believed that the presence of multiple local agents for one foreign manufacturer was the main reason for the interruption of importing registered medicines as depicted by the quotes below.

"The new multiple agency initiative might have a positive aspect but if I show you data on Chinese and Indian companies each have acquired over 14 to 15 local agents. This is very disastrous because all 15 open up LCs for similar, say six products. FMHACA claims that over 5000 molecules have been registered but we notice a battle over some 10 products. This will lead to wastage and expiry of products and a limitation to the range of products patients can access." (Importer 08)

"I believe the disadvantage outweighs the advantage. I would rather say that multiple manufacturers be encouraged to be registered for one product than multiple agents importing from one manufacturer. This offers options to consumers; you increase the number of alternatives so a consumer could use another brand if his usual brand is unavailable. Price competition would also be amongst manufacturers and not local agents." (Importer 04)

On the contrary, some respondents believed that the presence of multiple local agents for one foreign manufacturer has an advantage for the continued availability of medicines in the market as shown by the quotes below.

> *"Having more than one agent will be very useful to avail the product for the nation because there could be difficulties with just one agent. I believe availability is the most important advantage because it could be frustrating to the agent as well if it were a sole agent and was struggling to avail the product. If one faces an obstacle then the second, third or fourth agent will import the product so it will assure continuity." (Importer 01)*

> *"Having many agents for one manufacturer could lead to price competition and this might be good to lower product price.'' (Importer 04)*

6.3.2. Foreign currency related

Foreign currency delays and shortage: Almost all key informants mentioned that foreign currency shortage and delays as a major cause of medicines' unavailability as depicted by the following quotes.

> *"The first and foremost is the issue of forex. In this Ethiopian budget year, the government allocated to us not more than 300,000 USDs but our actual demand was 17 million USDs. So, with the currency we've been granted we imported products we could attain the fastest and distributed products to our most demanding customers." (Importer 10)*

"We are highly expectant of the Commercial Bank of Ethiopia (CBE), but it took us about 9 to 10 months to receive the LC. And when what we have received is compared with our range of products what has been allocated is very minimal." (Importer 05)

6.3.3. Manufacturing related

Presence of locally produced medicine: Even if most key informants believed that at this moment the presence of locally produced medicines was not influencing their importation of registered products, few respondents said that they stopped their importation because of the presence of locally produced medicines as shown by the quotes below.

"We haven't completely stopped importing locally manufactured products but it has definitely influenced the market. For example, we used to import large volume IV fluids but not anymore because there is a large amount of IV fluid produced by a local manufacturer. In comparison to the previous amount we have cut down significantly." (Importer 09)

"Companies approached us with Amoxicillin suspension, capsule, Metronidazole and Diclofenac so we had them registered and imported to fill the gaps in the market. But we are no longer importing them due to local production. Similarly, we outsource cough syrup from the local market." (Importer 08)

On the contrary, most respondents believe that at this moment local manufacturing had no impact on the importation of the registered medicines because of price and quality

advantages on the one hand and foreign currency shortages to import raw materials on the other hand as depicted below.

> *"It has no impact on us. Sometimes our products might even be of better price and quality when compared with locally produced products." (Importer 04)*

> *"It could go beyond sensitization, beyond just propaganda and actually enable manufacturers to produce. Because what manufacturers are saying is that they find it difficult to compete with imported items since China & India imported products are much cheaper due to the advantage of bulk production. Like importers, manufacturers are also affected by foreign currency because they have to import APIs as well. (Importer 08)*

6.3.4. Government related

Disruptions due to regulatory actions: Some respondents believed that disruptions due to regulatory actions as one of the main reasons for the disruption importation of some medicines as shown by the quotes below.

> *"Some might be due to registration problems, registration problems could arise from company problems or from lack of meeting renewal time or it could be related to site inspection." (Importer 05)*

> "*Some manufacturers do not meet GMP requirements, for example there were malaria medications that we had registered but did not import because of lack of GMP pre qualifications". (Importer 04)*

Lack of coordinated imported medicines database: Lack of coordinated imported medicines database was identified as a hindrance for the uninterrupted supply of medicines by most respondents as depicted below.

> *"The Ethiopian pharmaceutical market is very difficult for forecasting; it is easily influenced. Let's say PFSA has good supply then the importer stocks freeze and since there isn't a satisfactory FMHACA database on the percentage of product entry, and on the percentage of pending orders for a product; we are forced to import products that aren't market guaranteed…" (Importer 03)*

The key informants therefore recommend for the establishment of a national database to improve the situation as shown below.

> *"There should be a national database available on a product, say ampicillin, so that everyone will not import ampicillin at once." (Importer 03)*

> *"There is a very wide gap and problem within the sector in reference to demand so the health bureau, FMHACA and Importers Association should seriously review the matter and improve supply. If FMHACA release timely reports on products sufficiently available like they post ranges for product registration, it will avoid competition by all importers over one product." (Importer 08)*

Illegally sourced products: Illegal diversion of pharmaceuticals from the public sector may create or exacerbate shortages in public health facilities and discouraging the private importers from importing the registered medicines. In addition to this, the availability of illegally imported medicines in the market will distort overall demand and may result in

the introduction of substandard or falsely labeled products into the supply chain. Some key informants believe that these kinds of activities will finally push legally imported medicines out of the market as depicted by the following quote.

> *"A government imported (owned) medications could be stolen by an individual, a group or a body and recirculate back into the market as a legal product. Since this product was stolen and acquired for free then it could be sold at any price. There are also medications that enter tax free through travelling individuals; which could be sold at any price as well. Even though the quality of the medication might be in question, since rent, tax and other factors isn't an issue for these individuals the product prices could disturb the market". (Importer 03)*

On the contrary, others believe that at the time the presence of illegal medicines in the market had no impact on the importation of the registered medicines as depicted below.

> *"I actually have a different opinion on illegal product and its distribution in Ethiopia. I think authorities might have exaggerated the extent of the problem. I say this because what are considered to be illegal pharmaceuticals are legally acquired products re-entering the stream illegally. I can't say for sure about boarder activities in Ethiopia, but strictly referring to Addis Ababa I think counterfeit products are very limited to certain groups, like oncology products, anti-D, products with shortage and with limited number of user patients. I have worked in this sector, in Addis Ababa for 17 years and I do not believe this has had significant impact on the market". (Importer 08)*

Government policy change: Some of the key informants felt that abrupt changes of policies may also cause disruption of the continued availability of medicines as shown by the quote below.

> *"At one point in time, there was a malaria outbreak in the country and different dosage forms of malaria products were registered but because the government had taken over malaria management our imports were no longer necessary. Similarly, insulin is being imported into the country custom free by the government so despite having different forms of insulin registered we're forced to stop importing it." (Importer 03)*

Other respondents also strengthen this idea citing that the government supplies some of the products where they were unable to import such as program medicines as illustrated below.

> *"We don't privately bring in TB, HIV and Malaria products like I mentioned earlier because the government provides them". (Importer 07)*

Customs taxation related: Some of the key informants explained that customs authority has its own pricing system and it is not depending on the commercial invoice. This pricing procedure has apparently led to price increases and consequently may influence medicine availability as shown below.

> *"Customs always prefers the highest pricing system for taxation. With products imported with lesser price, we will be expected to sell with that high taxation price; if not accusations of underpricing will arise. So, if customs could accept original*

chambered price documents or even request price directly from suppliers there won't be confusion and this would be a much better approach". (Importer 04)

7. Discussions

To the best of my knowledge, this was the first qualitative and quantitative study to investigate the import status of registered medicines and associated factors for the non-importation of registered medicines in Ethiopia. As the study revealed, less than 40 percent of the registered medicines were imported. Supply and demand-related, economic-related, and manufacturing-related issues were the main factors for the non-importation of the registered medicines.

As the analysis indicated from a total of 2804 registered medicines within the study period only 37.7% were imported. Based on the national drug list therapeutic classification, the import status of all medicines in their respective therapeutic groups was below 50 percent. This level of importation was low when compared with similar studies from South Africa where 54% of registered generic brand medicines were imported (Leng et al, 2015) and in Moldova, on average 70% to 80% of the registered medicines were imported (Ferrario et al., 2014). Another study in Estonian showed that 10% and 74% of nationally and centrally authorized products respectively were not available in the market in the past three years (Ferrario et al., 2016). This obviously will have implications on the availability of medicines.

The findings from the present study also revealed that the import status of some therapeutic categories was worse for some such as antineoplastic & adjuvants (15%) and antidotes & other substances used in poisoning (0%) among others. A similar scenarios were observed from other countries such as Moldova where medicines for cancer and cardiovascular conditions were affected (Ferrario et al., 2014). Similar issue was also identified in other former Soviet Union countries (Ferrario et al., 2014). These findings

are further indicative of the impact of non-importation on the availability of vital medicines and ultimately affecting patient care.

Generally, medicines were imported from 41 countries 42% of the medicines were imported from India, 8% from Germany, 6% from Cyprus, 5% from Turkey, 4% from China and Malaysia each, 3%, United Arab Emirates and France each 2% from Italy and 19% from other countries. 4% of imported medicines were from African countries particularly from Egypt, Kenya, South Africa, and Tanzania. As the study indicated the market share of African countries was very low as compared to Tanzania in which 28.6% was imported from African countries and 36.8% from India (Access and Delivery Partnership, 2016). The study showed that much more is expected to increase regional integration through regulatory harmonization to increase the market share of African countries by maintaining quality.

This study explored the reasons behind the non-importation of registered medicines from the perspective of pharmaceutical importers in Ethiopia. The most common stated reasons for the interruption of continuous supply of registered medicines were lack of coordinated imported medicines database system, registration of the product by imposition from suppliers, foreign currency shortage, government tender, government policy change, regulatory actions, price competition, and low demand custom taxation and presence of illegal medicines. The result of this study was more or less consistent with reported studies except for some country-specific reasons (FIP, 2013; Birgli, 2013 & Ferrarioet al., 2014).

According to the results of our study, foreign currency shortage was considered as the main problem for the importation of the registered medicines. Currently, it took on average from six months to one year to get a bank permit /L/C /, and even at this time they were getting 10 to 15% of their L/C demand. It was also stated that even if there was a new directive set by the Commercial Bank of Ethiopia to prioritize pharmaceuticals, but how much of that was practiced was questionable. A previous Ethiopian study also showed that even if the national bank of Ethiopia declared on its directive dictating that at least 50% of the foreign currency must be directed to essential imports like pharmaceuticals and oils, delays for receiving allocations for essential imports in a state-owned bank were said to be four months, in a private bank twelve months. Besides this, banks do not always allocate the full value of the LC to the applicant mostly received only 50% of the foreign currency they requested (Lloyd & Teshome, 2018, Birgli, 2013). Further study should be conducted regarding L/C allocation.

According to this study, demand change and price competition were some of the reasons for medicine discontinuation in the Ethiopian market. Some companies were also forced to drop out of the market because of the launching of competitive products with lower prices. Similar results published in other European countries showed that among the factors that trigger the manufacturers to permanently or temporarily reduce the production of a drug were diminishing demand and insufficient profits (Leng et al, 2015; European Healthcare Distribution Association, 2013 FIP, 2013). For example, in Greece, 203 products were withdrawn from the market in 2012 and 25 of them have no generic equivalent (Birgli, 2013).

The findings also revealed that there was no satisfactory regulatory database on the percentage of product entry, and on the percentage of pending orders for a product which led to importers importing products that were not market guaranteed. Sometimes when the government had a good supply then the importer stocks would freeze and no one could sell them which later on led to shortages because no one was interested to import. A similar study also strengthened this point that there was no enough information to explore the magnitude of the problem at the international level. In addition, the characteristics of medicines shortages differ from country to country, and the lack of reliable information hindered the establishment of a globally coordinated action (FIP, 2013). To solve unavailability problems of medicines certain countries like the USA and European Union set a reporting mechanism for a shortage of any medicine (FDA, 2013 & EFPIA, 2020).

In this study, the involvement of the government in international tendering was cited as the main reason for the non-importing of registered medicines by private importers. Some program medicines like TB and HIV were imported by the government and provided for free. Importers were registering these medicines for tendering purposes only. In addition, EPSA purchases in large volume and with cheap price and it offer much cheaper priced products. Even though it is advantageous to the public it still could be discouraging to the private sector due to the same market target, be it for the government or the private sector and they would lose interest to import the registered products. Even if the scenario was different as mentioned in another study For instance, when a tender award exclusively for the lowest priced product(s) to be reimbursed, other players may lose interest in the

market, which ultimately reduces the availability of alternatives if the awarded manufacturers encountered shortages (FIP, 2013, Birgli, 2013).

The study revealed the illegal diversion of pharmaceuticals from the public sector to the private market as one reason for the non-importation of registered medicines. A study conducted in 11 African cities on antimalarial medicines indicated that 6.5% (58 out of 894) of collected antimalarial medicines were diverted one (Bate, Hess & Mooney, 2010). Diversion of medicines illegally may cause shortages in public health facilities and discouraging the private importers from importing the registered medicines. In addition to this, the availability of illegally imported medicines in the market will affect overall demand and may cause the introduction of substandard or miss labeled products into the supply chain.

The study revealed that customs authority always prefers the highest pricing system for taxation and it is not depending on the commercial invoice value. This pricing procedure has led to price increases and consequently may influence medicine importation. A similar study showed that Importers were extremely disparate with the pricing system of Ethiopian revenue and customs authority. The transaction values importers come with are mostly rejected and the higher price is imposed on them. This is the most challenging for importers during customs valuation (Mersha, 2016). Customs Tariffs are a vital determinant of prices as they can considerably increase the prices of imported medicines which ultimately target the sick (Olcay & Laing, 2005).

Different countries have different pharmaceutical distribution systems. In Ethiopia, one manufacturer can have multiple local importers and conflicting views were reflected in

this study, some supporting and others opposing for different reasons. Literature reveals that in developed regions like the United States of America, European Union, Japan, and other similar regions of the world, there are commonly three to five major distributors to cover 90% of the market share. On the other hand, the distribution system in most emerging markets is fragmented and has too many small players which results in poor coordination in the distribution channel and encountering difficultly in ensuring affordability, and also creates supply chain inefficiencies (Yadav & Smith, 2014). In developing countries, it is harder to audit and enforce quality in such a fragmented and multi-tiered wholesaling/distribution market since the resource is limited but further study is needed.

8. Strength and limitation of the study

The strengths of this study include that this study which used both quantitative and qualitative methods is the first to be reported at the country level. On the other hand, previous studies were conducted on few products at health facility levels. However, this study included all the medicines imported to the country by the importers.

On the other hand, the study didn't include the views of stakeholders like banks, custom and regulatory authority and focused on a one-year data.

9. Conclusions

Most of the registered medicines are not imported to the country. Lack of imported medicines data, imposition from suppliers, government tender, foreign currency shortage, price competition and low demand are the main reasons for on availability of registered medicines.

10. Recommendations

- The government needs to establish an organized imported medicines database which will enable importers to forecast the demand appropriately.
- Manufacturers and importers should provide early alerts when they decide to withdraw from the market so that the regulatory authority will search alternative mechanisms for this EFDA should establish a national notification system of medicine shortages.
- EFDA should identify those medicines which have no therapeutic alternative from registered medicine data base and encourage the government procurement agency to avail continuously.
- Most of the medicines imported by the government are not registered one and it shows a double standard so the regulatory authority should create a system for the EPSA to register the products.
- The banks should be abided by the government directive for the prioritization of pharmaceuticals for foreign currency allocation.
- Impact of the presence of multiple local agents for a manufacturer on the continuous supply of medicines should be studied again.
- Registering a lot of medicines by itself is not a guarantee for access so the government should create a system for importation of the registered medicines.

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12. Annexes

Annex 1: List of registered medicines

Available on: https://www.eris.efda.gov.et/products

Annex2: Consent form

Introduction and Consent

My name is _____ I am here on behalf of Mr. Abebaw Gessesse, a postgraduate student at School of Pharmacy, College of Health Sciences, Addis Ababa University. He is conducting his research entitled "Import status of registered medicines and their associated factors in Ethiopia "for the partial fulfillment of the requirements for the degree of Master of Science in Regulatory Affairs.

The purpose of this study is to assess the import status of registered medicines and identify associated factors at the pharmaceutical importers level in Ethiopia. The findings of this study will be used to develop strategies and to take appropriate measures to solve shortage of medicines by revising a means that registration and purchase order approval of the country will be speeded up.

I, thus, kindly ask you to participate in this study. The first part is a self-administered structured questionnaire which will be followed by an interview. The total duration of the study will be approximately 30 minutes. I assure you that the data I get will be kept strictly confidential, and will not be disclosed to anyone other than member of our survey team. Furthermore, the finding report will maintain anonymity and not reveal individual nor organization identity. Your participation is totally voluntarily; it is possible to withdraw and skip from answering questions which you are not interested to respond. This study will not have any harm for study participants. Hopefully, you will respond for this study since the response is very crucial.

Do you want to ask me anything about the study?

Are you willing to respond for this study? 1. Yes 2. No (if No, thank for your time)

Signature_____

Date_____

Data requested by _____Signature_____Date_____

Annex 3: Self-administered structured questionnaire

Introduction

The objective of this study is to assess import status of registered medicines and their associated factors in Ethiopia. The findings of this study will serve as input for policy makers to take appropriate measures to solve shortage of medicines. Hence, I kindly request you to fill out the questionnaire responsibly and honestly. I would assure you as all your responses will be kept confidentially.

NB!

- There is no need of writing your name and mobile number on the questionnaire
- Please read each question carefully and answer by putting tick (√) mark in the boxes or writing short answer in the blank space provided.

  Thank you in advance for taking time out of your busy schedule to answer my questions.

I. Socio-demographic variables

101. Sex: male ☐ female ☐

102. Age:

a. 19-30 ☐

b. 31-40 ☐

c. 41-50 ☐

d. >50 ☐

103. Year of establishment of your organization_____

104. What is your current job level?

a. President ☐

b. General Manager ☐

c. Technical manager ☐

d. Other _____

105. How many years of experience do you have in pharmaceuticals?

a. 0-5 years ☐

b. 6-10 years ☐

c. 11-15 years ☐

d. 16-20 years ☐

f. More than 20 years ☐

106. How many employees does your company have in total?

a. 10 or fewer ☐

b. 11-20 ☐

c. 21-50 ☐

d. >50 ☐

II. General questions

. 201. How many suppliers do you have? Of these, how many of them are manufacturer and trade houses?

202. For how many suppliers, you are first agent? _____

203. How many products your company has registered? _____

204. From the registered products, how many products are actively being imported?

Annex 4: Semi-structured questionnaire for key informant interview

Introduction

The objective of this study is to assess import status of registered medicines and their associated factors in Ethiopia. The findings of this study will serve as input for policy makers to take appropriate measures to solve shortage of medicines. Hence, I kindly request you to give information responsibly and honestly. I would assure you as all your responses will be kept confidentially.

III. Qualitative study interview guide

301. Can you please tell me in general about the import activities of your registered products?

302. Why your company didn't import some drugs that are registered? Please mention all the factors that become a hindrance for importation.

Probe on:

- Availability of unregistered medicines? How is the depth of the problem? In what way do you think this medicines avail in the market?
- Re-registration related problem? What was the problem?
- Product quality problem? What kind of quality problem?
- Closure or change of manufacturing facilities
- Consolidation of firms
- Foreign currency how long it took to get your last L/C permit?
- Price related
- Insufficient profit margins
- Sole market authorization
- Dependency on a single supplier
- Low market demand
- Shortage of raw materials
- Stringent supply quotas imposed by pharmaceutical manufacturers
- Presence of competitor products
- Regulatory measures on the importer or on the product? What was the measure?

- Other-------

303. What do you propose to reduce import process problems in Ethiopia?

304. How do you see having more than one local agent for a manufacturer?

- Can it help in the facilitation of importation of registered medicines?
- Do you think the number of agents should be limited?
- If so, how many agents there should be for one manufacturer? And why?
- If your answer for question number 305 is no can you mention the reason(s) how it is contributing for importation?

305. How local production affected your importation of registered products?

- Is there any registered product which you didn't import now because of local production of the same product?

306. What government policies and regulations may contribute for the unavailability of more new products, and how could these be modified to prevent or limit impacts on importation?

ክፍል ሦስት፡ <u>መሃበራዊ እና ስነ ህዝባዊ መረጃ ማሰሻ ጥያቄዎች</u>

101. ፆታ ወንድ ☐ ☐

102. እድሜ

ሀ. 19-30 ☐

ለ. 31-40 ☐

ሐ. 41-50 ☐

መ. >50 ☐

103. ድርጅቱ የተመሰረተበት ዘመን----------

104. በድርጅቱ ውስጥ ያለዎት የስራ መደብ?

ሀ. ፕረዚደንት ☐

ለ. ማናጀር ☐

ሐ. የቴክኒክ ሀላፊ ☐

መ. ሌላ ካለ ይጠቀስ----------

105. በመድኃኒት ንግድ ዘርፍ ስንት አመት ሰርተዋል?

ሀ. 0-5 ዓመት ☐

☐

ለ. 6-10 ዓመት

ሐ. 10-15 ዓመት ☐

መ. >15 ዓመት ☐

106. የድርጅቱ አጠቃላይ የሰራተኛ ብዛት ስንት ነው?

ሀ. 10 ወይም በታች ☐

ለ 11-20 ☐

ሐ 20-50 ☐

መ ከ50 በላይ ☐

ክፍል ሁለት፤ <u>ጠቅላላ ጥያቄ</u>

201. ስንት የመድኃት አቅራቢ ድርጅት አላችሁ? ከዚህ ውስጥስ ስንቶች አምራች ናቸው? ስንቶችስ ትሬድ ሀውስ/የንግድ ድርጅቶች/ናቸው?

202. ለስንት ድርጅቶች የመጀመሪ ወኪል ነው?

203. ድርጅቱ ስንት መድኃኒቶችን አስመዝግቧል?

204. በአሁኑ ወቅት ከተመዘገቡ መድኃኒቶች ውስጥ ስንቶችን እያስመጣችሁ ነው?

ክፍል አራት፤ <u>ማብራሪያ የሚሹ ቃለ መጠይቆች</u>

301. በአጠቃላይ የተመዘገቡ መድኃኒቶችን የማስገባት ሂደቱ ምን ይመስላል?

302. ድርጅታችሁ ካስመዘገበቸው መድኃኒቶች ውስጥ አንዳንዶችን ለምን እንደማያስመጣቸው ቢብራራ? መድኃኒቶችን ወደ ሀገር ውስጥ ለማስገባት አስቸጋሪ የሆኑ ሁሉንም ምክኒያቶች ይጠቀሱ?

- የህገወጥ መድኃኒች ገበያ ላይ መኖር ነው? ከሆነስ የችግሩ ስፋት ምን ይመስላል? በምን መንገድ የሚገቡ ይመስልዎታል?
- ዳግም ለማስመዝገብ ተቸግረዋል ከሆነስ ችግሩ ምን ነበር?
- ከመድኃኒቱ ጥራት ጋር የተያያዘ ከሆነ ምን ነበር ችግሩ?
- የአምራች ድርጅቱ መዘጋት ነው
- አምራቶች በሌሎች አምራቶች መጠቃለል
- የውጭ ምንዛሬ እጥረት ከሆነ መጨረሻ ላስገባችሁት ምርት የባንክ ፍቃድ በስንት ጊዜ አገኛችሁ?
- ከዋጋ ጋር የተገናኘ ነው
- አነስተኛ የትርፍ መጠን መኖሩ
- አንድ አቅራቢ ብቻ መሆኑ
- የገበያ ፍላጐቱ አነስተኛ መሆን
- የጥሬ እቃ አቅርቦት ችግር
- አምራቹ እንዲጫንለት የሚፈልገው አነስተኛ መጠን ከፍተኛ መሆን
- ሌሎች ተወዳዳሪ ምርቶች መኖር
- በአስመጭው ላይ በተቆጣጣሪ መስሪያ ቤቱ የተወሰደ እርምጃ መኖር
- ሌሎችም ካሉ----------

303. በማስገባት ሂደት ውስጥ የሚያጋጥሙ ችግሮችን ለመፍታት ምን አይነት የመፍትሔ ሀሳብ አለዎት?

304. ለአንድ አምራች ከአንድ በላይ አስመጭ ወኪል መኖሩን እንዴት ያዩታል?

- የተመዘገቡመድኃኒቶችን ያለማቋረጥ ለማምጣት ያግዛል ብለው ያምናሉ?

- የአስመጭ ወኪሎች ብዛት ውስን መሆን አለበት ብለው ያምናሉ? ከሆነስ ስንት ቢሆን ብለው ያምናሉ ምክኒያቱን ቢያብራሩ?
- የአስመጭ ወኪሎች ብዛት ውስን መሆን የለበትም የሚሉ ከሆነ ጥቅሞችን ቢያብራሩ?

305. በድርጅቱ የተመዘገቡ መድኃኒቶች በአገር ውስጥ በመረታቸው ምክንያት ወደ አገር ውስጥ ለማስገባት የሚፈጥሩት ተፅእኦ ምን ይመስላል?

- ተመሳሳይ መድኃኒቶች አገር ውስጥ በመመረታቸው ምክንያት ምን ያህል መድሃኒቶችን ወደ አገር ውስጥ ማስገባት አቁመዋል? የመድኃኒቶቹ አይነት ቢጠቀስ

306. አዳዲስ መድኃኒቶች ወደ አገር ውስጥ እንዳይገቡ የትኞቹ የመንግስት ህጎችና ፖሊሲዎች አስተዋፅኦ አድርገዋል? ችግሩን ለመፍታትስ በምን መንገድ ቢሻሻል ይላሉ?