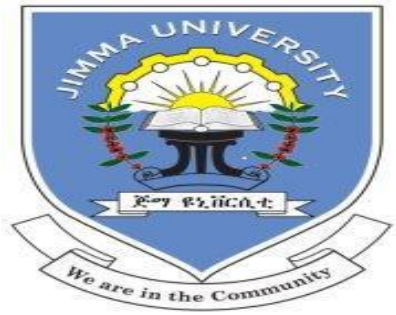

COLLEGE OF LAW AND GOVERNANCE STUDIES

DELAY IN CUSTOM CLEARANCE AND DETAINING OF MEDICNES BY CUSTOMS AUTHORITY: ASSESSING CUSTOMS CONTROVERSY AND THEIR IMPACT ON ACCESS TO MEDICNES

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Declaration

Daba Tesema, hereby declare that this dissertation is original and has never been presented in any other institution. To the best of my knowledge and belief, I also declare that any information used has been duly acknowledged.

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List of Acronyms

ACTA	**Anti-counterfeiting Trade Agreement**
BCBP	**Bureau of Custom and Border Clearance**
CBCE	**Central Board of Excise and Custom**
IDF	**Import Declaration Form**
SON	**Standard Organization of Nigeria**
WTO	**World Trade Organization**
WCO	**World Custom Organization**
FMHACA	**Food, Medicines and Health Care Control Authority**
ERCA	**Ethiopian Revenues and Customs Authority**
TRS	**Time Release Study**
UDHR	**Universal Declaration of Human Right**
ICCPR	**International Convention on Civil and Political Right**
ICESCR	**International Convention on Economic, Social and Cultural Right**
TRIPs	**Trade Related Intellectual Property**
GATT	**General Agreement on Trade and Tariff**
DSU	**Dispute Settlement Understanding**
ASYCUDA	**Automated system for custom**
CET	**Common External Tariff**
NAFDAC	**National Agency for Food and Drug Administration Control**
CO	**Certificate of Origin**
ECOWAS	**Economic Commission of West African States**
US	**United States**
EU	**European Union**

Chapter 1 **INTRODUCTION**

1 **BACK GROUND OF THE STUDY**

Medicines are the most significant tool that society possesses to prevent, alleviate, and cure disease.[1] Millions of people especially in least developed and developing countries rely on affordable medicines produced in other countries to stay alive. It is estimated that between 1.7 and 2 billion people worldwide have inadequate or no access to life-saving medicines. Low-income levels, weak healthcare systems, rising costs of medical supplies and poor custom administration have been identified as some of the chief culprits of impeded access.[2] After the presence of trained health professionals, medicines are the single most critical element in the maintenance of health and the successful treatment of disease and illness. Shortages of medicines because of several factors undermine the ability of healthcare workers to respond appropriately to patient needs and this in turn often erodes the confidence and trust patients and their families will have on local health systems. Most illnesses, especially transmittable diseases, are either preventable or to some extent treatable with a relatively small number of medicines. [3]However, accessibility of such medicine is being hampered by several factors which are becoming global concern for the past of couple of decades.

Basically, sequences of steps are required from the conceptualization and production of medicines to the dispensing of them and, at times these steps are complex. Medicines, seen as marketable commodities by many, are subject to commerce, tax and other policies and regulations both at national and international levels. States are attacking medicines by taking a number of different forms such as –free trade agreements, international treaties, and customs regulations[4]. Of the above reasons, the ones taken under custom regulation is causing a huge problem in which at several occasions pro access to medicine advocators calls for governments to take off their hand from taking of medicines under custom regulations.

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[1] (taskforce, 2012)
[2] (Ibid)
[3] (Ibid)
[4] (Ibid)

Ensuring access to medicine is undoubtedly contributing to the right to health which is by now embodied in many of the states domestic constitution. Access to health is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity[5]. This right is protected in major international human right instruments and further domesticated into states statutory enactments.

Ensuring access to medicines is a key and crucial point for several reasons. Clinicians facing sick and injured on daily bases can easily understand the importance of medicines[6]. But some unless they become sick and injured may not easily understand the benefit. Broadly speaking, giving due consideration to medicines has the following justifiable reasons:

- Medicines save life and improve health,
- Medicine promotes trust and participation in health system,
- Medicines are costly, and
- Medicines are different from other consumable products.

Despite the fact that access to medicine is the right, states are detaining medicines for infringement of customs regulations or simply put, under custom clearance procedure. Some states do have a procedure to detain and clear medicine, rules to follow and hence there are no arbitrary actions. On contrary, custom authorities in certain states tend to detain medicines without due process of law and compliance with laws under pretext of custom clearance. While so doing, states act is found to contravene human right instruments and other international instruments such as WTO rules specifically Doha round negotiation on access to public health.

The World Custom Organization (WCO) on the revised Kyoto Convention on standardization and harmonization of Custom administration calls the world to maintain custom control to the minimum necessary to meet the main objectives of the convention and requires them to carry out on a selective basis using risk management techniques

[5] (Ecosoc, 2000)
[6] (MSH, 2012)

to the greatest extent possible[7]. Here WCO gives much emphasize to minimization of risk in which denial of access to medicine is one those risks which needs a close consideration.

Ethiopia is also a member to World Custom Organization since 1973 in which the government commits itself to facilitate trade and its environment by simply ratifying the conventions[8]. Despite the fact that these conventions are regarded as part and parcel of law of the land, there are practical problems with regard to imported medicines as a result of which access to medicines fell under threat. There are reasons associated with delay in custom clearance and wrong seizure of medicines which this research paper discusses in detail.

2 STATEMENT OF RESEARCH PROBLEM

The world we live in had experienced an array of socio-economic, legal and other problems over the past couples of decades. One of such problem is the one associated with detaining of medicines and delay during custom clearance of medicines.

The power by states to detain medicines for custom clearance requirement principally originates from statutory declaration with in respective states. States are controlling medicines with an aim of balancing trade and also protecting sovereign authorities and health in their territory. Here controlling quality of medicines is essential as letting all imported medicines to the state will affect the health of society whereas, delaying for the sake of control also affects the health system.

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7. The World Customs Organization (WCO) was founded in 1952 as the Customs Co-operation Council, adopting its current name in 1994. Its early attempt is simplifying and harmonizing Customs procedures w/c resulted in the Kyoto Convention of 1973, & was put into force in the following year. Due to the shifting trade patterns, globalization, and constantly evolving technology – the WCO revisited the Kyoto Convention in 1999

8. In Ethiopia once ratification or accession to major international documents are made, they will be considered fortiori integral part of law of the land as enshrined in current constitution of Ethiopia article 9.

This shows the fact that, the major challenge of customs administration is balancing of administration and facilitation role. Controlling quality and the potential impact of such medicines is an administrative issue. On contrary, delaying the consumption of medicines is detrimental to the role of customs authority which is facilitation of movement of goods including that of medicines. On top of this, some state does have detailed rules, procedures and formalities for custom clearance while others are simply taking actions on medicines arbitrarily.

The existence of large gaps between availability of drugs and access to treatment in many poor nations led to the adoption of World Health Assembly resolution in May 2001; where states were rallied to explore systems for improving custom administration with a view to ensure access to medicines. [9]

Adding to the WHO resolution, others have called for the examination of custom rules and roles in supporting access to medicines. Although, there is now a growing consensus that medicines and other health commodities warrant preferential status from other products and services, this realization has not translated into action. For example, a 57-country study conducted by European Commission in 2003 examined issues associated with customs on pharmaceutical products used in the treatment of communicable diseases.[10]

The study found out that many of the countries that have weak custom facilitation have poor access to medicines. In Nigeria for instance, less than 20 percent of the population has access to essential medicines[11]. The figure is 25% in Ethiopia according to the 2005 E.C Ethiopian pharmaceutical association report on assessment of pharmaceutical sectors in Ethiopia. What explains this phenomenon? Possibly, it is a combination of several factors which contributed for this and various survey-based studies have lent further credibility to the position that absence of properly established custom role would jeopardize access to medicines improvement that would save thousands of lives.

[9] (WHO, 2001)
[10] (research, 2011)
[11] (Ibid)

Of course, we do not live, in an ideal world, meaning that tainted custom administration (no screening or inspection) leads to tax avoidance and unimpeded entry or exit of illegal medicines. This will expose the government to likely raise less revenue than it could and illegal medicines will slip over borders with impunity. Thus, Customs must strive to achieve the balance between administration responsibility and facilitation role.

Similarly, Ethiopian Custom Authority establishment proclamation (859/2014) grants to custom authority the power to detain goods because of several reasons of which failure to comply with custom requirement is one of it. In addition, the law sets maximum months (days) during which goods must be cleared from customs authority. According to the data I obtained from Food, Medicines and health care administration and control authority of Ethiopia (FMHACA), there are about 206 importer and whole sellers of medicines (both human and animals) in Ethiopia[12]. They are importing medicines/medical supplies after complying with formality requirements such as FMHACA health related requirements, bank related such as invoice, offer, letter of credit and custom related requirements such as bill of lading and related.

According to the Data I obtained from Ethiopian Customs authority on the questioner response given, custom clearance of medicines is taking an average of 8 days and they also detain medicines[13]. While so doing, there are different problems such as materialization of expiry date of the medicines, keeping in a store not recommendable for medicines which are prone to temperature such as antibiotics and other problems which traders of medicines are grappling with. Furthermore, customs delay and detaining of medicines arbitrarily is reducing health purpose of temperature sensitive medicines, deteriorating the health purpose of the product, damaging product carton and packing list, increasing theft and corruption, increasing cost of doing the business. I strongly argue that an account of all of these will result in denial of right to medicine as they will no longer serve their intended purpose.

12. (FMHACA, 2005, p. 23)
13. The figure is the one taken from Ethiopian revenues and customs authority based on annual declarations made on imported medicines. To that end, days of exit and entry of imported medicines for clearance were taken on average to calculate the exact date as it can be evidence in table 2 of chapter four of the research

Besides, despite the claim by Customs authority on number of days which custom clearance of medicines took, the World Bank study of trading across borders ranking puts the country at 104th in the world. While, on average, sub- Saharan African customs delays are the longest in the world, the average delay is 12 days in the region compared with 7 days in Latin America; the longest delays in the region are in Ethiopia - where the average trader has to wait 44 days for customs to clear goods.[14] The issue is then why delay, who is responsible for the delay, what are the causes, what is the implication of delay on access to medicines which this paper entertains.

3 OBJECTIVE OF THE PAPER

(i) OVERALL OBJECTIVE:

The overall objective of the research paper is to study the current problems and a constraint related to border clearance and seizure of medicines in Ethiopia and others and proposes actionable recommendations that help improve the business environment.

(ii) Specific Objective:

The specific objectives of the research paper are to:

- Describe how custom clearance and detaining of medicines by custom authority is regulated under Ethiopian legal system and other jurisdictions
- Describe what procedures are to be followed during custom clearance and detaining of medicines
- Correlate the procedures of custom clearance of medicines by custom authority of different jurisdictions
- Identify shortcomings and constraints of the current clearing system in terms of, among other things, customs and other legislations relevant to the importation and exportation of medicines, procedures and practices of customs
- Examine the nexus between Custom role in custom clearance, detaining medicines and access to medicine

[14] (2014, p. 166)

- Examine whether the current legal and institutional framework of the country provides conducive environment for ensuring access to health
- Indicate possible solution for the identified problems and inform stakeholders, mainly the government and its agents thereof

4 RESEARCH QUESTIONS

This paper tries to answer the following major research questions;

A. What are the major reasons for delay and detaining of medicines by customs authority?
B. What are the implications of delay of medicines on ensuring states obligation of access to medicine?

5 SIGNIFICANCE OF THE STUDY

This study will:

- Acquaint readers with the necessary knowledge as to the legal and institutional frameworks and arrangements on customs clearance of medicines in different jurisdictions and Ethiopia
- Inform the readers on the impact of delay of custom clearance of medicines by customs authority on access to medicines
- Shows the actual and potential problems that may impede the realization of access to medicines by customs authority under customs regulation
- Enable the government to come up with policy, law and institutional rearrangements to cope up with the challenges and pursue better customs role and development of access to medicines
- Serve as the basis for further studies in the area

6 METHADOLOGY OF THE STUDY

In this research, both qualitative and quantitative legal research methods have been used to study the Impact of delay of medicines by custom authority for custom clearance on access to medicines. The number of tools aimed at examining and describing the current practice of delay, both at global and domestic level and the

impact of such on access to medicine were utilized to substantiate the finding. The researcher used the 2013 annualized data of the ERCA in which more than 78% of custom clearance took at Kaliti, Modjo dry port and Bole airport terminal to validate the finding. Combining descriptive and **analytical** approaches, this research endeavors to find out the practices and rules on detaining of medicines under pretext of custom clearance and the impact of such on states obligations to ensure access to medicines.

Different literatures written on such area have been used to understand and analyze the practice of custom clearance of medicines by other countries on the stated research problem. Legislation's, conventions, declarations, books, journals, policies, plans of actions, strategies, unpublished materials such as reports, archives, judgments, and other materials released by different organs were also consulted. Also, electronic and print media were used to get the relevant information about the subject matter under discussion.

7 SCOPE OF THE STUDY

Although the practice of delay and detaining of medicines by customs authority is found in many states, the research focuses on specifically entertaining the practical problems and challenges of delay and detaining of medicines and its impact on ensuring access to medicines by taking Ethiopian Customs authority to substantiate the finding.

The research paper also includes the experiences of some other Africa's, USA, Europe and other Asians custom authorities to describe how delay of medicines in other jurisdictions is taking place and how the act is affecting access to medicines.

8 LIMITATION OF THE STUDY

Resources utilized in conducting this study in terms of time, finance and the resultant decisions have restricted the research to assess Ethiopian context only despite the fact that a comprehensive study could have been made as custom authorities are heterogeneous. Besides, customs authorities' employees' inaccessibility has also influenced the research to some extent.

9 STRUCTURE OF THE STUDY

The paper has been prepared in a structured form as indicated below. It has an aim of enabling readers to grasp the essential points on practice of detaining medicines by customs authority for custom clearance and the impact of such on access to medicines, and then to look more deeply into areas of particular interest backed by empirical evidences.

Chapter I present the general background, the research objective, research problems, key research questions which the paper tries to address and, methodologies pursued to conduct the study. Chapter II outlines the relationship between seizure and detaining of medicines, custom clearance and its human right perspective. While so doing it elaborates customs role and examines to what extent the customs authority are affecting states obligation of meeting right to health. Under Chapter III detailed overview about the practice of custom clearance of medicines in other jurisdiction is dealt with. In so doing, the legal regime regulating the act, procedures and other things were discussed. Besides, the implication of delay and detaining of medicines for custom clearance on access to medicine (health) is also discussed. Chapter IV deals with specific context of Ethiopian customs authority in their power and practice to control medicines under the guise of custom clearance and enforcement of custom law. In so doing, the statutory powers, practices and other issues were discussed. In addition, the relationship and the impact of custom clearance on access to medicines is also briefly discussed. Chapter V summarizes the whole paper and recommends actions to be taken to improve access to medicines and to contribute to the development of Human right and mitigation of unjustified customs delay and power.

Chapter 2 CUSTOM CLEARANCE AND DETAINING OF MEDICINES BY CUSTOMS AUTHORITY: UNDERSTANDING CUSTOMS AUTHORITIES ROLE AND REALIZING ACCESS TO MEDICINES

1 INTRODUCTION

Customs authority does have a wide range of responsibility. Of course customs role, major power and duties vary from states to states and they are subject to regular review

and modification to ensure their ongoing relevance in a constantly changing world. In many of the states, Customs has been responsible for implementing a wide range of government policies, spanning areas as diverse as revenue collection, trade compliance and facilitation, interdiction of prohibited substances, protection of cultural heritage and enforcement of intellectual property laws.[15] one of those areas where custom authorities are given power is implementation of customs regulation. While so doing, they are undertaking several functions in which delay of medicines is one of it and their act has been condemned for violation of access to medicines which is enshrined in many human right instruments.

Custom authorities are delaying custom clearance because of several reasons. Some goods are prohibited ones while some are restricted one which their importation demands a comprehensive scrutiny. The issue here is the difference between both; as both terms are commonly used in many states tax laws.

The main difference between prohibitions and restrictions is that -prohibited goods are never allowed to enter or exit under any circumstances whereas, restricted goods are allowed to enter or exit only in certain circumstances or under certain conditions, for example on production of a permit, certificate or letter of authority from the relevant government department, institution or body[16].

Examples of prohibited goods are cocaine's and related whereas, medicines fell under restricted goods as they need permission from concerned authority. For instance in Ethiopia, medicines will be examined by Food, Medicines and Health care control authority (FMHACA) before consumption by society[17].

[15] (Widdowson, 2013)
[16] (Article 11 of Customs proclamation)
[17] As indicated on article 5 of regulation 189/2010, one of the objectives of FMHACA is to ensure the safety, efficiency, quality and proper use of medicines. Article 5 of the regulation lists different kinds of objectives of the establishment of the authority (FMHACA) which inter alia includes food safety and quality, safety, efficiency and properness of medicines, competence and ethics of professionals, standard of health institutions, hygiene and environmental protection.

This chapter will discuss about what are medicines and accessibility, why custom clearance, role of custom authorities, procedures of clearance, and other issues associated with custom clearance and delay of medicines.

2 DEFINING MEDICINE AND ACCESSIBILITY

(i) Defining Medicine

The term medicine which is also known as pharmaceutical drug is defined in various ways in various jurisdictions. For instance, in Europe, the term is "medicinal product", and it is defined by EU law as: "(a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis[18].

In the US, a pharmaceutical drug is widely defined as: [19]

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device. As far as the US approach is concerned, biological products are also included within this definition and are generally covered by the same laws and regulations.

In Ethiopia, medicine is defined as any substance or mixture of substances used in the diagnosis, treatment, mitigation or prevention of a disease in human and includes narcotic drugs, psychotropic substances and precursor chemicals, traditional medicines,

[18] (27.2004, 2004)
[19] (US Federal)

complementary or alternative medicine; poisons, blood and blood products, vaccine, radioactive pharmaceuticals, cosmetics and sanitary items and medical instruments[20].

World health organization did also defined medicines which are essential. Accordingly, essential medicines are "those that satisfy the priority health care needs of the population[21]. It also lists essential medicines and further elaborates that selection of list of essential medicines is subject to due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. In addition, WHO also encourages states to have their own respective lists of essential conditions, as such listing is believed to enable the countries to critically set their priority for national drug policy and make decisions about how to allocate resource for health budgets. These, essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.[22]

(ii) Defining accessibility and access frame works

The WHO did not define what accessibility is meant. It rather, sets frame works under which accessibility needs to be measured. Many factors define the level of access, such as financing, prices, distribution systems, appropriate dispensing and use of essential medicines. World Health Organization has formulated a four-part framework to guide and coordinate collective action on access to essential medicines. These four frame works includes: availability, accessibility, acceptability and quality which among others includes sub elements such as impartial price information, implementation of generic policies, fair and equitable price, eliminate taxes, customs and duties on major essential medicines and related, sustainable financing, reliable supply system and rational selection and use of medicines are also pillar frame works mentioned by WHO[23].

[20] (661/2009)
[21] (WHO, Equitable access to essential medicines, framework for collective action, 2004, p. 1)
[22] (WHO W. W., Promoting access to medical technologies, 2013)
[23] (Ibid)

All of the above frame works are interrelated. For instance price increment of medicines can reduce patients purchasing capacity. Increment can be caused by several factors such as long days to clear as delay in clearance can increase transaction cost. Because the more delay in custom clearance, the more an importer will be exposed to additional expenses. To cover such expense, they may increase the selling price of such medicines which in a return will decrease the buying capacity of patients. The other issue is eliminating custom clearance of essential drugs. The world health organization in this frame work calls for elimination of custom administration requirement of essential drugs as custom administration enforcement can potentially delay clearance of medicines. Hence, I can boldly say that, the assumption behind calling for elimination of customs regulation on essential medicines and other frame work is associated with the fact that ensuring access is enhancing of right to health and delay of medicines for custom clearance will jeopardize access to medicines and hence denial of the right.

3 DEFINING CUSTOM CLEARANCE AND CUSTOM CLEARANCE PROCEDURES

All countries have in place some customs controls for revenue generation, domestic economic interests, and national security purposes. While there are similarities between countries (like the need for shipment documentation, including commercial invoices and Bills of Landing) there are local, specific requirements that have to be addressed. Leaving the difference beside, let me capitalize on defining of custom clearance and major procedures involved during custom clearance.

Broadly defined, customs clearance is the set of functions undertaken by a national customs authority, which include, but are not limited to:

- ✓ Processing of import, export, and transit declarations
- ✓ assessment of origin, value, and classification of goods
- ✓ collection and processing of duties and fees
- ✓ physical inspection, examination, and release of cargo
- ✓ conduct of post-clearance audits
- ✓ processing of urgent consignments

- ✓ Administration of waivers and exemption schemes and drawback (re-exportation) schemes[24].

Principally, custom clearance involves a series of steps, which are terms of trade deal (quantity, price, payment method, and terms of shipment), declaration of goods, terms of insurance, custom payments and related steps. Development of Customs clearance in terms of time, cost and other factors is in rapid evolution across the world. Such development could be described from three stages namely; from physical inspection and paper work, from reduction of fraud and maximization of revenues and finally from facilitation of trade through internal checks, process management, and development of electronic device data exchange.[25]

The latter stage which is facilitation of trade calls for enhancing of speedy clearance and avoiding of unnecessary delay and seizure. This is so because, delay in custom clearance under the guise of border measures increase transaction costs for traders of medicines and will ultimately jeopardizes enjoyment of access to health which includes access to medicines as one component. As a result of elongated custom clearance for imported goods in general and that of medicines in particular, undertaking business in states where there is custom related problems have impeded business, jeopardizes right to health and hinders trade facilitation. Hence, reducing such border-crossing times has been identified as a key element in achieving development goals of states and facilitation of trade[26].

The commission for Africa on its 2005 report states that, Africa needs custom reform. The commission further stresses the fact that Africa suffers from highest average custom delay in the world, 12 days on average. Estonia and Lithuania seeks one day for custom clearance while Ethiopia averages 30 days. Delay in custom is found to contribute to 10% costs of export and import[27].

[24] (Gerald, 2005)
[25] (Ibid)
[26] (Appels, 2008)
[27] (Kireeva, 2013)

4 ROLE OF CUSTOM AUTHORITY DURING CUSTOMS CLEARANCE

The responsibilities of customs authority vary from country to country, and are often the subject of regular review and modification to ensure their ongoing relevance in a constantly changing world. Traditionally, however, Customs has been responsible for implementing a wide range of government policies, spanning areas as diverse as revenue collection, trade compliance and facilitation, interdiction of prohibited substances, protection of cultural heritage and enforcement of intellectual property laws[28].

This breadth of responsibility reflects the fact that customs authorities have long been entrusted with administering matters for which other government ministries and agencies have policy responsibility, such as health, agriculture, environment, trade statistics and in some cases, immigration. This is generally achieved through the implementation of a diverse range of service level agreements, with Customs having regulatory responsibility at the point of importation and exportation. Such border management responsibilities stem from the more traditional customs role of collecting duties on internationally traded commodities, a common extension of which is the collection of other forms of tax, such as Value Added Tax (VAT) and excise duties[29].

For several decades now, there has been mounting pressure from the international trading community to minimize government intervention in commercial transactions, and a growing expectation for customs authorities worldwide to place an increasing emphasis on the facilitation of trade in which unjustified delay during custom clearance, illegal detaining and other points were figured out to be obliterated so as to facilitate trade[30].

Therefore one can conclude that apart from collection and controlling of goods imported and exported, roles of custom authorities in our classical world is facilitation of trade, promotion of human rights and other corporate responsibilities. The custom authorities are having different kinds of corporate responsibilities. These responsibilities are

[28] (Widdowson, 2013, p. 1)
[29] (Ibid)
[30] (Id, p. 2)

environment related, public security and related. For instance, if we take enforcement of illicit goods, one of the enforcement mechanisms is burning of such good. In so doing, place where such act has to be taken and steps are required to be environmental friendly.

5 PRINCIPLES OF CUSTOMS CLEARANCE PROCEDURE

Now days, many countries are striving to simplify clearance procedures of their customs administration in a bid to ease the cost of doing business to importers and exporters, thereby benefiting the national economies as discussed earlier. It is because of these compelling reasons that the custom clearance procedure is under continuous change. Hence one can understand that the major custom clearance procedures are: simplicity, decreasing cost of doing business and benefit to national economy.

To ensure and maintain the principles uphold, many countries are conducting time release studies following the guideline developed by the WCO. As defined by World customs organization, a Time Release Study (TRS) is a systematic and standardized way to measure the average time taken between the arrival and release of goods, and can also be used at each step. It is a diagnostic tool providing concrete baseline data for identifying any bottlenecks in the clearance process and logistics. It helps to evaluate the impact of reform or modernization initiatives taken by the public and private sectors for custom clearance. [31]

The implementation of the TRS (time release study) has brought changes in some countries. For instance, Ghana has brought a significant change in simplifying custom procedure, expediting custom clearance times, and increasing revenue collection. Besides, it also contributed for the development of other state obligation like ensuring of access to essential medicines, responding to customers need and related. [32]

Therefore, states are endeavoring to maintain their custom rules consistent with basic principles advocated by world custom organization which is calling states to make their custom system simple and expedious and beneficial to national economy.

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[31] (Organization, 2013)
[32] (Ibid)

6 RELATIONSHIP BETWEEN RIGHT TO ACCESS TO MEDICINES, RIGHT TO HEALTH AND RIGHT TO LIFE

Health is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity. As articulated by the United Nations Economic and Social Council, and as I have discussed in earlier part of the paper, right to health contains both freedoms and entitlement. The freedoms include the right to control one's health and body and the entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health. Furthermore, the right to health is an inclusive right, extending not only to timely and appropriate health care, but also to the underlying determinants of health and right to health is broad concept that can be broken down into more specific entitlements including access to essential medicine.[33] From the above sentences, it can be concluded that right to health is an inherent part of right to life with entitlements including access to medicines. Hence, the human rights dimension of access to medicine has provided an important legal and policy vantage point for consideration of public health and pharmaceutical issues both internationally and domestically.

7 APPLYING THE JUS COGENS OF INTERNATIONAL HUMAN RIGHTS LAW TO MEDICINES SEIZURES CASE

Jus cogens also known as a peremptory norm of general international law is a norm accepted and recognized by the international community of States as a whole as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character. [34]

According to this definition, an important requirement for a norm to attain the status of peremptory norm is that it should be accepted and recognized by the States as a whole. That means, there has to be established state practice of a norm without any derogation. Applying the same analogy, one can say that the norms of human rights as specified in the Charter of United Nations, the Universal Declaration of Human Rights (UDHR) and their replication in the subsequent treaties like the International Covenant

[33] (Suppandi, 2012)
[34] (Article 53 of the Vienna Convention of Law of Treaties)

on Civil and Political Rights (ICCPR), the International Covenant on Economic, Social and Cultural Rights (ICESCR), the American Charter of Human Rights, the African Charter of Human and People's Rights, the European charter of Human Rights as well as many other UN' and its subsidiary agencies declarations and conventions have embodied access to medicines as one component and hence, it is logical to deduce that access to medicines should have attained the status of jus cogens .

As an essential and important human right, right to life, right health and right to access medicines are also guaranteed under various conventions as I have tried to discuss earlier. For example, Article 25 of the UDHR states that everyone has the right to a standard of living adequate for the health and well-being of himself and of his family including food, clothing, housing and medical care and necessary social services and the right to security in the event of unemployment sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control. Article 12 of ICESCR enshrines right to health as the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and a duty is imposed on the state to take steps to provide conditions which would assure all medical services and medical attention in the event of sickness. Right to health is also guaranteed under various conventions. Article 16 of the African Charter of Human and People's Rights also says that very individual shall have the right to enjoy the nest attainable state of physical and mental health. Replication of right to health in all these conventions and its inclusion in states domestic laws and practice shows the fact that access to medicine is recognized as right to health. Given these facts, seizure of medicines by states for various reasons more specifically illegitimate reasons shows the fact that it is violation of the human right provision which entitles citizens to have access to medicines.

8 APPLYING THE JUS COGENS OF INTERNATIONAL HUMAN RIGHTS LAW TO MEDICINES SEIZURES DISPUTE SETTLEMENT CASE

On this part the discussion is about how jus cogens of international human rights law as discussed above is supposed to be applied in disputes associated with seizure of medicines. To that end, custom measures taken by Dutch customs authority on Indian manufactured drugs on their route to Brazil and Nigeria will serve as an empirical case. It was on December 4, 2008, a 570 kilo consignment of Indian-manufactured generic

medicines on a route to Brazil was detained by Netherlands customs officials in port. The medicine detained was “losartan potassium”, a product that is not patented in either the country of origin or in the country of destination, and was not meant for domestic use within the European Union. Again, on March 4, 2009, a forty-nine kilo shipment of generic “abacavir sulfate”, a second-line HIV/AIDS medication, on a route from India to Nigeria was detained by Dutch customs authorities under the claim that it contained counterfeit goods.[35]

From the outset, India and Brazil claimed that the Indian consignments seized by Dutch customs authorities contained legal goods. Aside from this issue, India and Brazil further argue that Dutch customs authorities did not detain the Indian consignments temporarily, as would be permissible by international trade rules. Instead, the Dutch not only held India's shipments for months, but also initiated procedures to destroy the medicines. India and Brazil maintain that such actions constitute a confiscation of goods and run counter to the spirit of both GATT and TRIPS. [36]They claim that an in-transit seizure of goods violates the freedom of transit provision of GATT Article V, and is inconsistent with the mandate of the TRIPS Agreement that all enforcement procedures against goods involving IPRs should neither bar legitimate trade nor be used abusively.

The EU, on contrary, claims that Dutch customs authorities detained India's consignment of losartan potassium in conformity with EU regulations (regulation no 1383/2003) and international trade rules. In defense of the Netherlands, the EU states that the Dutch actions comply with both Article V of GATT, which permits customs authorities to suspend the release of goods, and Article 51 of the TRIPS Agreement, which allows customs authorities to temporarily detain any good suspected of infringing an intellectual property right. The EU maintains that it has no intention to hamper any legitimate trade in medicines or create legal barriers to prevent movement of drugs to developing countries. [37]

[35] (Koberg, 2009)
[36] (Ibid)
[37] (Ibid)

The issue now is, can jus cogens as discussed above will be applied to resolve such kind of dispute by World Trade Organization? The law applicable to the WTO disputes is discussed in the rules set in the WTO Dispute Settlement Understanding (DSU).[38] Article 3.2 of the DSU mandates that, interpretation of the WTO agreements shall be in accordance with the customary rules of interpretation of public international law.[39] On other hand, the Law of Treaties which provides the customary rules of interpretation prescribes that a treaty is void if, at the time of its conclusion, it conflicts with a peremptory norm of general international law.[40] In the present case of medicines seizure as justified under the EC Regulation 1383/2003, two issues have to be resolved. One is EC regulation which is in violation of the WTO and the TRIPS Agreement. Second is the WTO member's obligation to be bound by peremptory norms of international law. Considering the actions taken by Dutch customs authority to the present case of seizures, it is logical to deduce that, Dutch custom authority have violated the international human right norms which are peremptory norms of international law.

Furthermore, as already established earlier, the right to health and access to medicines are inherent parts of right to life which is already a peremptory norm of international law. And it is also a wise approach to understand that WTO member states are bound by their human rights obligations and they cannot derogate from their obligations which are also peremptory norms of international law. Therefore, according to Article 53, it would be right to say and conclude that EC Regulation 1383/2003 has not only violated the WTO and peremptory norms of international law but has also violated its obligations towards human rights.

From the above drawn conclusion and from acts of Dutch customs authority on medicines on transit, one can grasp the following basic facts.

a. There exist strong linkage between right to health and access to medicines. When states took an action on access to medicines, such act in one way or another will influence citizen's right to access to health.

[38] (agreement)
[39] (DSU)
[40] (treaties)

b. Seizing medicines by states is violating of states obligation towards ensuring access to medicines which is a non derogable human right commitment of states.

Chapter 3 CUSTOM CLEARANCE AND DETAINING OF MEDICINES BY OTHER STATES CUSTOMS AUTHORITY AND ASSESSING THEIR IMPACT ON ACCESS TO MEDICINES

1 NIGERIA

(i) Overview about Nigerian custom system

Nigerian custom system has gone through numerous reorganizations, leadership changes, and changes of jurisdiction since independence of Nigeria in 1960. But its current form, in terms of structure, mission and technology, can traced back to 1999 following the restoration of democracy into the country in general and final reorganization of NCS in 2004[41].

Since 2004, NCS has brought a significant change on areas of; pre-shipment inspection by introducing destination inspection (DI) regime: introduced ASYCUDA++, increase salary and provided on job and off job training to staff, furnish physical and ICT

[41] (NCS, 2012)

infrastructures and built partnership with World custom organization to better modernize custom clearance.[42]

(ii) Role of Nigerian custom authority

Nigerian custom authority principally entrusted with the power of serving the interest of Nigerians by facilitating the legitimate commerce that enriches the nation and protecting the nation from threats that will affect the economy, citizens and development of the country. The major core responsibilities of Nigerian custom authority among others include: [43]

- ✓ Collecting and accounting of revenues from Customs and Excise.
- ✓ Anti-smuggling activities to safeguard the country from dangerous imports or exports and developing national economy.

Nigerian customs authority works in collaboration with other government agencies[44] such as:

A. The Standards Organization of Nigeria (SON) and the National Administration for Food and Drugs Administration and Control (NAFDAC), to ensure that imported goods are legal and safe for Nigerian businesses and consumers;

B. The National Drug Law Enforcement Agency (NDLEA), to combat the scourge of illegal narcotics;

C. The State Security Service (SSS), Nigeria Police Force, Military Intelligence, and others to combat the flow of illegal weapons that can fuel criminality and terrorism in the homeland.

(iii) Custom clearing and forwarding in Nigeria

Basically, custom clearing in Nigeria took place after complying with the legal requirements needed for the purpose. The major documents required are[45]: Certificate

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[42] (Ibid)
[43] (Ibid)

[44] (Id, pp. 24-25)
[45] (Id, pp. 53-55)

of Origin (CO**)** which will be utilized to verify where the goods in a consignment were produced, Combined Certificate of Value and Origin (CCVO) which will serve to outline details about labor and packing costs, royalties or commissions (if applicable), freight charges and any overseas insurance costs, Pro-Forma Invoice (PFI) which describes detailed pints on quantity of goods imported, weight and other issues, packing list, bill of lading, phytosanitary documents and others such as bill of inspection by NAFDC. Custom clearing in Nigeria commences by filling of Form M which will be issued by central Bank of Nigeria and attaching of all necessary documents indicated above with customs authority.

Having saying so the next issue is then how many days will custom clearance in Nigeria took, what procedures are followed during delay in custom clearance? Who is responsible for delay and detaining of medicines are the issues.

As far as the custom clearance days of goods in general and that of medicines in particular are concerned, it has been progressively improving from time to time in Nigeria. According to the World Bank doing business report, number of days for clearing of custom slightly reduced from 53 days to 39 days in 2011 and to 5 days in 2014[46]. Introduction of ASYCUDA++, single window, and other automation coupled with reduction of number of signatories from 71 to two or three in 2014 has contributed for the improvement of custom clearance delay.

Despite the improvement, the Nigerian custom authority is still working to reduce number of days custom clearance is taking. The Nigerian custom system is suffering from lack of custom integrity, duplication of clearance or works as several agencies involved in clearing wants to do the same thing, involvement of too many agencies and weak coordination between them, inadequate infrastructure, and compliance shortcomings.[47]

The World Bank report in doing business calls for the improvement comparing Nigeria custom administration with other neighboring states given the economic position of the

[46] (WB, Doing business report, 2013)
[47] (NCS, 2012, pp. 44-46)

state. For instance Nigeria, when compared with its Neighbors has still a lot to work to reduce delay in custom clearance as it only took one day in Liberia, four day in Senegal and three days in Ghana. [48]

As far as detaining of medicines is concerned, Nigerian customs authority has detained medicines at several occasions. For instance, on the Customs today report[49] of March 5, 2015, the National agency for food and drug administration and control authority declared one of the importer of medicine as most wanted as he is found to contain counterfeited drugs valued about N1 billion. There are many of such instances in Nigeria in which counterfeited drugs were detained as detaining of such medicines is also part of the responsibility of the NCS which says protecting the nation from threats which is directed against the citizens and economy. However, many of the pro health advocators calls government action detrimental to access to health as protecting counterfeited drug is a private right while ensuring access to health is a collective right. Besides there are also instances where NCS wrongly detained medicines but latter official excuse was made. However, it was found out that such approach is unfair and contrary to ensuring citizens right to health.

The NCS on its 2014 report states that the number of seized drugs has decreased from 3114 in 2006 to that of 2895 in 2012 and that of 2214 in 2014. The figure is promising but, according to the World Bank logistic performance index, the NCS has a lot to do as the country stood 75 on the world[50]. Problems such as in adequacy of infrastructure, outsourcing of quality control to other agencies, inadequacy of man power, corruption and in efficient collaboration between stakeholders are contributing for the delay and wrong seizure as pointed out in the earlier part of this study

2 INDIA

(i) Overview about Indian custom system and role

India is a country that imports medicines and other goods to other developing countries. The Customs Act of 1962 is the basic statute which regulates the entry/exit of different

[48] (paper, 2012)
[49] (Nawaz, 2015)
[50] (WB, Logistic performance index , 2014)

categories of vessels/crafts/goods/passengers etc., into or outside the country. Various allied laws and regulations also apply. As far as administration of custom in India is concerned, there are several departments that are operating under the department of revenue. It is the Central Board of Excise and Customs (CBEC or the Board) of India that deals with the formulation of policy concerning levy and collection of Customs and Central Excise duties and Service Tax, prevention of smuggling and administration of matters relating to Customs, Central Excise, Service Tax and Narcotics. [51]

When we come to the role of Indian customs, the important Customs related functions which the board deals with includes: [52]

a. Collection of Customs duties on imports and exports as per the Customs Act, 1962 and the Customs Tariff Act, 1975;
b. Enforcement of various provisions of the Customs Act, 1962 governing imports and exports of cargo, baggage, arrival and departure of vessels, aircrafts etc
c. Discharge of agency functions and enforcing prohibitions and restrictions on imports and exports under various legal enactments;
d. Prevention of smuggling including interdiction of narcotics drug trafficking; and
e. International passenger clearance

India, as a member of the World Customs Organization, has adopted various International Customs Conventions and procedures including the Revised Kyoto Convention, Harmonized Classification System[53], and GATT based valuation etc.[54] besides; India has introduced a Risk Management System (RMS) [55] to reduce dwell in clearance time, reduce cost of transaction and to facilitate trade.

Customs authorities are given appropriate office place and requisite facilities in the dock area as well as in international cargo complexes/ICDs etc., to discharge their functions in relation to imports and exports such as supervision of loading/unloading of goods

[51] (India, 2014)
[52] (Ibid)
[53] (Risk Management System (RMS) is a system introduced to examine goods that are believed to be risky and facilitate the remaining ones. In so doing)
[54] (The Harmonized Commodity Description and Coding System of Tariff Nomenclature)
[55] (Customs valuation is a customs procedure applied to determine the customs value of imported goods. As indicated on article VII of GATT)

from vessels/crafts etc., supervision of stuffing or de-stuffing of containers, inspection and examination of goods which are imported/presented for exportation before Customs clearance formalities etc.

In India, like in any other jurisdictions, there exist restrictions and prohibitions on imported goods. Prohibited Goods" are defined in Section 2(33) of the Customs Act of 1962 as "any goods the import or export of which is subject to any prohibition under the Customs Act or any other law.[56]

(ii) Custom clearing and forwarding in India

In India, before any imported goods can be cleared for home consumption or warehoused for subsequent Customs clearances, the importers as well as exporters are required to comply with prescribed Customs clearance formalities.[57] Essentially, these involve presentation of certain documents along with a prescribed application normally termed 'Bill of Entry' which gives essential particulars in relation to imported goods, country of origin, particulars of vessel/aircraft seeking clearance of goods for home consumption/ warehousing etc.[58] The importer either himself handles the import clearance documents or appoints Customs Brokers,[59] who are trained and experienced in Customs clearance work and are licensed by Customs for such work in terms of the Customs Broker Licensing Regulations, 2013. While so doing, they have significantly reduced time clearance of imported or exported medicines as they are well trained on clearance.

(iii) Issues for concern in custom clearance delay and detaining of medicines in India

In India, seizure and delay in custom clearance along its consequence is regulated by 1962 custom act. Normally, the goods liable for confiscation under the Customs Act, 1962 are seized by the Customs. However, in some cases where seizure is not practicable, the goods can be detained for further investigation. The provisions for detention of goods are contained in Section 110 of the Customs Act, 1962. The goods

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[56] (Id, p. 69)
[57] (Id, pp. 21-22)
[58] (Ibid)
[59] (Custom Brokers are those that work on behalf of importers. According to the Indian custom act)

are detained for various reasons and at the instance of various agencies such as the Directorate of Revenue intelligence, the Directorate of Central Excise Intelligence, Narcotics Control Bureau and Directorate of Enforcement and even other agencies, like the Central Bureau of Investigation. Once order for detention of goods is served to the owner of the goods, he cannot remove, part with, or otherwise deal with the goods except with the prior permission of the proper officer of the Customs.[60]

The Indian Custom act in addition to giving the power to detain medicines, it also imposes an obligation to cover the warehouse cost by importers even though the detention/seizure is finally found to be improper/illegal as the Apex Court of India examined the matter in the cases of International Airport Authority of India vs. Grand Slam International 1995 and Trustees of Port of Madras vs. Nagavedu Lungi & Co. in 1995.[61]

Besides, to avoid delays in the release and minimize hardship to the trade of goods, an expeditious assessment/investigation can be made subject to certain procedural requirements. In so doing, the custom act of India plays a pivotal role in avoiding unnecessary delays. On top of this, there is also a citizen charter in which the customs operators commits themselves to provide service as early as possible there by setting service delivery time of maximum five hours. The charter, requires the officers to carry out their assigned tasks with integrity and judiciousness; courtesy and understanding; objectivity and transparency; promptness and efficiency.[62]

India has taken certain measures to overcome the problems associated with wrong detention and delay in custom clearance of medicines in particular and that of goods in general.[63] These measures are; provision of management Information system (MIS); a system that generates daily report of bill of entry and provides information to importers and exporters, accessibility of senior officers to respond to application by complaints, establishment of different committee such as public grievance officer committee, watch dog committee and trade facilitation committee.

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[60] (Id, pp. 130-133)
[61] (Id, p. 249)
[62] (Ibid)
[63] (Ibid)

Despite the above reforms taken in India, the country stood 54th scoring 3.54 out of 5 scaling according to the 2014 World Bank logistic index report and the country goes from 47 in 2007 to 54 in 2014.

The issue is then why the country is taking days to clear? Why its status went down? For these questions, a number of reasons were figured out. Among them poor infrastructure, inadequate man power and weak coordination were the major ones as pointed out by World Bank logistic performance index of 2014.

India as one of the major exporting medicines to Africa and other developing states has suffered a lot by acts taken by other states custom authority. For instance, as discussed in earlier part of this paper, Dutch custom Authorities have detained Indian manufactured drugs for the fact that these drugs are counterfeited and hence contrary to European Commission regulation and TRIPS. The government of India did object to the act and did submit formally to WTO an application justifying the nature of medicines and objecting to seizure alleging that it is contrary to TRIPs agreement. This shows that, the problem is still pending and ensuring access to medicines demands a cautious approach. This is so because, on the Doha Declaration signed by developed and developing WTO member countries alike, members have agreed that: “the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Members have accordingly asserted that, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all. [64]

3 OVERVIEW ABOUT FRENCH CUSTOMS AUTHORITY AND ROLE

French custom authority as a signatory member of Anti counterfeiting trade agreement, it has shown a remarkable achievement since 2013. The service it provides and providing has been improved since then. The French custom authority is the oldest in Europe and contributed a lot for the development of custom laws in many of European

[64] (WTO, 2001)

countries. As indicated in the French custom law, the major responsibility of custom authority inter alia includes: [65]

- Collecting of revenues from imports and exports
- Supporting French economy and facilitating international trade
- Protecting the country from illegal goods and related

In 2013, a strategic five-year plan[66] for French Customs was drawn up. The plan is a response to a request, by the ministers responsible for the economy, foreign trade and the budget, that the Directorate General of Customs and Excise carry out its mandates in a more efficient manner, in line with the best practices of EU customs administrations, to support the competitiveness of the French economy, effectiveness and responsive taxation, and the protection of France's territories and citizens, while striving to provide the best working conditions for its employees[67]

French custom authority as a country is a member to European commission; has ratified a convention called anti counterfeiting trade agreements shortly called ACTA) and is a signatory to European Union custom regulation. [83] Based on the enforcement of ACTA French custom authority has detained a large number of medicines on transit at several occasions which has been subject to criticism by pro access to medicines advocators.

(i) Custom clearance in French and issues of concern for custom clearance delay and seizure of medicines

French custom authority has a remarkable achievement in terms of time clearing of goods in general and that of medicines in particular. Like in any other jurisdiction, a number of documents are required to clear imported goods into French territory. These documents inter alia include; invoice, document about quantity and other issues related with imported goods.

One of the most key peculiar features of French custom system is introduction of single window service, provision of paperless service and fully fledged infrastructures. While

[65] (communication, 2013)
[66] (The five year strategic plan is called the Douane plan and it calls for greater professionalism in risk analysis)
[67] (communication, 2013, p. 28)

so doing, the custom system has clearly understood the benefit of cutting waiting times for clearance and lowering of costs of businesses by providing just-in-time service, falling costs, speed, fluidity, safety. [68.] In the space of 10 years, the average customs clearance time has been cut by two thirds which is 4 minutes 30 seconds against 13 minutes in 2004. [69] The strength of French custom system is also witnessed by the World Bank on the performance logistic index of 2014. Accordingly, the country stood 13th in terms of the overall performance index and timeliness of clearing goods on the world. Several factors such as online processing of supporting documents, online publication of requirement for custom clearance procedure, involvement of skilled custom clearance brokers and single window service has contributed for the status of French.

Despite expedite custom clearance, French custom authority have detained medicines subject to enforcement of European commission regulation[70]. They particularly detained them for the sole fact that these medicines are believed to be counterfeited ones. But the concept of counterfeited is still confusing and creating a huge loophole on accessibility of medicines. The impact of detaining medicines for the fact that they are counterfeited will be discussed after discussion of USA custom system will be made.

4 OVERVIEW ABOUT USA CUSTOM, THEIR ROLE AND CLEARANCE

The 2001 September attack on USA has to some extent influenced the country in having strict border regulation. The country since then has strict border protection measures and has well facilitated facilities to undertake the custom clearance. According to the World Bank logistic performance index of 2014, the country stood 9th in terms of performance but in terms of custom it stood 16th on the world.[71] The custom administration in USA is decentralized one and is based on custom act of 1930 as amended. In addition to the custom act, the country has also ratified anti-counterfeiting agreement.

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[68] (Ibid)
[69] (Ibid)
[70] (IP)
[71] (WB, Trade logistic performance index and its indicators, 2014)

As far as importing medicines to the USA is concerned, there are certain requirements enacted by Bureau of customs and border protection (BCBP) as in any other jurisdictions. Foreign firms that manufacture medicine and medical devices must comply with applicable U.S. regulations before, during, and after importing into the U.S. or its territories.

Accordingly, in order to import medical devices and/or products into the U.S., the product must meet FDA (Federal and Drug administration Authority) regulatory requirements in addition to Bureau of customs and border protection requirement.[72] FDA does not recognize regulatory approvals from other countries and hence each importers and exporters of medicines must comply with drug regulation enacted by the above stated authority only. These requirements inter alia includes; registration establishment, listing of devices and product, manufacturing in accordance with the quality system regulation, and Premarket Approval if applicable.

The major responsibility of BCBP is to administer the Tariff Act of 1930 as amended. Primary duties include assessment and collection of all duties, taxes, and fees on imported merchandise; administration and review of import entry forms; the enforcement of BCBP and related laws.[73] The custom clearance process begins by submitting the necessary entry information to the local BCBP district office. Entries will be made electronically and under exceptional circumstances paper entry is permitted.[74] The USA government owning to the importance of medicines, custom clearance is taking place expediently. On contrary however, the custom authority under counterfeited medicines, have detained a large tones of medicines. The custom authority justifies its act under the pretext that it contributes to protecting and developing of IP whereas, others are challenging it as the anti-counterfeiting agreement create a wider room for abusing facilitation role of customs authority promotion of access to medicines.

[72] (protection, 2014, pp. 32-34)
[73] (Ibid)
[74] (Ibid)

5 POLICY AND OPERATIONAL LESSONS FROM EXPERIENCES OF ABOVE STATES.

Administration and facilitation role of custom varies from state to state. Since recently however, many of the roles of custom is more or less becoming similar in nature. Under the current custom system, the policy orientation is towards facilitating international trade, contributing to the wellbeing of citizens such as facilitating right to health and related.

In Nigeria, clearance procedures were tedious and costly in terms of required documentation and procedures, resulting in lengthy clearance times. Clearance procedures often included redundant verifications and multiple steps that lacked business rationale whose objectives were overtaken by modern business practices. Also, in most cases all shipments were subject to physical inspection, and procedures were largely paper-based and inadequately supported by customs IT. In addition, corruption, lack of deploying well qualified and trained employees are major problem. In India, the custom system is relatively better but the practical problems such as detaining for custom clearance did exist on medicines it exported. Such detention will increase the cost of medicines as according to their law, such cost will entirely be covered by an importer or exporter of medicines. This in turn will increase the cost of medicines which will ultimately reduce the purchase capacity of patients thereby denying access to medicines.

India also suffers a lot from acts taken by other states custom authority such as Dutch custom authority and other EU members. The French custom in terms of clearance time has a remarkable achievement and there are several reasons that contributed for this. Introduction of single window service, provision of paperless service, fully fledged infrastructures and involvement of skilled custom clearance brokers are inter alia factors. However, the country still detains medicines for counterfeiting and the number of such detained medicines has been increasing over times. The USA approach also resembles that of France. Both USA and France are signatories of anti counterfeiting agreement and the agreement entitle them to seize or detain medicines for infringing of IP rights. Generally speaking the following major points can be grasped from practices of aforementioned states:

a. As medicines are the most important goods, states are taking reforms in order to ensure their availability, accessibility and utilization by patients and those who needs medicines. They also discovered that, temporary delays of medicines means denying patients of having access to life saving drugs as medicines are different from other goods.
b. As far as delay and seizure is concerned, many of pro access to medicines are challenging them from the fact that it is contrary to Doha declaration signed by World trade organization. Indians are the forerunners in advocating the approach. They further elaborates that, the Doha Declaration, signed by all members of the World Trade Organization, affirms that TRIPS can and should be interpreted and implemented in a manner supportive of right to promote public health. Hence, seizure of medicines particularly for enforcing of intellectual property rights violates Doha declaration agreement which puts access to public health as a right to be enjoyed by citizens.
c. The states must balance the responsibility of controlling medicine in terms of quality, efficiency and effectiveness from that of protecting of privates right for infringement of intellectual property rights. The justification behind the argument is that, protecting public health's right is a bigger one and must be given priority than protecting individuals rights whose rights were infringed and are most commercial in nature.
d. Enabling custom authorities to detain medicines on a mere allegation of the claim of infringement of right by right holder paves away for abuse of border measures as claiming without showing prima facia evidence threat access to medicines . Furthermore, actions by states custom authority under protecting intellectual property rights such as seizure and detention of medicines, temporary injunction and related undermines judicial role of protecting right to health and balancing of private intellectual property rights with larger public interest.

Generally, effective customs operations and ensuring of access to medicines consist of coherent and interlocking sets of processes and integration among stakeholders. An overall customs reform program which needs to be placed to achieve the intended

outcome plays a greater chance of yielding effective and sustainable results in ensuring access to medicines. Such reform demands, political support and continuity of leadership for its success. The reform must be realistic and consist of measures that can be implemented. They includes strengthening application of IT-based customs processing, full automation of clearance procedures, placing adequate and skilled man power, well furnished infrastructure, well educated brokers, integrated and holistic policy, comprehensive benefit packages and committed leadership are among the strategies to deal with the problems associated with delay in custom clearance and detaining of medicines with ultimate target of enhancing access to medicines.

Chapter 4 DELAY OF CUSTOM CLEARANCE AND DETAINING OF MEDICINES BY ETHIOPIAN CUSTOMS AUTHORITY

1 ANALYSIS OF ETHIOPIAN CUSTOM LAW AND POLICY

The Ethiopian custom law is characterized with frequent amendments and changes. It is not only the law that underwent changes, but also institutional structural adjustment of the authority did also. The current customs administration is the responsibility of custom division under Ethiopian revenues and customs authority (ERCA). Ethiopian Revenue and Customs Authority (ERCA) came into existence on 14 July 2008 by the merger of the Ministry of Revenue, Ethiopian Customs Authority and the Federal Inland Revenue Authority. The merger is the result of the BPR conducted in 2007. The study was conducted to enable the authority to: [75]

- Collect customs revenue effectively;
- Meet requirements of trade and investment;
- Effectively control the import and export of prohibited and restricted goods;
- Protect legal traders from illicit trade;
- Record and maintain reliable trade statistics; and
- Protect the system from vulnerability to corrupt practices.

[75] (ERCA, 2007)

The BPR conducted did also recognize certain problems with regard to custom clearance procedures. The study reveals that there is a cumbersome procedure; there is duplication of efforts, lengthy documents, lack of delegation of authority, unnecessary delay because of controlling illicit goods and related. [76] The major responsibility of custom authority can be found in the customs establishment proclamation preamble (procl 859/2014) paragraph I and II. Accordingly, the custom authority is mandated to encourage development of investment and manufacturing industry with a view of expediting customs and contributing to growing needs of international trade and having strong enforcement to control contraband and other illicit activities. As far as role of custom authority is concerned, its major role inter alia includes; revenue collection, facilitating of trade and combating smuggling.[77]

2 CUSTOM CLEARANCE PROCEDURE

A number of documents and steps are required to clear imported goods including that of medicines to Ethiopia. The standard processes for the clearance of, for instance, imported pharmaceutical drugs[78], include the following steps:

a) Submission of complete import declaration by importer. The declaration must be complete one and has to be supported by other supporting documents as discussed on article 9 & 10 of procl 859/2014. It has to be noted here that absence of the supportive documents will not bar an applicant from commencing the custom clearance as provisional goods declaration can be allowed. However, the declaration must contain a basic information and other remaining should be furnished with in specified period authorized by authority.[79] But the problem here is lack of uniformity in number of granted days and subjectivity of the days to concerned authority.
b) Medicine importer states his intent for import by completing an Import Declaration Form (IDF) on the Customs Server; which is currently ASYCUDA++. After complying with supportive legal documents, inspection, classification and

[76] (Ibid)
[77] (preamblel)
[78] (By pharmaceutical drugs, I am referring to section 6 chapter 30 of Ethiopian revenue and customs authority 2007 harmonized system of tariff version, volume 1, p 160-163)
[79] (Article 11 of Customs proclamation)

valuation will be undertaken put simply assessment note. After assessment note payment of custom and other subsequent actions will be taken.

c) No importer makes declaration unless he/she adduces supporting documents. Pursuant to Proclamation 854/2014 article 10, the following original supporting documents shall be supplied to Customs:
   - ✓ Transportation document;
   - ✓ Invoice;
   - ✓ Bank Permit;
   - ✓ Packing list;
   - ✓ Certificate of Origin; and
   - ✓ Other relevant certificates/permits from relevant regulatory bodies. Among such kind of documents is the one prepared by Food, medicine and health care administration and control authority.

To deal with the problem of delay of custom clearance, the custom authority has enacted a decree. According to the decree 41/2002, medicine is among those commodities that will be given priority during clearance as indicated on article 4(A). As indicated on the preamble of the decree, the very justification for enacting of the decree is to avoid delay around those commodities, list items of goods deserving priority and enhancing of efficiency. Article 2(1) defines goods as "ዕቃ" ማለት በቀላሉ የሚቀጣጠል፣ የሚተን፣ የሚበላሽ፣ ለታለመለት ዓላማ ኢንዲውል በአስቸኳይ የሚፈለግ ሲሆን በመጋዘን ውስጥ በመቆየት በንብረት ወይም በሰው ላይ ጉዳት ሊያደርስ የሚችል ማንኛውንም ዕቃ ይጨምራል:: one can understand from the definition that, one of the reason to accord priority to those goods is because of their nature and need towards meeting their purpose. Article 5 of the decree elaborates that, an application for expedite clearance of those goods including medicines can be made before arrival of goods or within eight hours after their arrival. Article 6 of the same decree further mentions an authority has to respond within an hour and failure to act accordingly entails penalty envisaged on the customs proclamation. [80]of course proclamation 859/2014 sets number of days in which goods must be cleared. These date ranges from 30 days to that of one year depemding on the nature of the goods as discussed on article 51. Despite all the efforts on the part of law maker to maintain speedy custom

[80] (ደንብ 41/2002)

clearance of medicines, custom clearance is taking days than what is aspired by law making organ because of certain practical challenges the details of which will be discussed below.

3 IMPORT CLEARANCE TIME AND DETAINED MEDICINES IN MAJOR CUSTOM CENTERS

In Ethiopia there are about 8 imported medicines related custom clearance centers. The total number of imported medicines into Ethiopia in 2014 G.C is 2649 declaration and in terms of CIF value, it is 7, 403,676,540.15. Of these numbers, the major custom clearances were handled by Bole Cargo center, Modjo dry and Akaki Kaliti goods center respectively. This shows that the aggregate collection of these three custom centers constitute for 78% of medicines cleared. [81]

Table 1 Number of imported medicines in Ethiopia by respective Customs Station (2014)

custom stations	Number of medicines imported (declarations made)	Share in total import (%)	Number of seized/detained medicines
Bole Cargo terminal	1434	54.13	No processed data
Kaliti Branch	279	10.50	
Modjo dry port	371	14.01	
Others	566	21.36	
Total	2649	100	

- The statistics is obtained from ERCA information technology directorate. By others custom centers it includes that of Dire Dawa, Mekele, Metema, Jigjiga, and AA post office. As far as seizure of medicines is concerned, there is no automated data both at Ethiopian revenue and custom authority and Food, medicines and health care control authority of Ethiopia. But, Mr Abebewu

[81] (Refer table 1 below)

Gesese, one of Director of the department of Food, medicines and health care control authority of Ethiopia told me that, the value of detained medicines in terms money 2014 G.C is about seven million Ethiopian birr. He further told me that these medicines were detained because of several reasons such as expiry of date, lack of certificate of analysis for medical devices, failure to maintain in cold room of laboratory regents, Importing of unregistered medicines and finally limited shelf life of imported medicines.

- From the above data, the major custom center for imported medicines is that of Bole Cargo terminal. The addition of three of the major custom clearance centers namely; Bole cargo, Akaki Kaliti and Modjo dry port constitute 78.64% of imported medicines.

Table 2 Import clearance time at major custom centers

custom stations	**Number of medicines imported (declarations made)**	**Custom declaration time (on average)**
Bole Cargo terminal	1434	7 days
Kaliti Branch	279	8 days
Modjo dry port	371	8 days and six hours
Others	566	9 days and four hours

Source: Own computation based on Custom declarations made at major custom clearance centers. To that end, I have reviewed 420 declarations made at Bole Cargo, Kaliti and Modjo dry port centers. As to how these days were figured out, I have reduced entry day of imported medicines from exit day and took an average day based on declarations made by importers. Here the day custom declarations made and goods collected from warehouse were calculated to see the figure. The problem on custom declaration is that, some of the declarations are not well kept at custom centers. For instance, while the imported medicines are still under clearance, they sometimes keep

as if they were cleared. The figure of custom clearance delay above is contrary to the one undertaken by World Bank. According to 2014 doing business of World Bank report, it puts the country 166 out of 189 states up on whom the survey is made. The survey states that, custom clearance took 44 days in Ethiopia.[82]

In addition to delay in custom clearance, as discussed above, there is seizure of medicines because of those reasons pointed earlier. Even though seizure because of justifiable health related grounds are logical ones, seizure for reasons such as failure to maintain in cold rooms, lack of certificate of analyses goes against the spirit of the custom law and other legislations enacted to implement the law.

4 PRACTICAL SOURCES OF CLEARANCE DELAY AND SEIZURE

The following practical problems were figured out during assessing the practical problems of delay in custom clearance and seizure of medicines by customs authority. Based on the feedback supplied, its impact on access to medicine is also mentioned.

a. The 'Great Disconnect' or lack of coherence

Private sector respondents[83] to the interview engaged on importing of medicines gave evaluation or verdict of the existence of a great disconnect or lack of coherence on the character of customs officials. In particular:

- **i.** The most senior officials were helpful and understood the problems faced by importers.
- **ii.** The frontline officials were officious, indecisive, susceptible to petty corruption, and suspicious of importers. In addition to such disconnect between the strategic and the operational levels in Customs, there was a remarkable difference between officials in Addis Ababa, who were generally more business-friendly and understandable than their counterparts in other custom centers. Example Modjo dry port

[82] (WB, Doing business, understanding regulations for small scale and medium sized enterprise, 2014)
[83] (Private respondents are those who are engaged in importing of medicines. Accordingly, there are about 114 importers in 2005 of E.C and out of them, an Interview with 14 of the sales division of those companies namely; Addis pharmaceutical drug and medical)

b. Poor relationship b/n importers and customs

Relations between Customs authority and importers lack genuine dialogue on the procedure of clearance, needed documents and hence, the relationship is mutually antagonistic. The absence of such coherence will influence the effective operation of customs which will ultimately result in unnecessary delay of medicines.

Comparing Ethiopian customs authority with other African states; if for instance we take the customs authorities of Kenya, Uganda, Tanzania and Rwanda, they all have made taxpayer consultation an important part of their approach to achieve the intended customs authority objectives which as discussed earlier aimed at facilitating of movement of goods. In order to attain the intended objective they are holding regular seminars and workshops, celebrating tax payer's day as it has been done in Rwanda and others as strategy. If for instance we take Uganda, they held such events every month.[84] In Ethiopia however, Ethiopian public private consultative forum (EPPCF) which is established by a memorandum of understanding signed between Ministry of trade and Industry and Chamber of Commerce in 2010 has undertaken a public dialogue workshop for eight times only since then. It principally aims to conduct the workshop twice a year. [85]

c. Insufficient supporting infrastructures

Infrastructure facilities are poor and some of them are outdated. Even though there is an automated computer system on major custom clearance most of them are not active because of power failure and network failure. Besides some infrastructures to conduct inspection for medicines are lacking. The other problem here is lack of well furnished ware house and handling equipments to deposit medicines until clearance.

d. contribution of other agencies

There are several agencies that are involved in custom clearance of medicines. These include transistors, other government agencies such as Food, medicine and health care

[84] (Kireeva 9. C.)

[85] (Refer report made by Mamo Mebratu, Program Manager of Ethiopian public private consultative forum, March 10-13, 2015 Copenhagen. The report states that since the establishment of the forum, a dialogue for 15 times and national business conference for 2 ti)

and control authority to regulate the quality and efficiency of imported medicines. Their presence has contributed for the delay as for instance medicines cannot be cleared without authorization by Food, medicine and health care control authority. Employees of the authority are not adequately deployed in all custom centers. Besides they will not operate on Saturday and Sunday unlike custom operators for the sole fact that they are not entitled to compensation except for insignificant overtime paid to them. In addition, transistors are also contributing for the delay as they are submitting incomplete custom declaration, ignorance of filling the declaration and creating of inconsistency with the declared document and physically inspected medicines.

In addition, transistors are not in most cases preparing the documents in advance like in other jurisdictions rather they will facilitate the process after the goods reaches Djibouti port. Once the goods reach the port they will commence the clearance and makes the process reactive. Hence they lack a proactive approach.

e. Corruption

Corruption is another institutional limitation that is delaying the custom clearance. Importers are paying money for legal activity under the pretext of facilitating the work. This payment is called as facilitation payment. Unless payment will be effected, operators will not hasten or expedite the speed of the work in which custom clearance is suffering greatly from this.

f. poor level of automation

Level of automation is poor despite the fact that all custom centers become automated. This is so because; the declaration and other required documents are being processed using ASYCUDA++ (authorized system for custom data). However, the system suffers frequently from network failure as a result of which declaration is taking place manually. It is obvious that, conducting the clearance process manually will delay the process greatly. In addition all the systems are not integrated centrally and hence there are problems associated with data management.

g. Product Classification problem

Reasons for delay in clearance time of export/import medical products include cases where the imported medicines may be new and thus require interpretation that is likely to demand the decision of MoFED. In Ethiopia, no medicines will be consumed until registered with concerned bodies such as ministry of health, Ethiopian radiation agency and other related agencies. This problem, coupled with the lack of adequate number of competent customs officers for product classification and data entry.

h. lack of skilled man power (problem of technical competency of operators)

The problem of medical product classification is related to the technical competence of customs officers who are few in number and that reportedly cannot readily and automatically classify such goods. This is one of the other sources of significant delay. The major constraint in customs is the lack of technical knowledge and professionalism of customs employees deployed to inspect/ classify/valuate import products. Because of incompetence, it is normally taking up to three days to inspect and classify a container of imported medicines. During these times no other container will be opened unless inspection of an opened container is completed. This takes up a lot of time, and results in delays for the release of imported medicines. Under such circumstances, it is common for most imported medicines to take as much as days, with inescapable warehouse charges. This will frustrate traders in the business and discourages the, from importing of such medicines. They are even detaining of medicines when one document is missing claiming that it is contraband good.

i. Misplacement of consignments of medicines

This is a problem that usually occurs in customs ware house centers until medicines will be cleared. Here when medicines will be placed in ware house until clearance, there exist misplacement of consignments which as a result until identified couple of days will be spent. This is a major problem for imported medicines at Bole cargo terminal. The problem here is contrary to decree 40/2002 ware houses must have necessary standard which among others includes facilities, man power and detailed procedure. For instance, as far as necessary requirements for imported goods are concerned, article 5 sub article of D of decree 40/2002 states that “ለመድሐኒት፣ ለምግብ፣ ለአደገኛና ለሌሎች ዕቃዎች ኢንደ ባህሪያቸው ለማከማቸት ወይም ለማቆየት የሚችል የተሟላ መሣሪያ ያለው ልዩና ዝግ መጋዘን:: Despite such clear

requirement from the law, the ware houses lack those requirements such as safe box, shelfs, generators, waiting room for operators, clothes and others as discussed on article 5 sub article 5 of the same decree.

j. Absence of single window service

The presence of different departments and agencies in custom clearance is greatly influencing the custom clearance and is one of the contributing factors for the delay. Despite the inauguration of the single window service, the data's are not harmonized and consistent with international standards.

k. contribution of the law (Loopholes created by law)

As clearly indicated above, one of the requirements to clear imported medicines is securing letter of permit from Ethiopian Food, medicines and health care control authority. The authority among other things is entrusted with the power of controlling and deterring illicit production, trafficking, and use of narcotic drugs psychotropic substances, and precursor chemicals as stated on preamble statement of proclamation establishing food, medicines and health care control authority of Ethiopia. Despite the intention of law makers in deterring production of illicit medicines which consists narcotics and other substances, article 18 on contrary allows importation of such medicines subject to special permit and authorization with the executive. This creates a misunderstanding as what is prohibited by the preamble did exceptionally being imported by authorization of executive organ. Furthermore, article 13 and the following articles of the proclamation (622/2009) talks about issues associated with medicines. Article 13(1) state that production and importation of medicines is impossible unless these medicines are duly registered after complying with the requirements of safety, efficiency and quality. Here the very intention of registration is to assess efficiency, effectiveness and quality. Besides, the law prohibits importing of counterfeited drugs. As defined on article 25 of the same proclamation, counterfeiting" is defined as using in any way, the packing material, identification or trademark, trade name or any special mark thereon of an authentic product of a manufacturer and presenting such falsely labeled and packed food or medicine as if it is manufactured by the genuine manufacturer or altering content and properties of food or medicine that cause health hazards to human.

While making an interview with one of the medicine importer (Baro Pharmaceuticals Human Medicine and Medical Supplies Importer and Wholesaler) owner Ato Biniyam Aseggid in Addis Ababa at Gullele where his company is located, told me that because of writing problem while labeling the medicine, they wrote the name Amoxil instead of Amoxicillin as a result medicine imported was detained for about 27 days; but after subsequent investigation it was found out that the problem is the one that occurred as a result of writing made while making the labeling. The problem here shows that the controlling agency is not controlling what is expected of it by law as discussed earlier which is controlling quality, efficiency and effectiveness. The above medicine is detained because they thought that is a counterfeited one. The definition of counterfeited includes not only labeling issue but also trade mark related issues. But what constitutes trade mark is not defined on the definition despite the fact that the definition can be seen in other legislations. Such gap has resulted in unjustified seizure. Besides, while seizing there are no clear procedures such as notification, and other procedural requirements.

5 EVALUATION OF THE FINDINGS

Evaluations of the findings of this study is made here and discussed in light of the report of the World Bank, the BPR undertaken by ERCA, and best practices and views of stakeholders interviewed while conducting the study and spirit of the law.

a. The world bank report, the finding versus access to medicines

As discussed earlier, the World Bank report states that custom clearance of imported goods including medicines took 44 days in Ethiopia. [86]On contrary however, based on the data analysis I have made, as indicated on table two of the above, the custom clearance took an average of eight days. Besides, on the interview conducted with private respondents, the custom clearance days pointed by them is eighteen days on average.[87] The finding of the result is quite different from the clearance time pointed out by World Bank. For me the most visible one is the one directly pointed by importers and hence on average clearance time is eighteen days. Hence, the World Bank report is a

[86] (Supra note 82)
[87] (Supra note 83)

bit exaggerated one. But the fact that custom clearance of imported medicines is taking eighteen days greatly influences access to medicine right of citizens.

According to the World Health Organization and as discussed earlier, accessibility of medicines will be entertained from four dimensions. The first dimension is that of availability. The frame work states that medicines must be available in a reasonable quantity. The second frame work is accessibility which incorporates existence of facilities including medical equipments. Accordingly medicines and medical equipments must accessible. The third frame work is acceptability whereas the fourth one is quality. All these frameworks are interrelated. When I compare the finding of the result with the World Health Organization accessibility frame work, delay in custom clearance and seizure violates these frameworks as seizure and delay are exposing importers to incur additional expenses/costs and such costs will ultimately fell up on consumers. Furthermore, seizure and delay will result in scarcity of medicines which as a result limits equal accessibility of such medicines. United nation commission on Economic, social and cultural right on its 20th session meeting held on December 12th 2000, concludes that states are both legally and morally responsible to respect, protect and fulfill access to health which includes access to medicines as one component. It further concluded that states failure to undertake international obligations constitutes violation of human rights provisions. Therefore, it is imperative to affirm that delay in custom clearance and unjustified seizure constitutes denial of right to access to medicines.

b. Institutional BPR conducted, the finding and access to medicines

On the BPR study conducted by Ethiopian revenues and customs authority, it sets a target of eight hours for import clearance in Ethiopia. (Import clearance time set by the BPR is the time to clear the goods after arrival of the goods at the customs clearing stations assuming every documentary requirement is fulfilled by importers). In line with the BPR study conducted, customs personnel were provided with training in order to achieve the target. The Ethiopian Government did also take measures to reduce delays in clearance time by establishing dry ports at Semera and Modjo.

As indicated earlier, the weighted national average clearance time for import goods is 18 days. When the result is considered against the best performers (France, USA and

others), this time indicates that there is delay in the clearance of import cargo in Ethiopia. This fact has been recognized by the BPR study of ERCA undertaken in 2007.

The reasons for the delay as discussed earlier includes documentary requirements of many regulatory bodies, constrains during transit and at custom stations. Hence, the eight minute target set by BPR study for clearance now seems unrealistic. One of the very reason for conducting BPR are to identify institutional problems such as custom clearance so as to expedite the clearance considering the implication custom delay will have on meeting states obligation of facilitating of trade, enhancing of wellbeing of citizens which includes access to medicine as one component.

c. The Findings vis-à-vis the Best Practices

Many countries have undertaken series of time release measure and other measures which are believed to expedite custom clearance. Besides, they have also introduced a system that restricts scope of power of seizure of medicines unjustifiably. Accordingly, Indian government has brought about a significant border clearance time improvements through implementation of pre-lodgment of documents i.e., the submission of documents prior to the arrival of the ships, aircrafts or vehicles conveying the goods. Similarly, the modernization initiatives implemented by French Customs, including computer-based risk management, an automatic clearance system such as Single Window and pre-arrival declarations, as well as paperless service, have contributed to substantial reductions in border clearance time. In addition, India has adopted a system that held's custom operators accountable for unjustified seizure and delay.

In general, countries like France, USA and India undertook time release study and identified their respective constraints regarding border clearance. They also undertook comprehensive and successive time release study involving all stakeholders in order to ensure that improvements are attained. In so doing, these countries have made sure that all stakeholders have involved in ensuring improvements have been

registered. Such successful countries implemented full automation of customs procedures, pre-lodgment of documents, embraced the private sector in recognition of its role as an engine of economic growth, etc. Compared to the experiences of these countries, no effective time release study pursuant to the World Custom Organization guidelines, has undertaken in Ethiopia. As indicated earlier, ERCA undertook a BPR study in 2007 as an in-house exercise and is currently developing its own time release study.

D. Finding vis a vis legal analysis (spirit of the law)

As discussed on the earlier part, the very reason of the law maker in setting customs law and other legislations related with trading of medicines is to benefit the society, ensure safety, effectiveness and quality of medicines and to facilitate trading of medicines. As medicines are among goods deserving priority given their benefit, custom authority has enacted a decree with an aim of expediting their clearance. In addition, a decree that determines standard for warehouse where medical products will be kept is enacted to enable those medicines serves their purpose. Besides, the law sets administrative as well as criminal sanctions that will be taken against those who unduly delay s and seize goods including medicines. Despite these statutory enactments, the practical challenges surrounding medicines are contributing a lot for the delay and unjustified seizure. The practical problems are therefore limiting government commitment in meeting citizen's right to health which includes medicines and is also articulated under Ethiopian domestic laws.

6 IMPACT OF SEIZURE AND CUSTOM CLEARANCE DELAY ON ACCESS TO MEDICINES

Custom clearance in Ethiopia is creating a huge problem because of the involvement of several procedures which increases the cost of transaction for imported medicines and lack of speed in delivery. As pointed out by importers engaged on importation of medicines and discussed earlier, custom clearance is taking eighteen days in Ethiopia. Despite this fact, there are no documented data's for seized imported medicines but the seizure is estimated to be about seven million in terms on money. The detention and delay are intended to ensure that residents of Ethiopia will get quality and efficient

medicines as well as those who engage in that sectors are complying with the necessary legal requirements.

The practice however, reveals that there are so many reasons for delay which if supported by adequate policies and support would better ensure access to medicines. Because of delay and seizure, the scarcity of medicines would more likely occur. For instance Ethiopian pharmaceutical association on its 2005 E.C report states that there is scarcity of essential drugs.[88] From the report, it is truly evident that the supply of medicines in Ethiopia is not as it is supposed to be. One of the contributing factors for this is an onerous requirement of conducting the business and delay in custom clearance and unjustified seizure as discussed earlier. The issue here is what does this imply? How will this be considered from human right perspective? How many people's will die because of lack of these medicines daily? In addressing these questions, one has to take a look into world health organization access frameworks, international human right instruments and other related issues.

In Ethiopia, there are no well documented data's as to how many people did lost their lives because of such seizure and delay. Absence of such data's will obviously influence not to better analyze the finding. However, based on access framework set by World health organization, it is vivid to argue that delay in custom clearance and unjustified seizure will frustrate access to medicines. Furthermore, states with best experience are proving the fact that lack of presence of medicines is resulting in scarcity of medicines which as a result limits equal accessibility of such medicines. Therefore, failure to undertake international obligations on access to medicines which is ensuring of accessibility of those medicines constitutes violation of human rights provisions. Therefore, it is imperative to affirm that delay in custom clearance and unjustified seizure constitutes denial of right to access to medicines.

[88] (Assessment of pharmaceutical centers in Ethiopia)

Chapter 5 CONCLUSIONS AND RECOMMENDATIONS

1 CONCLUSION

The importance of time in custom is not subject to question. Each additional day imported medicines spent in custody of custom clearance do have a number of adverse impacts on the medicines imported. These medicines may expire while undergoing clearance and may be subjected to other problems. Besides, wrong detention of medicines and detaining for the sole benefit of protecting private intellectual right specially by those pro intellectual property right is found to undermine states commitment to WHO Doha round negotiation and non compliance with major human right instruments.

As far as custom clearance and seizure in other jurisdiction is concerned, many of the states are working towards custom reform. In Nigeria, clearance procedures were tedious and costly in terms of required documentation and procedures, resulting in lengthy clearance times. Clearance procedures included redundant verifications and multiple steps that lacked business rationale whose objectives were overtaken by modern business practices. The fact that procedures were largely paper-based and inadequately supported by customs IT, corruption, lack of deploying well qualified and trained employees are major problem contributing for the delay. The country is also seizing medicines for the sole fact that they are illicit ones. In India, the custom system

is relatively better but the practical problems such as detaining for custom clearance did exist. Such detention will increase the cost of medicines as according to their law, such cost will entirely be covered by an importer or exporter of medicines. This in turn will increase the cost of medicines which will ultimately reduce the purchase capacity of patients thereby denying access to medicines. French custom in terms of clearance time has a remarkable achievement and there are several reasons that contributed for this. Introduction of single window service, provision of paperless service, fully fledged infrastructures and involvement of skilled custom clearance brokers are inter alia factors. However, the country still detains medicines for counterfeiting and the number of such detained medicines has been increasing over times. The USA approach also resembles that of France. Both USA and France are signatories of anti counterfeiting agreement and the agreement entitle them to seize or detain medicines for infringing of IP rights. As medicines are the most important goods, states are taking reforms in order to ensure their availability, accessibility and utilization by patients and those who needs medicines. It has been found out in all these states that temporary delays of medicines means denying patients of having access to life saving drugs as medicines are different from other goods. In addition, pro access to medicines are challenging seizure and delay as the they conclude that acts of seizure and delay is contrary to the intention of Doha round negation, defeats the intention of controlling medicines which is quality, efficiency and is creating border abuses.

In Ethiopia, the custom law is oriented towards facilitating of trade and serving of other macro objectives such as benefiting national economy, contributing to health and etc. To that end, custom laws are enacted with ultimate aim of meeting the intention of law makers, which is expediting custom clearance and avoiding of unjustified seizures with ultimate aim of contributing to enable citizens to exercise right to access to medicines. The general finding of the study indicates that there exists delay in custom clearance and unjustified seizures despite the fact that medicines are the most essential goods to mankind. The study further figured out that there is no compliance between the practice in ERCA's custom clearance of medicines and what is actually designed in BPR for clearing of such goods and that of decrees enacted by customs authority. In addition, compared to the best performers in custom clearance and careful and systemized

approaches to seizure of medicines, Ethiopia has still a long way to go. There are various reasons for delays relating to importation of medicines to the country. The common causes in major custom clearance centers for delays of medicines in Ethiopia inter alia includes incomplete documentation, negligence of declarants in submitting documents on time, discrepancies between declaration, lack of adequate technical competence of customs officers and related. As far as seizure is concerned, Ethiopia is not different from other states. Medicines are being detained for various reasons such as short shelf life, expiry of imported medicines, non registration of medicines, non fulfillment of formality requirement, and infringement of intellectual property rights such as trade mark, labeling and related. The study evidenced that even though detaining of medicines is good as their importation jeopardizes the health of the community, their seizure and delay for unjustified reasons which do not have the potential to affect the effectiveness and quality of such medicines will deny citizens access to such medicines.

The combination of all these factors has contributed for inadequacy of medicines in the country. Besides, the unjustified seizure and delay is contrary to the enjoyment of citizen's access to medicines right as the World Health Organization has clearly indicated in access to medicines frameworks. Those frameworks are interrelated as for instance unjustified seizure and delay can cause increase in price of drugs because of additional costs incurred there, can influence availability of drugs, can further threats states health policy. Hence, given population increase in the country unless access to medicines are addressed systematically, non accessibility of medicines will jeopardize the health care delivery and finally can result in denial of right to health of citizens which as one content embodies access to medicines.

To sum up, in as long as medicines are not like any other commodities, facilitating their accessibility by taking of measures such as custom reform thereby avoiding of unnecessary custom delay and seizure and taking other measures that expedite the clearance are necessary to ensure states obligation of ensuring right to getting access to medicines by citizens.

2 RECOMMENDATIONS

In light of the foregoing major practical problems, the following recommendations were given for implementation by those concerned stakeholders. Accordingly;

a. **Introducing a system of pre lodgment of documents**; to this end, intensive sensitization training must be provided to those transistors and other agencies engaged in importation of medicines. Submission of documents before the arrival of imported medicines goes a long way in reducing delays in border clearance procedures. Thus, separation of release from clearance of goods could be beneficial to the trader as well as the customs body since this practice could reduce customs warehouse costs, inventory and insurance costs as well as storage and warehouse infrastructural requirements

b. **Undertaking Time Release Studies** The lessons one learns from the experiences of best performers is the need for undertaking a series of studies until measurable improvements are registered in the customs clearing process. In keeping with the lessons from the experiences of these performers, a time release study should be conducted and well activated in Ethiopia.

c. **Full Automation;** a versatile automated system for processing all customs declarations and related issues such as payments needs to be developed and deployed. Full automation calls for the enactment of new legislation that recognizes

electronic processing of transactions and payments. Hence the government has to work and develop a law that recognizes electronic payment and clearance.

l. **Establishing uniform custom standards and procedures**: Access to medicines must be a concern of International organizations and states. Even though custom clearance procedure and detain of medicines is primary concern of respective states, as access to medicines can be influenced by respective countries custom laws and practices, WCO has to work on this and must prepare policies and guidelines so that states can maintain consistency in their respective custom law and policies.

m. **Making complete custom law and policy**: States, must as much as possible endeavor to work towards making complete custom law and policy and again enforceability should not be the other headache. In as far as ensuring access to medicines is an element in countries human right instruments, it is perhaps wise for countries to consider their custom policies and practice in such a way that it is conducive to ensure states obligation of maintain access to medicines.

n. **Building technical capability of custom operators**: in order to enhance performance of custom operators, in addition to provision of training, a mechanism through which they will attend regular class must be facilitated. Even though the custom authority of Ethiopia has a partnership agreement with Ethiopian Civil Service University the numbers of admitted students are few. Therefore a separate custom school and training institution must be established.

o. **Creating accountability for illegal seizures**: a system that held's custom operators for wrong detention and delay must be put in place. The system must embody penalties that could be taken against such employees despite the current existing administrative measures.

p. **Integrating of laws**: as laws regulating custom clearance and delay of medicines in Ethiopian context are regulated by several government bodies, creating a law that integrates these functions must be enacted and enforced.

q. **Combating corruption**: as combating corruption demands a political commitment, the government must stand firm and put in place a system that combats corruption.

r. **International society must address the issue of illegal seizure:** even though the existing laws are fighting illicit medicines, by the same token a system that supports issue of wrong seizure must be enacted. As international societies are pro intellectual property right advocators, they must also support and come up with a policy that condemns illegal seizure of medicines and delay.

s. **Call for joint action:** international level, there has to be a corporate responsibility to ensure access to medicines. By the same token, domestically different agents must work together to ensure access to medicines. Hence a corporate responsibility must exist both domestically and internationally. To that end, the government including world health organization for international medicines related issues has to make a call for joint action

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