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INTERNATIONAL STANDARD AND ETHIOPIAN LEGISLATIVE FRAMEWORK ON THE INTRODUCTION OF FALSIFIED MEDICINES

BY
SAMSON TEGENE

ADVISOR: DOCTOR TESFAYE ABATE (L.L.D)

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BY SAMSON TEGENE

ID N0 GSE/ 8468

Approved by

1. Advisor's Name ……...

Signature……..

2. Examiner's signature

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Acronyms

WHO-	**World Health organization**
WCO	**World Custom Organization**
IPR	**Intellectual Property right**
IPRs	**Intellectual Property rights**
EU	**European Union**
UNODC	**United Nations Office on Drug and Crime**
IJRC	**International Justice Resource Center**
ICESCR	**International Convention on Economic, Social and Cultural Right**
CRC	**Convection on the Right of the Child**
UDHR	**Universal Declaration of Human Right**
CCPCJ	**Commission on Crime Prevention and Criminal Justice,**

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INTERNATIONAL STANDARD AND ETHIOPIAN LEGISLATIVE FRAMEWORK ON THE INTRODUCTION OF FALSIFIED MEDICINES

The THESIS SUBMITTED IN PARTIAL FULFILLMENT FOR THE REQUIREMENT OF MASTER DEGREE IN INTERNATIONAL LAW

Abstract

The introduction of falsified medicine is an increasing occurrence in the world. Economic and socioeconomic problems empirically asserted in addition its specific impact on Health. Responding to the growing crimes related with the introduction of falsified medicine may save life and protect the negative impacts. Doctrinal legal research method used to answer the questions of; what are the legal bases to combat at international level? Is there any national legal gaps? These questions critically assessed the existing international standards and examined how individual countries may fasten together for efforts and cross the challenges in combating the offences. The thesis identified the Ethiopian legal gaps related with criminalization, and provided the possible recommendations to fill it.

CHAPTER ONE

International standards and Ethiopian legislative framework to regulate the introduction of falsified medicines

1.1. Introduction

Investigating the global governance on the introduction of falsified medicines may help to determine the status of individual country expected to comply with the existing legislative frame work. Specifically worrying about whether the compatibility of Ethiopian legal framework with international standards enables to navigate fundamental gaps and the way to fill it in accordance with global governance system. Recently, the international comminutes are concerned with the production of falsified medicines. Falsified medical products pose a considerable public health threat as they can fail to cure, may harm and even kill patients, and these threats to public health have led the international community to call for a stronger and more coordinated response.[1] Regulating the introduction of falsified medicines can be more complex task. It is evident that the international community's apprehension to regulate the introduction of falsified medicines is in coordinated manner. Every country is supposed to ensuring a safe and reliable drug supply.[2] Despite the fact that, regulatory activities encompasses different measures and activities, however this paper examines the International standards and the required legislative frame work in the prevention and suppression of introduction of falsified medicines. Reliable drug supply held out four main responsibilities: regulating the responsible manufacture of safe and effective medicines; preventing falsified and substandard drugs from entering the market; detecting them when they do; and punishing those who knowingly manufacture and trade them.[3] Performing these responsibilities requires strong national legal frame work for drug regulation, under this situation the title enables to navigate the existing and the extent of Ethiopian's obligations or responsibilities to prevent and suppress the introduction of falsified medicines.

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[1] United Nation office on Drug and Crime Trafficking in falsified medical products website <https://www.unodc.org/unodc/en/fraudulentmedicines/introduction.html > 22 Nov 2019

[2] Bookshelf An International Code of Practice for Falsified and Substandard Medicines <**https://www.ncbi.nlm.nih.gov/books/NBK202535>** 23 Nov 2019 at 3:02 PM

[3] Ibid

1.2. Objective of the study

The aim of this study is systematically identifying the international normative and legal standards which should be compiled by individual states, identifying the Ethiopian legislative gap with regard to criminalizing the introduction of falsified medicines and looking a better way for Ethiopia to govern the introduction of falsified medicines.

1.3. The Background and Problem

The growing phenomenon of the falsification of medical products threatens the right to life and health as enshrined under international human rights instruments.[4] Member States to put off trafficking in falsified medicines by bring in legislation, covering, in particular, all offences correlated to fraudulent medicines, such as anti- money laundering, corruption and smuggling, as well as the confiscation and disposal of criminal assets, extradition and mutual legal assistance, to ensure that no stage in the supply chain of fraudulent medicines was overlooked.[5] There is gap under Ethiopian legal frame work in the covering all particular offences correlated with fraudulent medicines, Special investigative techniques which applied by the competent authority in order to conduct appropriate investigation and detecting the introduction of falsified medicines. Even though, Ethiopia currently promulgated new law with regard to food and medicine administration Proclamation No 1112/2019, unfortunately the proclamation did not comply the international standards, and haven't a competence on its provisions for prevention and suppression of specially in the fulfilling special investigative techniques, adopting necessary definition and designing appropriate legal frame work to criminalize those offenders who participate in the introduction of falsified medicines. Besides according to World Health Organization, developing countries' i.e. including Ethiopia is faced under the problem of introduction of false medical products. The study clearly indicated that falsified medical products are most likely to be found where access to affordable, quality, safe and effective medical products is constrained, standards of governance are low or the tools and technical capacity to ensure good practices in manufacturing, quality control and distribution are limited.[6] The country's law as much possible should be strong, but as we have seen there is a clear legislative gap with regard to the introduction of falsified medicines governance such as appropriate

[4] United Nation Office on Drug and Crime, Combating falsified related crime medical products a guide to good legislative practice. P.1 published in 2019.
[5] ibid
[6] ibid

definition, legislating special investigation techniques such as Under Cover operation, Control delivery i.e. law enforcement technique that allows the transport of illegal drugs or other contraband, under law enforcement supervision, to those persons who have arranged for the shipment, this is to identify arrest and prosecute those persons that are responsible for financing, forwarding or organizing a consignment of illegal drugs. [7] Introducing new law with regard to the introduction of falsified medicines may fill all the gaps, or else it may entail several problems in the effectiveness of the controlling and suppressing.

1.4. Research questions

The first basic question is due to the recent phenomenon on the expansions as well as increasing of the production and supply of falsified medicines, what legal mechanisms have been developed at the international level and how Ethiopia should comply to prevent and suppress the introduction of falsified medicines?

The following sub questions are address in this study:-

- What are the existing international norms to prevent and suppress the introduction of falsified medicines?
- What specific international law encourage and urge states to enact law for the prevention and suppression of the introduction of falsified medicines?
- Under Ethiopian context are there any specific gaps and what solutions can be provided for the existing gaps if any?

1.5. Literature Review

In order to be aware of the global phenomenon of falsified medicines, literature review has been conducted to identify knowledge gaps and deliver insights for further research. Lack of universally accepted definitions on various forms of illegal medicines remains the most obvious obstacle for stakeholders in taking effective actions to address the phenomenon of falsified

[7] <https://www.police-academy.com/demos.html > e learning law enforcement course, by Know2 Law enforcement certification accessed on 5/12/2020

medicines.[8].The emergence and prevalence of falsified medicines takes on different forms between developing and developed nations due to political, economic and social factors and in the flourishing e-commerce opens up a virtual market where falsified medicines can infiltrate legitimate supply chain and reach directly to the consumers whose awareness of this issue is still rather low. Among healthcare professionals, knowledge of falsified medicines is also alarmingly limited.[9] International human rights instruments and other relevant soft laws are urging and supporting to legislate and combat the crimes related with falsification of medical products. Most importantly WHO and UNODC provide soft norms to give the right direction on prevention of the crimes of the introduction of falsified medicines. By the initiations of the Commission on Crime Prevention and Criminal Justice on its resolution 20/6 United Nations office on Drug and Crime has been prepared a guide to good legislative practice to combat falsified medicines. In the UNODC legislative practice guiding documents Member States expected to prevent trafficking in fraudulent medicines by introducing legislation, as appropriate, covering, in particular, all offences related to fraudulent medicines, such as money-laundering, corruption and smuggling, as well as the confiscation and disposal of criminal assets, extradition and mutual legal assistance, to ensure that no stage in the supply chain of fraudulent medicines was overlooked.[10]

With regard to Ethiopian legal framework there are number of anticipated areas which can be considered as expected to cover for combating the introduction of falsified medicines. Specific proclamations which are enacted to regulate with regard drug issues is Proclamation No 1112/2019. It enacted to provide for Food and Medicine administration. The proclamation immensely covered with regard to Medicine and Medical products regulations, necessary offences and its punishment. Unfortunately the proclamation missed important legal coverage in terms of criminalizing the crimes related with the introduction of falsified medicines. Another important legal area which should be covers the issues of falsified medicine the law which is promulgated to protect the end users. In this regard Trade practice and Consumer protection proclamation no 685/2010 is important proclamation to protect the consumers form all kinds of products. However the proclamation also not covered important substantive and procedural

[8] Rui Liu* & Susanne Lundin Falsified Medicines: Literature review *Working Papers in Medical Humanities* https://journals.lub.lu.se/medhum/article/view/15308 *accessed on may 13 at 5:30 am*

[9] ibid

[10] n 4 p1

issues to combat the crimes of the introduction of falsified medical products. There is also the proclamation with regard to prevention and suppression of money laundering activities. Ethiopia enacted proclamation 780/2013 to prevent and suppress organized criminal activities related with money laundering. The proclamation aims to punish those offenders who engage in the process of conceal, disguise, or hide the property which gained from criminal activities. It is obvious the nature of money laundering a process of disguising or hiding a property which is gained from criminal activities it means that mandatorily it required predicate offence. In this regard as we have discussed with regard to relevant proclamations they have missed to consider as predicate offence the introduction of falsified medicines crimes. Hence it is very important to reflect on the proclamations coverage and the missing in detail for answering to my research question with regard the Ethiopian legislative gaps and they way to fill it in terms of the introduction of Falsified Medicine.

All materials which are used to conduct this systematic examination could be selected based on their content. The fundamental human rights materials help to examine the international legal order which individual state should comply especially on the right to life and health.

There are different materials available in the law library and in the internet which contained about the falsified medicines, special investigation techniques, and International cooperation's. Hence it helped me critically examine the Ethiopian laws with regard to consumer protection, anti-money laundering, criminal code and food and medicine administration proclamation and its coverage to protect and suppress the introduction of falsified medicines. The materials helped me to know more about the international standards and the gap which should be filled under Ethiopian law. Recently all available World Health Organization studies as well as United Nations Office on Drug and Crimes documents explained that the introduction of falsified medicines is current global problem. For e.g., according to UNODC documents criminal groups have been involved, in the production and supply of falsified medicines, by this reason UNODC recommends the revising in appropriate way the existing legal frame work. This more help me to know more about the legislative gap under Ethiopian context and the way to fill the necessary gaps which are identified in Ethiopian legal system in combating the introduction of falsified medicines crimes.

For effective controlling mechanisms and implementation it requires common standard that all states must be participated. Where one state fails to comply with rules and principles which stipulated to prevent for the above the problem it will very challengeable. Recently at the international level different standards have been developed to protect and suppress the introduction of falsified medicines. However, there is big challenges in the developing process at international level it may be different in taking the magnitude of the problem and complying the existing international standards. First of all states must understand the magnitude of the problem on the perspective of Health, Economic and Social issues. According to World Health organization studies falsified medicines endanger health, prolong illness, kill, promote antimicrobial resistance and the spread of drug-resistant infections, undermine confidence in health professionals and health systems, create distrust about the effectiveness of medical products, waste resources, cut into the limited budgets of families and health systems and provide income for criminal networks.[11] At the national levels the study, based on international standards enables to legislate capable of convey first-rate effect in protecting health economic and social problems which appear in relation to falsified medicines. At the international level this study identified the appropriate standards as well as obligatory factors to create common responsibilities among nations. I believed that international community has to work together to create common standard for common serious problems; all states also must respect such common standards. In this respect all should critically examine the possible solutions for the gaps, and through systematic investigation it should clearly identify the extended obligations of states by looking different legal doctrines and the circumstance as well as reasons in combating the introduction of falsified medicines. Hence Ethiopia should fill all the existing gaps in combating the crimes related with falsified medical products.

1.6. Methodology

For answering all research questions, and to fill the gaps which identified in this research the doctrinal legal research method utilized. Within the doctrinal legal research methods the researcher used different approach for navigating all issues related with the topic. The first approach was Hermeneutic (interpretative methods). The researcher critically examined through

[11] World Health organization, a study on the public health and socio economic impact of substandard and falsified medical products p 21

interpretation the international human right laws and literatures for the purpose of knowing the obligation of states which extend to protect the right to life within the combating of crimes related with the introduction of falsified medicines. The interpretative methods clearly show to the researcher human life is threaded by falsified medicines; furthermore the method was used to know to what extent states are obliged to protect human life from falsified medicines, what legal doctrines has been developed incretion of common standard which considered as obligatory nature of the right to life under international law. The method used for inquiring to know more about the subject matter and the ground to protect and suppress falsified medicines. In addition to knowing the ground to protect and suppress the falsified medicines, interpretative investigation may serve to stipulate the exiting international standards which can be taken as law at international level. The relevant legal doctrines are explored; existed in different legal texts; the way to interpret this doctrine may be varied as the subject of interpreted legal doctrines. Legal doctrines which existed in the different legal text book such as the right to life and the right to health, was examined through different perspective: - one is the historical back ground of the doctrine, second the content of the doctrine, and finally the possible effect of the doctrine in the future. The sequence of interpretation depended on the relevancy of the interpretation. Generally, the researcher navigated the international legal text through hermeneutic approach by looking specific points and rules which existed in hard and soft international laws which are currently taking as regulating the issue in respect of as international standards by all states to protect and suppress the introduction of falsified medicines. The researcher used second argumentative method in order to find out specific reasoning for research questions. The method was used to consolidate the ideas by taking arguments from different scientific studies. By using the method researcher could borrow reasons from other fields' of studies to construct logical reasoning. More importantly the researcher used the method to show the logical connection between preservation of the right to life and health also related with combating the introduction of falsified medicines. Finally both primary and secondary sources are utilized in this thesis to assess the existing legal coverage under international level and the Ethiopian legal system status and its gaps as well as the way to fill the gaps with regard to the crimes related with the introduction of falsified medicines.

1.7. Limitation

There were some kinds of limitation in this thesis with regard to the ontological issues to find out the reality it was difficult to get the full fledges of the magnitude of the problems with regard to falsified medicines. The prevention and protection strategies has been formulated recently, it was also very challengeable for asserting the practical application of international standards. However In order to minimize the challenges I was browed from other fields or disciplines in certifying the magnitude of the problem of falsified medicines. Other international approaches which are used to prevent and suppress the trafficking issues helped me to challenge in contextualising the international standards under Ethiopian legal system.

1.8. The structure and outline

The research consisted with five chapters; the first chapter contained the general back ground of the study. The second chapter deals with the international standards to protect and suppress the introduction of falsified medicines. Chapter three assessed the Ethiopian legal frame works and it pick up the gaps in governing the introduction of falsified medicines. Chapter four describes and systematically examines how the gaps filled under Ethiopian laws which should include based on international standards. Finally chapter five is conclusion and recommendation.

Chapter two

International law to protect and suppress the introduction of falsified medicines

2.1. Introduction

Time to time the regulation of falsified medicine has got great attention under the Global governance. Global governance is the combination of informal and formal values, rules, norms, procedures, practices, policies, and organizations of various types that often provides a surprising and desirable degree of global order, stability, and predictability[12]. Different literature indicates that the magnitude of the problem is the main factor for giving attention under the global governance. WHO study asserted that the impact of falsified medicines in different dimensions. According to the WHO study there are many findings on the impact of falsified medicines:-

Health impact, adverse effects (for example toxicity or lack of efficacy) from incorrect active ingredients failure to cure or prevent future disease, increasing mortality, morbidity and the prevalence of disease progression of antimicrobial resistance and drug-resistant infections loss of confidence in health care professionals, health programs and health systems.[13] **Economic impact**, increased out-of-pocket and health system spending on health care economic loss for patients, their families, health systems and manufacturers (and other actors in the supply chain) of quality medical products waste of human effort and financial outlay across the health system, further straining resources, staff and infrastructure increased burden for health care professionals, national medicine regulatory authorities, law enforcement and criminal justice systems.[14] **Socioeconomic impact**, lost income due to prolonged illness or death lost productivity costs to patients and households when seeking additional medical care, the effects of which are felt by businesses and the wider economy lack of social mobility and increased poverty.[15]

There are also lots of studies with regard to the magnitude of the problem of falsified medicines, but the scope this chapter focus on the international efforts to curb the production and distribution of falsified medicines particularly on the protecting and detecting criminal activities.

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[12] **Thomas G. Weiss D. ConorSeyleKelsey Coolidge, The Rise of Non-State Actors in Global Governance Opportunities and Limitations page 4 published by** One Earth Future Discussion 2013

[13] A study on the public health and socioeconomic impact of substandard and falsified medical products ISBN 978-92-4-151343-2 World Health Organization 2017 pp 21

[14] ibid

[15] ibid

The magnitude of the problem is not limited to single individual state. There is no boundary limitation on the distribution and manufacturing of falsified medicines, regardless of territory all states are subject to the impact of falsified medicines**.** It's a health scourge and constitutes an indirect and more violent threat to the physical integrity of millions of people and to national security around the world.[16]Another important issues giving attention worldwide response for falsified medicine is organized criminal groups engaged to get profit from the production and distribution of falsified medicines. The link between fake drugs and organized crime is well established: the large scale traffic of falsified medicines is a financial bonanza for the mafia and terrorist networks around the world. [17]

2.2. Nature and definition of falsified medicines

Different literature shows Drugs and medical devices are among the most stringently regulated products in the developed world. Regulation is the most important issue and it is obvious the fundamental purpose is to protect public Health. The regulations require that the developer or manufacturer must take appropriate steps to demonstrate and ensure the safety of the product under development and all medical products regulation should be aimed to achieve a number of core principles and concepts Safety, Efficacy Purpose Risk/benefit Quality[18]. The existence of substandard and falsified (SF) medical products is an unacceptable risk to public health. [19] The nature of falsified medical products can be explained in different ways. According to World Health Organization Falsified medical products may contain no active ingredient, the wrong active ingredient or the wrong amount of the correct active ingredient[20]. WHO asserted that Falsified medical products have been toxic in nature with either fatal levels of the wrong active ingredient or other toxic chemicals and furthermore Falsified medical products are often produced in very poor and unhygienic conditions by unqualified personnel, and contain unknown impurities and are sometimes contaminated with bacteria.[21] They often will fail to properly treat

[16] Study report « Counterfeit medicines and Organized crime » *Conterfeit medicines: the new face of organized crime* 25-sept.2013 – A new study of IRACM analyzes new criminal strategies in connection with counterfeit medicines trafficking. https://www.iracm.com/en/thematic-observatory/organized-crime/ 4:05 pm 3/4/2020
[17] Ibid
[18]*John J. Tobin, Gary Walsh*Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices p 1 publisherWiley-VCH 1 ed (2008).
[19] Substandard and falsified medical product https://www.who.int/medicines/regulation/ssffc/en/Accessed march 2/2020 at 10.53 am
[20] ibid
[21] ibid

the disease or condition for which they were intended, and can lead to serious health consequences including death.[22] Other studies show that Falsified medicine in developing countries mostly expanded around the world. Represent a serious problem for public health, especially in Africa; South-East Asia and Latin America[23] However Falsified medicines are not limited to a single type of medicines, targeted population or region. Products like analgesics, anti-inflammatory medicines, and blood products may also be falsified.[24] In wealthy countries in Europe, as well as in the United States, the presence of falsified medicines has increased considerably, especially online.[25]

2.3. Definition of falsified medicine

Giving universal definition for falsified medicines was very challengeable. One of the biggest challenges which makes difficult to give definition for falsified medicines is not easy to separate from other illegal medical products. The terms falsified and counterfeit are commonly used interchangeably in everyday language; these terms have diverging definitions in terms of pharmaceutical law.[26] Under European Union for trigging the applicability of different laws at EU level and local laws counterfeit and falsified medicines has been differentiated.[27] Falsified medicines refer to medicines which do not meet the standards of safety, efficacy and quality as are required under strict EU law.[28] Counterfeit medicines, on the other hand, medicinal products that infringe upon the intellectual property rights ("**IPRs**") owned by the proprietor of the said rights.[29] Although, the EU definition can make distinction between counterfeit and falsified medicine, but it could not make clear without refereeing other EU laws to understand comprehensively what falsified medicine mean. The WHO defines a falsified medicine as a

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[22] ibid pra 5

[23]Nayyar GM, Breman JG, Herrington JE. The global pandemic of falsified medicines: laboratory and field innovations and policy perspectives. Am J Trop Med Hyg. (2015); <.https://doi.org/10.4269/ajtmh.15-0221 >PMID: 25897072

[24]https://www.eupati.eu/safety-of-medicines/falsified-medicines/#Introduction (Accessed on March 6 /2020 at 3:18 pm)

[25]ibid

[26] The Difference between Falsified and Counterfeit Medicines <https://www.lexology.com/library/detail.aspx?g=fdada0ea-f064-454d-bb31-6018b79811b2 > (Accessed on March 6 at 3:23 PM)

[27] ibid

[28] ibid

[29] ibid

medical product that is deliberately and fraudulently mislabeled concerning identity and source[30]. Relatively the WHO definition is more precise and clear. To avoid legislative gaps and minimize risks to public health, a broad definition of medical products is used in UNODC Guide.[31]

The term "medical products" means medicines, excipients and active substances, as well as medical devices, their parts and materials, and accessories used in conjunction with medical devices[32]. Therefore it is better to take both WHO and UNODC definition.

2.4. International law and falsified medicine

In the global governance, there has been a prolific amount of scholarship regarding international law. Same literature articulate international law can be classified in two categories hard and soft law. This law and social science literature assesses the relative functional attributes and deficiencies of hard- and soft-law instruments as alternatives for international governance.

According to positive theory, the norms established in international agreements and those expressed in international custom are treated as legally binding, while resolutions, opinions and recommendations are not assigned this status, and all is the binary criterion that enables a distinction to be made between two types of international public law norms.[33] Positivists believe that soft laws have their own advantage under international regulation, some of the advantages of adopting soft laws are: -

- ✓ Lower negotiation costs,
- ✓ Less sacrifice on the part of states in terms of their sovereignty,
- ✓ Greater freedom to implement international standards in domestic law systems,
- ✓ The possibility to renegotiate provisions due to changing circumstances,
- ✓ Simplicity and speed of proceeding,
- ✓ Work on creating new regulations is open to other participants in international relations,

[30] n 4 p2 The WHO definition criticized with regard to medical products. The word medical products make slight gap with medical device. In this case criminal group may use the legislative gap as a defense. But the UNODC guide line has trying to minimize the legislative gap by giving the definition of medical products.
[31] ibid.
[32] ibid
[33] W. Reinicke, J.M. Witte, *Interdependence, Globalization, and Sovereignty: The Role of Non-binding International Legal Accords*, in *Commitment and Compliance: The Role of Non-Binding Norms in the International Legal System*, ed. D. Shelton, Oxford 2003, p. 75.

- ✓ The possibility of establishing a basis for binding legal regulations that will be formulated in the future.[34]

Constructive theory on the other hand articulates "Unlike positivism and materialism, which take the world as it is, constructivism sees the world as a project under construction, as becoming rather than being"[35] It is obvious representatives of constructivism focus on the process of creating and implementing the standards of international law. By adopting this assumption, constructivists focus on the role of law in the process of socialization, viewing the process of creating law as an opportunity to strengthen the shared system of norms.[36] Another important issue based on constructive theory state interests is formed through socialization processes means that state interest can be protected and preserved by interstate interaction i.e. possibility created by both hard and soft law facilitations.[37] When we see Rationalists, in contrast, contend that hard and soft laws have distinct attributes that states choose for different contexts.[38] The Rationalist theory support both soft and hard law can significant role under global governance. But positivist mostly favored for hard law because of the formally created by state and its binding nature upon them. But when came to Constructivists it often favor soft-law instruments for their capacity to generate shared norms and a sense of common purpose and identity, without the constraints raised by concerns over potential litigation.[39] As we have seen both hard and soft laws are very important for international system and global governance. The aim of this section is to navigate international standards which existed to regulate falsified medicines in the global governance. Same soft laws recently developed to address directly on the issues of falsified medicine at global level. As we have seen the previous section the magnitude of the problem of falsified medicine has been asserted by empirical research. It is very important to regulate falsified medicine by existing international governance system. The question which is related

[34]Cf. C. Lipson, *Why Are Some International Agreements Informal?*, "International Organization" 1991, p. 45; H. Hillgenberg, *A Fresh Look at Soft Law*, "European Journal of International Law" 1999, no. 3, pp. 499-515.
[35]E. Adler, *Constructivism and International Relations Theory*, in *Handbook of International Relations*, eds. W. Carlsnaes, T. Risse, B. Simmons, London 2002, p. 113.
[36] ibid:
[37] Hard vs. Soft Law: Alternatives, Complements, and Antagonists in International Governance <http://ssrn.com/abstract=1426123> accessed on April 24
[38] ibid

with what those laws are existed under international governance system will be systematically examined in this section.

2.5. International laws

2.5.1. Human right laws

States are required to take positive action to ensure that human rights can be realized.[40] Every state supposed to do their own effort to realize the rights, however, the extent of the obligation to fulfill varies according to the right concerned and the State's available resources[41]. Generally speaking, however, States should create the legal, institutional and procedural conditions that rights holders need in order to realize and enjoy their rights in full.[42] It is obvious the introduction of falsified medicines present to the end user. In the meantime right when the right holders used the product, they may face under complicated problems. Therefore, logically we can say that the rights could be infringed by the crimes which are related with the introduction of falsified medicines. Now all state should give the impression of being on combating of the crimes of the introduction of falsified medicine or else it is against the right to life, the right to health and the right to access to medicine.

I) The right to life

One of the prominent issues which states required to take positive action to ensure the right under human right is the right to life. The right to life is protected in the core regional and universal human rights instruments, including the following: African Charter on Human and Peoples' Rights (art. 4), American Convention on Human Rights (art. 4), American Declaration of the Rights and Duties of Man (art. 1),Arab Charter on Human Rights (arts. 5-8), Convention on the Protection of the Rights of Migrant Workers and Members of their Families (art. 9), Convention on the Rights of the Child (art. 6),European Convention for the Protection of Human Rights and Fundamental Freedoms (art. 2),Inter-American Convention on the Forced Disappearance of Persons, International Covenant on Civil and Political Rights (art. 6), Protocol No. 13 to the European Convention for the Protection of Human Rights and Fundamental Freedoms concerning the abolition of the death penalty in all circumstances, Protocol to the,

[40]United Nations (Office of the High Commissioner for Human Rights) Inter-Parliamentary Union 2016 Handbook for Parliamentarians number 26
[41] ibid
[42] ibid

American Convention on Human Rights to Abolish the Death Penalty Second Optional, Protocol to the ICCPR aiming at the abolition of the death penalty, Universal Declaration on Human Rights (art.3)[43] The right to life enclosed by much international documents and it is known that all international instrument conveyed global influence to ensure the right to life. As we have seen in the binging section of this chapter the magnitude of the problems of the introduction of falsified medicine may be further go to against the motherhood right. Hence states must take necessary action against the introduction of falsified medicines. We will discuss what states supposed to do against the introduction of falsified medicines under state obligation part.

II) The Right to Health

The right to health first emerged as a social right in the World Health Organization (WHO) Constitution (1946) and in the Universal Declaration of Human Rights (1948)[44]. The binding International Covenant on Economic, Social, and Cultural Rights (ICESCR) of 1966 details the progressive realization of the right to health through four concrete steps, including access to health facilities, goods and services.[45] The right to health has important concepts on the perspective of international law governance regarding the combating crimes related with the introduction of falsified medicines. States have great responsibility under global governance to ensure that the right is preserved in all aspects of protection, i.e. related with respecting, protection, and fulfillment. On the perspective of international standard the right to health has recognized and got attention included under different international instruments.

- ✓ European Social Charter[46]
- ✓ African Charter on Human and Peoples' Rights[47]
- ✓ African Charter on the Rights and Welfare of the Child[48]
- ✓ Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights[49]
- ✓ International Convention on Economic, Social and Cultural Right[50]

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[43] International Justice Resource Center https://ijrcenter.org/thematic-research-guides/right-to-life/ accessed on march 10/2020

[44] Access to essential medicines as part of the right to health <https://www.who.int/medicines/areas/human_rights/en/ > Accessed on March 10 /2020

[45] ibid

[46] European Social Charter (Turin, 18 October1961, entered into force 26 February 1965, 529 UNTS 89) art 11

[47] African Charter (Nairobi, 27 June 1981, entered into force 21 October1986, 1520UNTS217) art16

[48] (AddisAbaba,1 July 1990,entered into force 29 November1999,OAU Doc CAB/LEG/24.9/49) art14.

[49] (Protocol of SanSalvador) (SanSalvador,17 November 1988,enteredintoforce16 November 1999,OAS Treaty Series No 69 (1988), 28ILM156) art 10.

The issue of falsified medicines and the right to health is required to conjugate with others substantial questions: To what extent states must take steps by all appropriate means to secure the right to health? What are the obligations to secure the right to health progressively subject to available resources? The questions may lead us to examine the nature of the obligation imposed on states with respect to the specific measures listed in article 12 of the ICESCR and article 24 of the CRC. Article 12 of the ICESCR more elaborated by the United Nation on Economic and Social Committee from Normative up to detail content of the article.

The right to health in all its forms and at all levels contains the following interrelated and essential elements, the precise application of which will depend on the conditions prevailing in a particular State party: *(a) Availability;* functioning public health and health-care facilities, goods and services, as well as programs, have to be available in sufficient quantity within the State party; the precise nature of the facilities, goods and services will vary depending on numerous factors, including the State party's developmental level.[51] (b) *Accessibility;* Health facilities, goods and services have to be accessible to everyone without discrimination, within the jurisdiction of the State party.[52] (c) *Acceptability;* All health facilities, goods and services must be respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned[53]. (d) *Quality;* as well as being culturally acceptable, health facilities, goods and services must also be scientifically and medically appropriate and of good quality. [54] Human rights are interdependent, indivisible and interrelated.[55] Violating the right to health may often

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50International Covenant on Economic, Social and Cultural Rights Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966 entry into force 3 January 1976, in accordance with article 27) art **12**

[51]COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS Twenty-second session Geneva, 25 April-12 May 2000 Agenda item 3 SUBSTANTIVE ISSUES ARISING IN THE IMPLEMENTATION OF THE INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS General Comment No. 14 (2000) The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights) para 12 (a)

[52] ibid pra 12 (b)
[53] ibid pra 12 (c)
[54] ibid para 12 (d)
[55] Vienna Declaration and Program of Action (A/CONF.157/23), adopted by the World Conference on Human Rights, held in Vienna, 14–25 June 1993.

impair the enjoyment of other human rights. The importance given to the "underlying determinants of health", that is, the factors and conditions which protect and promote the right to health beyond health services, goods and facilities, shows that the right to health is dependent on, and contributes to, the realization of many other human rights.[56] These include the rights to food, to water, to an adequate standard of living, to adequate housing, to freedom from discrimination, to privacy, to access to information, to participation, and the right to benefit from scientific progress and its applications.[57]

- **Obligation of state**

✓ ***General obligation***

The obligations of states to protect the right to life are both positive and negative. That is, not only must States refrain from taking a life outside the circumstances described above, but they must also affirmatively act to protect against the loss of life.[58] Such positive obligations include: taking preventive measures in the face of known risk to life (for example, under our context prevent the introduction of falsified medicines), implementing national legislation which helps curb loss of life (such as in the regulation of hospitals and medical professionals), investigating and punishing wrongful acts resulting in death, and taking responsibility for the wellbeing of persons.[59] As we have seen the previous section the magnitude of the problem of falsified medicines are very extensive and it includes the deprivation of human life. Now it is obvious and empirically verified that the introduction falsified medicine against the right to life of the person. Provided, the government didn't take the positive action against falsified medicine the right to life will be at stake. Any Government who is party to the protocols and conventions which clearly indicates the right to life has an obligation to fulfil the ways and means to protect the right to life.

The United Nation Committee on Economic, Social and Cultural Right explained state's general obligations. The General state obligations under right to Health comprise; progressive realization, taking steps to realize the right to health and other core minimum obligation.

[56]The right to health, Fact sheet 31, Office of the United Nations High Commissioner for Human Rights and world health organization p 6 sec 1.6 Printed at United Nations, Geneva GE.08-41061–June 2008–13,600
[57] ibid
[58] n 43 accessed on march 23(2020)
[59] ibid

Through their ratification of human rights treaties, States parties are required to give effect to these rights within their jurisdictions. More specifically, article 2 (1) of the International Covenant on Economic, Social and Cultural Rights underlines that States have the obligation to progressively achieve the full realization of the rights under the Covenant.[60] The ICESCR in article 2 (1) simply states that the full realization of the rights contained in the treaty must be achieved through "all appropriate means, including particularly the adoption of legislative measures.

To ensure the state's general obligation on taking steps to realize the right to health the CESCR underlined the general indicator and benchmark. The Committee on Economic, Social and Cultural Rights has underlined that States should, at a minimum, adopt a national strategy to ensure to all the enjoyment of the right to health, based on human rights principles which define the objectives of that strategy.[61] Setting indicators and benchmarks will be decisive in the formulation and implementation of such a strategy.[62]

With respect to the core obligation on the right to health, the Committee has underlined that States must ensure:

- ✓ The right of access to health facilities, goods and services *on a non-discriminatory basis*, especially for vulnerable or marginalized groups;
- ✓ Access to the *minimum essential food* which is nutritionally adequate and safe;
- ✓ Access to *shelter*, *housing and sanitation* and an adequate supply of *safe drinking water*;
- ✓ The provision of *essential drugs*;
- ✓ *Equitable distribution* of all health facilities, goods and services.[63]

The like all human rights, imposes three types or levels of obligations on States parties: the obligations to *respect protect* and *fulfil*. In turn, the obligation to fulfil contains obligations to facilitate, provide and promote. The obligation to *respect* requires States to refrain from interfering directly or indirectly with the enjoyment of the right to health. The obligation to *protect* requires States to take measures that prevent third parties from interfering with article 12 guarantees. The obligation to *fulfil* requires States to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization

[60] n 56 p 23
[61] ibid
[62] ibid p 24
[63] ibid p 25

of the right to health.[64] Combating the crime related with the introduction of falsified medicines need efforts to specially protecting from crimes and criminal groups by adopting necessary Legal framework, fulfilling necessary equipments which serve for purpose of investigation, and taking all necessary measures upon offenders to deter them from other similar commission of crimes.

- ✓ ***Specific obligation***

The International standard supposed to do all states to perform both positive and negative obligations; it will be against international standard when states are reluctant in the prevention and suppression of falsified medicines. States specific obligation can lead to navigate the way and means to prevent and suppress the introduction of falsified medicines. In our context Specific means of prevention and suppression may directly and indirectly enables single state to identify specific response against falsified medicines and make possible to work together for all states in the prevention and suppression at the global level. Specific Obligations to *protect* include, *inter alia*, the duties of States to adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties; to ensure that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services; to control the marketing of medical equipment and medicines by third parties; and to ensure that medical practitioners and other health professionals meet appropriate standards of education, skill and ethical codes of conduct.[65]

2.5.2. United Nations Convention against Transnational Organized crime

Among other things United Nations Convention against Transnational Organized Crime mainly targeted for determining to deny safe havens to those who engage in transnational organized crime by prosecuting their crimes wherever they occur and by cooperating at the international level[66]. The scope of application of the conversion clearly can include the introduction of falsified medicines. The conversion stipulated states to adopt the criminalization of participation in an organized criminal group in their legal frame work. Each State Party shall adopt such

[64] n 51, para 33
[65] ibid para 35
[66] General Assembly resolution 55/25 of 15 November 2000, United Nations Convention Against Transnational Organized Crime New York,2004 page 2

legislative and others, measures as may be necessary to establish as criminal offences, when committed intentionally: those organized criminal groups agreeing with one or more other persons to commit a serious crime for a purpose relating directly or indirectly to the obtaining of a financial or other material benefit and, where required by domestic law, involving an act undertaken by one of the participants in furtherance of the agreement or involving an organized criminal group; conduct by a person who, with knowledge of either the aim and general criminal activity of an organized criminal group or its intention to commit the crimes in question, takes and active part in: 1st Criminal activities of the organized criminal group; 2nd Other activities of the organized criminal group in the knowledge that his or her participation will contribute to the achievement of the above-described criminal aim.[67] The convention endeavour to address all possible participants who organizing, directing, aiding, abetting, facilitating or counselling the commission of serious crime involving an organized criminal group.[68]

2.6. Soft International laws

According to constructive theory the world project is under construction and the construction process can be carried out through socialization process. We have seen even positives also believed that soft laws have their own advantage under international regulation. Some of the advantages of adopting soft law as a form of regulation are as follows: Lower negotiation costs, Less sacrifice on the part of states in terms of their sovereignty, Greater freedom to implement international standards in domestic law systems, The possibility to renegotiate provisions due to changing circumstances, simplicity and speed of proceeding, work on creating new regulations is open to other participants in international relations. Positivist finally believed that soft law will facilitate the possibility of establishing a basis for binding legal regulations that will be formulated in the future. Hence both soft and hard laws are very important in the global governance system. The aim of this section to navigate those international rules helps to prevent and suppress the introduction of falsified medicines.

2.6.1. Universal Declaration of Human right

The first notion of a right to health under international law is found in the 1948 Universal Declaration of Human Rights UDHR, which was unanimously proclaimed by the UN General

[67] ibid art 5

[68] ibid art 5 (b)

Assembly as a common standard for all humanity.[69] The Declaration sets 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.[70] The Universal declaration of Human right indicates the normative direction which state should comply to meet international standards. All states suppose to understand and complies the normative approach of UDHR. The right to health as with all international human rights, implementation and enforcement of the right to health critically depend on legislative and judicial action at the national level. normative obligations has permitted greater attention to be devoted to potential violations of the right to health by treaty-monitoring committees in their "concluding observations" or judgments on states' compliance as well as enforcement by quasi-judicial international institutions and national courts in specific cases[71]

2.6.2. Resolution by the Commission on Crime Prevention and Criminal Justice

The Commission on Crime Prevention and Criminal Justice (CCPCJ) was established by the Economic and Social Council (ECOSOC) resolution 1/1992. [72] The Commission acts as the principal policymaking body of the United Nations in the field of crime prevention and criminal justice. The General Assembly in its resolution, No 61/252 Authorizes the Commission on Crime Prevention and Criminal Justice, as the principal United Nations policymaking body on crime prevention and criminal justice issues. ECOSOC provided for the CCPCJ's mandates and priorities include improving international action to combat national and transnational crime and the efficiency and fairness of criminal justice administration systems.[73] In 2006 the General Assembly expanded the mandates of the CCPCJ to enable it to function as a governing body of

[69] *Universal Declaration of Human Rights, United Nations General Assembly Resolution 217 A (III)* New York, NY: United Nations; 1948

[70] UDHR art 25

[71] America public Health Association, The Right to Health under International Law and Its Relevance to the United States

[72] ECOSOC Organizational Session Establishment of Commission on Crime Prevention and Criminal Justice Resolution No 1/1992. ECOSOC Established the CCPCJ based on the General Assembly resolution 46/

[73] ECOSOC Organizational Session Establishment of Commission on Crime Prevention and Criminal Justice Resolution No 22/1992

the United Nations Office on Drugs and Crime (UNODC), and to approve the budget of the United Nations Crime Prevention and Criminal Justice Fund.[74]

2.6.3. Other relevant International organizations recommendations

As we have seen in the above sub-section and here under Specific organizations such as WHO and UNODC have an international responsibility to work on falsified medicine. World Health Organization (WHO) is the natural home for the negotiation, development, and adoption of the code of practice, article 2 of the WHO Constitution authorizes the organization, to act as the directing and coordinating authority on international health work.[75] The WHO should lead in the development of a code of practice on falsified and substandard drugs, in consultation with the World Customs Organization (WCO), the United Nations Office on Drugs and Crime (UNODC), and other stakeholders[76].

[74]Resolution adopted by the General Assembly on 22 December 2006 [*on the report of the Fifth Committee (A/61/592/Add.2)*] 61/252. Questions relating to the programme budget for the biennium 2006–2007 *The General Assembly*,

[75] World Health Organization, Basic Documents, Constitution of the World Health Organization, 45th ed., Supplement, October 2006. Chapter II, Article 2(a).

[76] Bookshelf n 2

Chapter Three

Ethiopian Legislative gap on the introduction falsified medicine.

Ethiopian legislative frame work with regard to falsified medicines

As we have seen on the previous chapter the magnitude of the problem is not limited to single individual state, and there is no boundary limitation on the distribution and manufacturing of falsified medicines. Regardless of territory, all states have been victimized due to the problem of falsified medicine. Another important issue which we have seen in the previous chapter is why states are giving due attention for falsified medicine is the link between organized criminal groups and the introduction of falsified medicines. Empirical studies asserted the link between organized crime and the introduction of falsified medicines. The studies indicated that fake drugs and organized crime is well established: the large scale traffic of falsified medicines is a financial bonanza for the mafia and terrorist networks around the world. Therefore states should check their legal frame work whether the existing law to what extent enable to give response for the magnitude of problem for the prevention and suppression. In this chapter we will see the Ethiopian legal frame works and its gaps which are existed to govern falsified medicines.

2.1. Food and Medicine Administration law

Food and Medicine law is a major one that regulates medicine. Most medicine and medicinal products and their fundamental substantive procedural governance as well as all regulative frames fall under this part of law. In Ethiopia there is law with regard to the issues and Proclamation No 1112/2019 enacted to provide for Food and Medicine administration. The proclamation immensely covered with regard to Medicine and Medical products. With other related laws it is very important to consider the proclamation in detail for answering to my research sub question in terms of the Ethiopian legislative gap with regard to the introduction of Falsified Medicine crimes**.**

2.1.1. Preamble part of the proclamation

The Preamble part of the Proclamation No 1112/2019 deals with the protection of public health from unsafe Food, unsafe and ineffective medicine and medical products as well as tobacco products. It is known that the Preamble part any proclamation covers the basic reason to enact the law which took emphasis on the intended to contain specific issues. The proclamation is

trying to address the basic issues within regard to Food and Medicine. Even though, the proclamation was enacted recently to regulate Food and Medicines, however the proclamation not addressed the issues of introduction of falsified medicines. It is obvious the issues must be addressed by the proclamation starting from the preamble part of the proclamation but it missed by unknown reason. The issue of Falsified Medicine should be covered by the preamble part of the proclamation based on two basic reasons. The First one is unsafe medicine and poor quality medical products are not similar with falsified medicine and medical products. It related with Sub- Standard medicine and medical products. The law should clearly separate the issues of Sub-Standard and Falsified Medicine and Medical in order to protect the adverse effects against the public Health. The second one is as we have seen the previous chapter the issues of Falsified Medicine currently has massive and complicated Public Health issues like Tobacco products, Unsafe Food and Sub-standard medicines. It requires great emphasis under the preamble part of the proclamation in order to give appropriate coverage for protecting and preventing the harmful consequences of Falsified Medicines.

2.1.2. Definition part of the proclamation

Under the definition part of the proclamation the word falsified medicine are not defined properly. Giving the meaning of Falsified medicine is essentially very important for shaping and governing the issues. Moreover it required for the protection and prevention of criminal activates. Giving the definition for Falsified Medicine are critically very important and helpful to identify criminal elements and criminalize those offenders who participated in different degree of criminal activities and participation in an offence. Absence of the definition may entails weak or ineffective as well as short of clarity on the prevention and suppression of the introduction of falsified medicine. However, article 2 of the definition part of the proclamation No 1112/20 entirely not defined the term falsified medicine.

2.1.3. Absence legal coverage for crimes related with introduction to falsified medicine

Among other things one of basic states responsibility for ensuring a safe, reliable drug supply is punishing those who knowingly manufacture and trade them. The criminal justice system must address all criminal elements from manufacturing and trading falsified medicines. It is obvious the production of falsified medicines can be conducted in a manner very complex and hidden circumstance. In responding to this criminal justice system must address all possible hidden

activities for prevention, detection as well as suppression. Under Article 67 contained elements on the medicines issues and it says any person who, by sub-standardizing, misbranding, or counterfeiting a regulated product, manufactures, import, store, wholesale or sell it in retail; or provide or distribute for use by the public shall be punishable by simple imprisonment for not exceeding three years and a fine not exceeding birr two hundred thousand; If the product's defect would cause grave harm to human health or life, he shall be punishable by imprisonment, not exceeding seven years and a fine not exceeding birr five hundred thousand.[77] It is obvious same of criminal elements included in the proclamation with regard to manufacturing, import, store, and wholesale or sell it in retail or distribute for use by the public. However from this substantive law expected to include more criminal elements in both Moral and Material elements. First of all from the very complex nature of the criminal activities the moral element should be classified based on the contribution as well as hidden nature of the crime. The first gap of the provision can be seen in light of basic criminal law rule. It is obvious under criminal law unless special laws explicitly indicated on their special part of the provisions negligence may not be punishable criminally. We will see in chapter four what specific activities should be included the negligence moral element to criminalize the issues of the introduction of falsified medicines. At this instant and discussion we have to see how the hidden nature of crime can be addressed by substantive provisions and how the perpetrator state of mind must be measured in less strict way. Another specific gap which we can pick from the above specific article the law missed specific nature of falsified medicine and mixed with other related issues. Specific provisions required for the introduction of falsified medicines for handling all criminal elements and measures to be taken based on criminal responsibilities. However the provision seems even didn't classify the word counterfeit and falsified mean. Another gap with regard to criminal liability the organization which involved in same criminal activities should be punishable by law; there are no specific provisions under the proclamation which talks about the liability of organizations based on their criminal activities. Failure to report should also be included as a crime to address all surrounded liability and to embark upon on the complex nature of the crime.

[77] Food and Medicine Administration Proclamation No 1112/2019 page 11099 25th year No 39 Article 67

2.1.4. Other Substantive and Procedural matters for preventing organized criminal group

Special investigative techniques required for law enforcement organs. We have seen in chapter two the link between organized criminal groups and the introduction of falsified medicines. As organized crime substantive and procedural matters should be addressed on proclamation. In particular, the substantive part of the law should address what organized crime mean and structured group to criminalize those who participated in organized form on a criminal activities. Special investigative techniques mostly known to trace and detect organized criminal activities should also be expected to cover by the proclamation. The United Nations Conversion against Transnational Organized Crime has intended for each state party to adopt special investigative techniques on their legal frame work. Provided, permitted by the basic principles of its domestic legal system, each State party Shall, within its possibilities and under the conditions prescribed by its domestic law, take the necessary measures to allow for the appropriate use of controlled delivery and, where it deems appropriate, for the use of other special investigative techniques, by its competent authorities in its territory for the purpose of effectively combating organized crime.[78] Ethiopia adopted special investigative techniques such as on anti-money laundering and anti-terrorism proclamation. However, the introduction of falsified medicine also required to establish special investigate techniques to trace and detect all criminal actives.

2.2. Trade Practice and Consumer Protection Law

Trade Practice and Consumer Protection law furthermore enacted for prevention the proliferation of goods and services that endanger the health and wellbeing of consumers, following the expansion of commercial activities, and to ensure their safeness and suitableness of human health in a sustainable manner, and to create the possibility that consumers get goods and services equivalent to the price they pay.[79] The scope of application as we all as the aim of the proclamation is very wide. In order to protect the consumers when they purchase goods and service the law wants to ensure safe and healthy as well as equivalent to the price they paid. According the proclamation medical products can be categorized under goods. The definitional part of the proclamation provides that goods means movable commodities that are being purchased or sold or leased or by which any commercial activity is conducted between persons

[78] n 66 UNCATOC article 20

[79] 16th year No 49 Trade practice and Consumers' Protection Proclamation 685/2010 page 5462 the preamble part of the proclamation paragraph three

except moneys in any form and securities.[80] Therefore, one can argue that if all medical products categorized under goods, and provided, the proclamation covers appropriate prevention and suppression mechanisms it will be enough to govern the introduction of falsified medicines. That is true same parts of the proclamation addressed same related issues. For instants, under the objective of the proclamation it stipulated that all goods and service should pass through sustainable human health and safety system.[81] Furthermore the proclamation prohibited unfair and misleading acts with regard to information or quantity or volume or acceptance or source or nature or component or use of goods and service may have; preparing or making available for sale or selling goods or services that are dangerous to human health and safety or those source of which is not known or are poisoned or have expired or are adulterated.[82] All put in plain words are important in the governance of the introduction of falsified medicines. However, there are limitations on the proclamations to address important issues on the prevention and suppression of the introduction of falsified medicines we can see in the next sub sections the gaps in govern the introduction of falsified medicines.

2.2.1. The proclamation focused on trade and related activities

Even though the scope of application of the proclamation wide on goods and service, it depend on a person's carrying on commercial activities and to any transaction in goods and services within the country. It always difficult to assert the relationship between commercial activities and any transaction with falsified medical products. It is obvious the process of manufacturing, distributing, stockpiling, acquisition, possession, export, use of the items, materials, equipments and technologies are more than commercial activities or any other transaction. Organized criminal groups can use both legal and illegal ways for the introduction of falsified medicines. When the law looking only commercial activities related with goods and service, it could be in missing position to combat the crime of introduction of falsified medicines. For instance criminals may also look other types of legal relation to hide their evil activities, and they can produce lots of possible defenses to conceal and disguise their true activities.

[80] ibid art 2(8)
[81] ibid art 3(2)
[82] ibid art 30(1)and (10)

2.2.2. Insufficient legal penalty

When we see the proclamation legal coverage with regard to same part of crimes related with introduction of falsified medicine the punishment which place specific article not enough. Other than business person who preparing or making available for sale or selling goods that are dangerous to human health and safety or those source of which is not known or whose quality is below standards set in advance or are poisoned or have expired or are adulterated punishable with fine only 30,000(thirty thousand) up to 50,000 (fifty thousand) birr and rigorous imprisonment from 2(tow) up to 4 (four) years.[83] I strongly argue that the punishment can't get across the intended general and special deterrence effects compared with the serious nature of the crime. Because it is obvious in the criminal activities other than business person may participate as principal offender in the selling and manufacturing goods which is dangerous to human health and safety including falsified medicine.

2.2.3. Procedural limitations

When conducting investigation the ministry of trade or Regional Bureau may use its own officer in order to carried out its powers and duties, however the law is not clear indicated the procedure how to enforce its power and duties by its own investigative officers; in the same place the proclamation directed the relevant provisions of the criminal procedure code of Ethiopia shall apply concerning the search and seizure power of the Ministry or the Bureau.[84] With regard to criminal procedure it is not clear the proclamation's intention what's more grating power for Ministry or Bureau to conducting investigation? Or else controlling the institutions within empty sphere working procedures? In any case either one of the answer or both could not be appropriate way of solving to the question of procedural gaps; because the existing old criminal procedure did not have sufficient methods for tracing and detecting the complex nature of the introduction of falsified medicine.

2.2.4. Lack of Organizational Liability

When a juridical person involved in a crime can be punishable as a principal criminal, an instigator or an accomplice. The Ethiopian Criminal code stipulated the possible criminal liability of juridical person under the General part of the code. A juridical person shall be deemed to have committed a crime and punished as such where one of its officials or employees

[83] ibid, art 8
[84] ibid art 42 (3) (4)

commits a crime as a principal, an instigator or an accomplice in connection with the activity of the juridical person with the intent of promoting its interest by an unlawful means or by violating its legal duty or by unduly using the juridical person as a means.[85] To ensure juridical liability the law shall clearly express under its special part regarding the offence which will considered as crime. When we are in place of Criminological looking the role of juridical person in the introduction of falsified medicines specially on the manufacturing, distributing, stockpiling, acquisition, possession, export, use of the items, materials, equipments and technologies the main responsibility may be in the hand of judicial person. It seems in some cases without the assistance of judicial person the crime would not be in effect.

2.3.Anti -money laundering law

Ethiopian money laundering proclamation contained essential rules and principles for preventing and suppressing organized crime. When we see Money laundering crime it depends on predicate offence. Money laundering is the Concealment or disguise of the true nature, source, location, disposition, movement, rights with respect to or ownership of property, knowing that such property is derived from an offence or offenses or from an act of participation in such an offense or offenses.[86] Money laundering predicate offense is the underlying criminal activity that generated proceeds, which when laundered, results in the offense of money laundering.[87] Money laundering under Ethiopian anti money laundering proclamation scope is very wide. Any person who knows or should have known that a property is the proceeds of a crime and who: converts or transfers the property for the purpose of concealing or disguising the illicit origin of the property or of assisting any person who is involved in the commission of the predicate offence to evade the legal consequences of his actions; conceals or disguises the true nature, source, location, disposition, movement or ownership of or rights with respect to the property; acquires, possesses or uses the property.[88] There is big gap with regard to the introduction of falsified medicines to cover on anti money laundering legal framework. The main reason is the introduction of falsified medicines has its own process and significant steps expected to verify the existence of it. On the issue Money laundering is another process which depended on the

[85] Proclamation No 414/2004 The Criminal code of The Federal Democratic Republic Of Ethiopia article 34 (1)
[86] Paul Allan Schott, Reference Guide to Anti-Money Laundering and Combating the financing of Terrorism 2nd edition world bank and monitory found January 2006.. p 21
[87] ibid
[88] Federal Negarit Gazette 19th year No 25 4th February 2013 prevention and suppression of money laundering and financing of terrorism proclamation page 6782 Article 29

introduction of falsified medicines processes. Therefore, both substantive and procedural gaps ought to be filled in order to govern all issues.

Chapter Four

Legislating the Introduction of Falsified Medicines

The International standard indicated that all National initiatives preventing from entering the falsified medicine requires comprehensive legal frame work. It is obvious at the global level all states should demonstrate their effort in their legal framework in combating the interdiction of falsified medicines domestically and at international level. Countries with weak control over the regulating introduction of falsified medicines may cause to problem for other neighboring countries, and reversely countries with uncompromising control over medicine sales and distribution can have their efforts undermined by illegal drugs markets in neighboring countries. Hence all state should improve their legal frame work in accordance with the international standards. The Ethiopian should fill the gaps which shown in legal frame works. And as far as possible the country should see the efforts in accordance with International Hard and Soft laws. In this chapter we will see how the Ethiopia legal frame fill its gaps and can be framed in order to give appropriate response for the introduction of falsified medicines.

4.1.The general way to integrate under Ethiopian legal system

Laws amendment and reform practice in Ethiopian legal system indicated that there are two basic options mostly used to integrate new issues in the legal system. No need to conduct further investigation to show the options because any one may understand when looking the amended or reformed laws. The first one is preparing new comprehensive law with regard to the issue. It is common practice under Ethiopian legal system to draft new law with regard the subject areas which are intended to govern by new law. Coming back to falsified medicine it is possible to enact new law to govern the issue what want to cover by new law. However, new legal framework must carefully drafted and sometimes over lap from other related issues such as counterfeit and sub-standard medicines, and in such case it face for ambiguity and interpretation. To avoid the clarity problem the new legal framework can itinerary the principle of inapplicable method. It is obvious as opposed to repealed method inapplicable method enables the laws to work collectively on their covering subject matter. The second commonly used method is improving the existing laws by adding together into one part of law or in the fragmented way. This option also commonly used in different parts of areas of law it easily enable to improving the existing laws in one areas of law or fragmented. This method is very clear the issues of

falsified medicines governing principles and rules can be incorporated under the existing laws by way of reform into one subject of law or in other areas of laws as it may necessary. Both methods are its own affirmative and off-putting effects; however this research will not focused on the comparison of the options rather it focus what rules and principles incorporated under the Ethiopian legal frame work which will use for prevention and suppression of the crimes. Therefore, both options are effective as long as fundamental concepts, principles, and detail rules are incorporated. The basic guiding principle to show in this chapter is answering on the question what the Ethiopian legal frame work supposed to include the issues of covering the crime of the introduction of falsified medicines.

4.1. Prioritizing falsified medicines

We have seen in chapter two the magnitude of falsified medicines. For more understanding and prioritizing the issues of falsified medicines we can see the sub-Saharan African study with regard to anti malaria drugs. Falsified and substandard anti malarias cause an estimated 116,000 deaths annually in sub-Saharan Africa, according to a WHO study.[89] The underlying report's focus is mostly on medicines that have been fraudulently manufactured, these medical products deliberately endanger the health of patients when containing no or false active ingredients.[90] Developing countries in Africa and South-East Asia are of particular interest as target markets for fraudulent medicines; weak health systems, combined with miscalculations concerning demand of health services, offer favorable conditions there.[91] Prioritizing the issues of falsified medicines under the legal frame work may manifested by different ways. However one of the most important methods is giving a place on preamble part of the law and incorporating important rules and principles based on the preamble direction. As we have seen in chapter three the issue of Falsified Medicine should be covered by the preamble part of the proclamation based on two basic reasons. The First one is unsafe medicine and poor quality medical products are not similar with falsified medicine and medical products. It related with Sub- Standard medicine and medical products. The law should clearly separate the issues of Sub-Standard and Falsified Medicine and Medical in order to

[89] The hidden danger of sub-standard and falsified medicines No 25 May 2019 Germen Check? Institute for International and Security Affairs Page 2
[90] ibid
[91] ibid

protect the adverse effects against the public Health. The second one is as we have seen the previous chapter the issues of Falsified Medicine currently has massive and complicated Public Health issues like Tobacco products, Unsafe Food and Sub-standard medicines. It requires great emphasis under the preamble part of the proclamation in order to give appropriate coverage for protecting and preventing the harmful consequences of Falsified Medicines**.** Ultimately, falsified medicines reach the end-user via illegal distribution channels or they find their way into legal supply chains. In order to build appropriate trust on the health care system it is very important prioritizing the issues of falsified medicine under core legal system.

4.2. Giving appropriate definition

With the absence appropriate legal definition it will be very difficult for shaping and governing to combat the crimes related with the introduction of falsified medicines. As we have seen in chapter two giving universal definition for falsified medicines was very challengeable. We have seen one of the biggest challenges which makes difficult to give definition for falsified medicines is not easy to separate from other illegal medical products. We have also seen this problem existed under Ethiopian food and medicine proclamation especially with regard to sub standard and counterfeit medicines. We have seen also the best example which can be taken as differentiating the terms in appropriate way seen Under European Union for trigging the applicability of different laws at EU level and local laws counterfeit and falsified medicines. it give us concrete knowledge the difference between counterfeit and Falsified medicines. to remind falsified medicine refer to medicines which do not meet the standards of safety, efficacy and quality as are required under strict EU law. Counterfeit medicines, on the other hand, medicinal products that infringe upon the intellectual property rights ("IPRs") owned by the proprietor of the said rights. Now the Ethiopian legal system may take the distinction between counterfeit and falsified medicine from European legal system. However no one should not forget that even though the EU definition makes clear distinction between counterfeit and falsified medicine, it could not make comprehensive meaning without refereeing other EU laws. Hence it is better to look other single definition with regard to Falsified Medicine. We have seen The WHO defines a falsified medicine as a medical product that is deliberately and fraudulently mislabeled concerning identity and source. Relatively the WHO definition is more precise and clear, however, we have seen in chapter tow the definition criticized with regard to medical products. We have to see the option to fill the definition gap or uncertainty because we have

seen in chapter two the main challenge of the WHO definition word medical products make slight gap with medical device. In this case criminal group may use the legislative gap as a defense. But the UNODC guide line has trying to minimize the legislative gap by giving the definition of medical products. To avoid legislative gaps and minimize risks to public health, a broad definition of medical products is used in UNODC Guide. The term "medical products" means medicines, excipients and active substances, as well as medical devices, their parts and materials, and accessories used in conjunction with medical devices. Therefore, for giving appropriate definition and shaping and governing in appropriate way it is very important to take both falsified medicine and medical products as one. Hence, taking into account the above discussion the Ethiopian legal definition should be framed as follows:-

Falsified Medicine means, medical products, such as excipients and active substances, as well as medical devices, their parts and materials, and accessories used in conjunction with medical devices that are deliberately and fraudulently mislabeled concerning identity and source.

4.3. Identification of falsified medicines

Identification of falsified medicines is not easy task. Substantive and procedural matters are critical in the identification of falsified medicines. It obvious the identification requires different professionals, institutional structures, advanced devices and working procedures. Falsified medicines should be differentiated from other types of medicines. Law enforcement organ which needs information with regard to falsified medicines has to support by relevant laws.

Generally we have seen that the issues of falsified medicines are not properly included in Ethiopian legal system. We have seen in Chapter three the laws which are enacted to govern the issues of medicines mainly talks about counterfeit and sub-standard medicines. It seems that identification process also narrowly focus on the counterfeit and sub-standard medicines. Measures which should take on falsified medicines supposed to be different from counterfeit and sub-standard medicines. We have seen in chapter three, Food and Medicine Administration proclamation has granted powers for executive organ with regard to basic administrative and regulatory issues. However, in my conclusion the executive organ substantive powers over medicines are not competent enough in identifying falsified medicines.

As we have seen relevant provision with regard to falsified medicine and the power of executive organ is identifying ingredients that caused death, sickness, disability, disorder, or other health

problems due to adulteration or other illegal activities on regulated products and take appropriate legal measure by conducting investigation of sample ingredients. The main problem with regard to the existing executive organ powers the law initially has not been enabled to classify the sub-standard and falsified medicine. It is obvious the issues of sub-standard and counterfeit medicines mostly involved with third party interest. The result of investigation challenged by those persons who have vested interest in civil matters and it is obvious same of the issues may bring to court with tangible evidence against the executive organ decisions. But the issues of falsified medicine it totally related with criminal activity which conducted in very complex way. Therefore, in order to establish proper legal framework for prevention and protection as well as suppression of the crimes related introduction of falsified Medicines the executive organ should have a power and working procedure enables to it in identifying Falsified Medicines. I strongly argue that the substantive power should enable the executive organs to identify separately from other types of medicines. In concluding my argument with regard to the executive power the substantive power and working procedure should be professionally designed and formulated to identify falsified medicine as per the definition means to identify excipients and active substances, as well as medical devices, their parts and materials, and accessories used in conjunction with medical devices that are deliberately and fraudulently mislabeled concerning identity and source.

4.4. Criminalizing the introduction of falsified medicines

Falsified medical product-related crimes occur along a supply chain that runs from the manufacturer of the falsified medical product to distributors and sellers and, ultimately, the end consumer.[92] The major offences identified at international level with regard to falsified medical products are:-

- ✓ Manufacture of a falsified medical product;
- ✓ Trafficking in falsified medical products;
- ✓ Possession of falsified medical products intended (or likely) to be used in manufacturing or placed in the distribution system;
- ✓ Offences related to trafficking in falsified medical products by electronic and distance selling;

[92] n 4 page 20

- ✓ Failure to report.[93]

4.4.1. Manufacturing of falsified medicines

For the purpose of criminalizing the introduction of falsified medicine the criminal act of "Manufacture" stipulated under international standard. The act is defined based upon different issues of elements namely the Manufacture of Medicine, an excipient or active substance Device, and Accessory. Manufacturing elements of crimes which stipulated under international standard as follows:-

- As regards a medicine, an excipient or an active substance – any part of the process of producing the medicinal product, or an active substance or excipient of such a product, or of bringing the medicinal product, active substance or excipient to its final state;
- As regards a medical device – any part of the process of producing the medical device, or the parts or materials of the medical device, including designing the medical device, the parts or materials, and of bringing the medical device, the parts or materials to their final state;
- As regards an accessory to a medical device – any part of the process of producing the accessory, including designing the accessory, or of bringing the accessory to its final state.[94]

The substantive elements of crime should be contextualized to integrate under Ethiopian legal system based on the existing circumstance of the working procedures, norms of other legal frame works. The moral elements which indicated by international standard is only for intentional acts. Ethiopia is developing country in all sectors including health regulation and law enforcement activities. Therefore, in order to support health regulation system and law enforcement activities the substantive criteria with regard to moral element should be less strict to comply with country's reality. However it does not mean that we should adopt substandard principle on the moral element we also should not be expand the issue in remote way to convict innocent person. In balanced way the manufacturing element can be designed as follows:-

Article xxxxx……. Manufacturing of falsified medicines

(1) Whoever intentionally for the purpose of manufacturing falsified medicine:-

[93] ibid
[94] ibid page 21

a) Producing the medicinal product, or an active substance or excipient of such a product, or of bringing the medicinal product, active substance or excipient to its final state;

b) Producing the medical device, or the parts or materials of the medical device, including designing the medical device, the parts or materials, and of bringing the medical device, the parts or materials to their final state;

c) Producing the accessory, including designing the accessory, or of bringing the accessory to its final state,

is punishable with rigorous imprisonment from five to ten years, with fine one million to ten million birr.

d) Where one of the acts specified in sub-article (1) a),b) and c) above is committed negligently, the punishment shall be not exceeding five years rigorous imprisonment, with fine five hundred thousand to five million birr.

(2) Any juridical person which participated in one of the crimes specified in sub-article (1) a),b) and c), shall be punishable in fine not exceeding one hundred million

As per international standard, and the country's existing circumstance, the above article enable to criminalize those natural and artificial person who will participating in the manufacturing of falsified medicines. With regard to juridical person criminal liability, in the decision of the amount of punishment it is better to left for courts discretion. The criminal code also understands the possible existence of the circumstance in fixing the amount of fine. The criminal code stated that in fixing the amount of the fine, the court shall take into consideration the degree of guilt, the financial condition, the means, the family responsibilities, the occupation and earnings there from, the age and health of the criminal.[95]

4.4.2. Trafficking in falsified medicines

The purpose of criminalizing trafficking in falsified medical products is not only to protect the domestic market from the entry of such products, but also to prevent their export to other markets; to allow States to exercise their jurisdiction over a broad range of acts, the term "trafficking in falsified medical products" is broadly defined in the glossary of terms above, as importing, exporting, storing, transporting, donating, dispatching, dispatching in transit, dispatching in free-trade zones, trans-shipping, distributing, brokering, offering, keeping for

[95] n 85 art 90(2)

offer, selling or supplying a falsified medical product, whether on one's own behalf or for a third party.[96] For Ethiopian context t is better to take broad range of material elements to combat falsified medicines trafficking. Therefore, the article can be designed as follows:-

Article xxxxx…….. Trafficking in falsified medicines

(1) Whoever whether on one's own behalf or for a third party intentionally importing, exporting, storing, transporting, donating, dispatching, dispatching in transit, dispatching in free-trade zones, trans-shipping, distributing, brokering, offering, keeping for offer, selling or supplying a falsified medicines,

is punishable with five years to fifteen years rigorous imprisonment and in fine not exciding five million birr.

(2) Where the crime is committed negligently, the punishment shall be not exciding five years rigorous imprisonment and in fine not exciding two million birr.

(3) Where the crime is committed by electronic or distance selling or by service provider the punishment not exciding ten years rigorous imprisonment and in fine not exciding five million birr.

(4) Where the offence is committed by juridical person which participate in sub article (1) of this article shall be punishable up to ten million birr.

Trafficking in fake medicines is a trans-national phenomenon and large numbers of players engage in this criminal activity for relatively long periods (on a regular, uninterrupted basis).[97] It would therefore appear to fit the criteria for organized crime, if we take the definition, albeit a particularly flexible one, used by the UN Convention on Transnational Organized Crime, signed in Palermo in 2000 and according to which "*an organized criminal group*" is "*a structured group of three or more persons, existing for a period of time and acting in concert with the aim of committing one or more serious crimes or offences established in accordance with this*

[96] n 4 page 24

[97] **Fake medicines trafficking in West Africa** Supply chains and distribution networks (Nigeria, Benin, Togo, Ghana)***Camille Niaufre****December 2014 page 22*

Convention, in order to obtain, directly or indirectly, a financial or other material benefit". [98]In Africa the organizations implicated in the trafficking of fake medicines come in all shapes and sizes; the smallest ones (with less than five members) rely mainly on e-trade and online marketing and they do import these products into the African continent. The largest organizations can bring together hundreds of individuals involved to a greater or lesser degree in the trafficking and they rely on complex transnational legal structures and on numerous "cover" companies and local subsidiaries.[99] Therefore among other things it is very important to include falsified medicines trafficking in organized criminal activity.

4.4.3. Possession of falsified medicines

International standard recommended to introduce provisions criminalizing the possession of falsified medical products where it is intended (or likely) that the falsified medical product will be used in a manufacturing process or placed in the distribution system for wholesale or retail supply; Offences of this kind may be useful to prosecutors where there is evidence of criminal activity related to falsify medical products but there does not appear to be sufficient proof of an act of trafficking.[100] The Ethiopian legal frame work should also introduce provision for criminalizing the possession of falsified medical products. More importantly the provision serves to simplifying the challenges to proof the manufacturing and trafficking of falsified medicines. Therefore the provision can be designed as follows;-

Article xxxxx……. Possession of Falsified Medicines

(1) Whoever intentionally possess falsified medicines where the falsified medicines intended that will be used in a manufacturing process or placed in the distribution system for wholesale or retail supply,

is punishable with not exciding five years rigours imprisonment, and in fine not exciding five million birr.

(2) Where the crime is committed negligently, the punishment shall be simple imprisonment or not exciding three years rigorous imprisonment, and in fine not exciding two million birr.

[98] ibid
[99] ibid p 23
[100] Ibid p 25

(3) Where the crime committed by judicial person the punishment shall be not exciding ten million birr.

4.4.4. Failure to report

Another important issue which recommended fighting falsified medicines is criminalizing those who have sufficient information with manufacturing, possession and trafficking of falsified medicines**.** Proactive measures to guarantee the integrity of the supply chain of medical products are thus crucial to mitigating the public health risks posed by falsified medical products. To assist authorities in the detection of falsified medical products, States are encouraged to introduce a proactive reporting system requiring actors at all stages of the supply chain of medical products to report transactions in falsified or suspected falsified medical products.[101]
Ethiopia may design the criminal act as follows:-

Article xxxxx…… Failure to report

(1) Whoever having a knowledge or should have known a falsified medicines manufacturing, trafficking and possession intended that will be used in a manufacturing process or placed in the distribution system for wholesale or retail supply, fails to inform the authorities thereof, or does not to the best of his ability to bring the criminal to justice, save in cases of force majeure or manifest impossibility, is punishable with rigorous imprisonment not exceeding three years

4.5. Other Necessary Procedural Frame Work

Regular criminal procedure may apply to all criminal investigation. However, international standard advised to use special investigative techniques and international corporations among countries. Transnational organized crime prevention conversion stipulated with regard to special investigative techniques, if permitted by the basic principles of their domestic legal systems, the necessary measures to allow for the appropriate use of controlled delivery and, where appropriate, other special investigative techniques such as electronic or other forms of surveillance and undercover operations. [102] Under Ethiopian context special investigative techniques are not new. Anti-corruption, anti terrorism law, and anti-money laundering law

[101] ibid p 28
[102] n 66 UNCATOC art 20

contained special investigative techniques. Easily, in order to compatible with special investigative techniques and international cooperation for falsified medicines decide on creating the legal link between laws which have it is very important. I strongly recommend the creation of link with Anti-money laundering law. Subsequently the investigator may use the special investigative techniques and international cooperation with other countries for predicate offence with regard to falsified medicines and money laundering which gained from the introduction of falsified medicine crimes.

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Chapter five

Conclusions and recommendations

4.6. Conclusion

We have seen in chapter two the magnitude of the problem of falsified medicine and its harmful effects on human health, economic and social issues. Eventually, to minimize the harmful effects falsified medicines at the international level conveys great emphasis to combat the crimes related with introduction of falsified medicines. The most important step-which have taken at the international level to fight against falsified medicines are comprehend due to the serious and trans-boundary nature of crimes, the involvement of organized criminal groups and the proliferation of falsified medical products and manufacturing business are in calling to give coordinated responses and active engagement at the international. Now efforts have been trigged in combating transnational pharmaceutical crime, and reducing the human cost of falsified medicines.

In the combating efforts, challenges are identified at the international level. The major challenges which identified at the international level are absence of clear legal definition, not criminalizing public health crimes, lack of cooperation among countries, lack of global standard and tracing technology.

All the challenges which identified at the international level are existed in the Ethiopian context. As perspective of developing country, in Ethiopia the challenges more strong than developed nation, and the magnitudes of the problems also more severe than those countries which have better controlling system. We have seen as well organized criminal groups are also preferred to expand their criminal activities in jurisdiction which has less regulation system. This thesis identified specific gaps under Ethiopian legislative framework which should fill without postponement. Absence of appropriate definition is the first identified gaps in the legal frame work. There is no legal frame work that enables to make clear distinction among the issues of sub-standard and counterfeit medicines which are different from falsified medicines. The second gap is absence of legal coverage to criminalize the introduction of falsified medicine. The Ethiopian legal frame work should take as public crimes which are the acts related with the introduction of falsified medicine. With regard to taking and covering as public crime the following issues are shown as a clear gaps: - Manufacture of a falsified medical product,

Trafficking in falsified medical products, Possession of falsified medical products intended (or likely) to be used in manufacturing or placed in the distribution system, Offences related to trafficking in falsified medical products by electronic and distance selling and failure to report. The absence of legal coverage extends to not criminalizing artificial person which involved in the commission of the introduction of falsified medicines. Other gap which detected by this thesis under Ethiopian legal frame work is absence of special investigative technique and international cooperation leading procedure. Criminals including organized criminal groups used different complex methods for the commission of crime related with introduction of falsified medicine. In Ethiopia legal system investigative authority may not able to use extra ordinary method to investigate and detect for the crimes related with the introduction of falsified medicines. There is no sufficient leading procedure which enable to the authority to carry out international cooperation among states. All the identified gaps should be felt with appropriate ways. In conclusion I provide the following recommendations to address and to fill the gaps on the issues introduction of falsified medicines.

4.7. Recommendations

- The first gap identified by this research should be addressed by providing appropriate definition. The major issue necessitate to need definition is there different pharmaceutical issues are existed in the area. Particularly the definition should clearly separate the issues related with sub-standard and counterfeit medicines. Therefore, the definition must see the other pharmaceuticals issues and giving appropriate meaning which will enable to identify illegitimate medicines. Therefore, it is very useful to use the definition which the researcher proposed under this thesis in order to avoid confusion and unwelcome over-reaches against illegitimate medicines.

- To fill the gap which identified with regard to absence of legal converge related with introduction of falsified medicines as public health crimes can be fill by drafting and integrating under the legal system. The major crimes have been identified by this thesis which should integrate under Ethiopian legal system. Hence Ethiopia should draft new provisions to criminalize those natural or artificial persons when they engage on the Manufacturing. Trafficking including via electronic ways, Possession, and failure to

report. The researcher designed the contextualized draft articles that can be incorporated under Ethiopian law to criminalize both artificial and natural persons. Using those drafted articles enables the country to take appropriate measure against the introduction of falsified medicines.

- The legal framework should acknowledge the general effect of special investigative techniques and international cooperation important in the prevention and suppression of the introduction of falsified medicines. In Ethiopian legal system the anti-money laundering law contained key special investigative techniques such as surveillance, undercover operation, and control delivery and international cooperation. In order to apply all special investigative techniques and international corporations the link should be created with anti-money laundering proclamation. The slit gap should also must be avoided where the introduction of falsified medicine covered by new legislation as predicate offence. For the reason that the crimes related with the introduction of falsified medicine requires conducting investigation and detection before occurring process of disguising money laundering crime. Therefore the researcher strongly recommends the creation of link with Ethiopian anti-money laundering proclamation. However the central authority must be identified based on the nature of crime, effectiveness on international cooperation and the concerned competent authority.

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