IMPEDIMENTS TO THE ATTAINMENT OF THE RIGHT TO HEALTH IN KENYA: A CASE FOR THE UTILIZATION OF TRADITIONAL MEDICINE

BY

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DECLARATION

I, **KIGEN CHERUIYOT ROBINSON**, do hereby declare that this is my original work which has not been submitted nor intended to be submitted for a degree in any other University.

DECLARANT: **.....**

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Date**.....08.12.2020.....**

This thesis has been submitted for examination with my approval as the University Supervisor.

SUPERVISOR: ....

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Date**.....27.10.2020.....**

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The journey towards completing my thesis was long and bumpy. Bumpy because as a litigation lawyer of over ten years, it was always easy to prioritize business over studies. Laxity was slowly creeping in. It was tempting to give up but I soldiered on.

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DEDICATION

I dedicate this to my lovely family. You are my great source of inspiration.

LIST OF CITED CASES

1. Law Society of Kenya v Hillary Mutyambai Inspector General National Police Service & 4 others; Kenya National Commission on Human Rights & 3 others (Interested Parties) [2020]eKLR.

2. Luco Njagi & 21 others v Ministry of Health & 2 others [2015]eKLR

3. Kenya Airports Authority v Mitu-Bell Welfare Society & 2 others [2016] eKLR

4. Mitu-Bell Welfare Society v. The Hon. Attorney General and 2 Others [2013]eKLR.

5. P.A.O & 2 Others v Attorney General [2012] eKLR.

6. Republic -v- Minister For Home Affairs and Others ex parte Sitamze Nairobi HCCC NO, 1652 OF 2004 [2008] 2 EA 323

7. Koigi Wamwere V Attorney General [2012]eKLR.

ABSTRACT

The promulgation of the Kenyan Constitution in the year 2010 heralded a new dawn for the recognition of the right to health as a socio-economic right and thus justiciable. The Constitutional underpinning of this right is Article 43 (1) (b) of the Constitution of Kenya that provides that every person has a right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care. The Constitution of Kenya envisages that full realization of highest standards of health by Kenyans is progressive. It is dependent on availability of resources, among others. This study explores the crucial role of state in promoting realization of the right to health in Kenya, lapses in the existing legal framework that poses threat to Kenyan's bid to access medicine hence undermine the right to health realization. The study makes an in-depth discussion of the role of traditional medicine and knowledge on it in promoting right to health and makes a case for an integration of traditional medicine into the conventional health care system to improve access owing to its affordability, accessibility to majority of Kenyans and contribution to the knowledge of the present scientists. Its integration can also ensure it meets the acceptable quality for safe use. As Kenya executes plan of action of the World Health Organization (WHO) on, *interalia*, public health, there are myriad of challenges that stifles the attainment of the right to health and which if addressed can enable millions of Kenyans to access medicine and thus realize right to health. The discussion in various chapters informs recommendations for reforms.

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ABBREVIATIONS

ARIPO	African Regional Intellectual Property Organization
CEDAW	Convention on the Elimination of All Forms of Discrimination against Women
cGMP	Current Good Manufacturing Practices
CPD	Continuous Professional Development
CPE	Continuing Pharmacy Education
CoG	Council of Governors
CoK	Constitution of Kenya
CTIS	Clinical Trials Information System
ECHR	European Convention on Human Rights
EU	European Union
HRA	Human Rights Act
FBO	Faith Based Organizations
ICESR	International Covenant on Economic, Social and Cultural Rights
IPRs	Intellectual Property Rights
NDP	National Drug Policy
PHP	Private Health Provides
PNFP	Private-Not-For-Profit
PSK	Pharmaceutical Society of Kenya
KEMSA	Kenya Medical Supplies Authority
NCMs	Non-Conventional Medicines
UDHR	Universal Declaration of Human Rights
R&D	Research and Development
STI	Science Technology and Innovation
TCMP	Traditional and Complimentary Medicine Providers
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TRM	Traditional Medicine
WHO	World Health Organization

WIPO	World Intellectual Property Organization

LIST OF LEGAL INSTRUMENTS

Kenya

1. Government of Kenya, Constitution of the Republic of Kenya, 2010.
2. Medical Practitioners and Dentist Act, Chapter 253, Laws of Kenya.
3. Public Order Act, Chapter 56, Laws of Kenya.
4. Protection of Traditional Knowledge and Cultural Expressions Act, Act No. 33 of 2016, Laws of Kenya.
5. Science, Technology and Innovation Act, Act No. 28 of 2013, Laws of Kenya.
6. Environmental Management and Coordination Act, Act No. 8 of 1999, Laws of Kenya.
7. The Treaty Making and Ratification, Act No. 45 of 2012, Laws of Kenya.
8. The Health Act, Act No. 21 of 2017, Laws of Kenya.
9. Judicature Act, Chapter 8, Laws of Kenya.
10. Constitution of Kenya, 2010.
11. Food, Drugs and Chemical Substances Act, Chapter 254, Laws of Kenya.
12. Radiation Protection Act, Chapter 243, Laws of Kenya.
13. Public Health Act, Chapter 242, Laws of Kenya.
14. Narcotic Drugs and Psychotropic Substances (Control) Act, Chapter 245, Laws of Kenya.
15. Science, Technology and Innovation Act, Act No. 28 of 2013, Laws of Kenya.
16. Science, Technology and Innovation Act, Act No. 28 of 2013, Laws of Kenya.
17. HIV and AIDS Prevention and Control Act, Act No. 14 of 2006, Laws of Kenya.
18. The Cancer Prevention and Control Act, Act No 15 of 2012, Laws of Kenya.
19. The National Government Constituencies Development Act, Act No. 30 of 2015, Laws of Kenya.
20. Kenya Medical Supplies Authority Act, Act No. 20 of 2013, Laws of Kenya.
21. Pharmacy and Poisons Act, Chapter 244, Laws of Kenya.
22. The Anti-Counterfeit Act, Act No. 13 of 2008, Laws of Kenya.
23. Pharmacy and Poisons Act, Chapter 244, Laws of Kenya.
24. Health Laws (Amendment) Act, Act No. 9 of 2019, Laws of Kenya.

Regional and International Instruments

1. African Charter on the Rights and Welfare of the Child.
2. Banjul Charter.
3. African Charter on Human and Peoples' Rights.
4. International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families.

CHAPTER ONE

1.1 INTRODUCTION

This Chapter delineates the structure of the study. It identifies the problem as well as justification and study significance. It identifies study objectives and sets out research questions as well as study assumptions that are related to the weakness within the regulatory framework and the inability of the state to enact a sound legislation that will regulate the practice of traditional medicine and knowledge on which it is based as a way of promoting access to medicines. It highlights theoretical framework as well as review of the existing literature on the area under study in terms of enhancement of right to health realization. It identifies methodology, scope and limitation of the study as well as the chapter breakdown.

1.2 INTRODUCTION AND BACKGROUND TO THE STUDY

On 10th December 1948, the General Assembly of the UN adopted and proclaimed the Universal Declaration of Human Rights (UDHR) as a common standard of attainment for all individuals and all countries. The same establishes that every person is entitled to basic necessities for his or her health and well-being, including food, clothing, housing, medical care, and other social services, as well as financial security in the event of unemployment, illness or disability, widowhood, old age, or any other inability to support oneself or one's family for reasons beyond his or her control.[1].

The new constitutional dispensation in Kenya in the year 2010 heralded a new dawn for the recognition of socio-economic rights. Article 43 (1) of the Constitution of Kenya, 2010 (CoK) is now the pinnacle of not only the fundamental right to health but also makes the right justiciable. It establishes that every individual has the right to, *interalia,* the maximum achievable health standard that comprises of the right to health care services, especially reproductive health care. Right to health is justiciable under the present constitutional framework.

The promulgation of the CoK, 2010 has expanded the space to stimulate the achievement of the right to health. It altered the status of international law instruments approved in Kenya into a law

[1] European Social Charter, Article 11 (revised) 1965.

source. Under the repealed independence Constitution, the sources of law in Kenya were the Constitution; Acts of Parliament; some specified UK statutes; the common law, doctrines of equity and statutes of general application in force in England on 12th August 1897; and finally customary law[2]. International law and principles did not form part of Kenyan law unless they were domesticated. CoK provides that the international treaties and conventions that are ratified by Kenya shall form part of the laws of Kenya.[3] Further, the general rules of international law form part of the law of Kenya.

While the CoK recognizes general rules of international law and any treaty or convention ratified by Kenya under the Constitution as part of our law of Kenya, there is still lethargy by the state in making sound legislative interventions that promotes access to medicine and by extension enhance right to health realization. Prices of medicines are still high and beyond the reach of many poor Kenyans. This is contributed by high costs of manufacturing, lack of tax incentives to pharmaceutical firms to reduce prices of essential medicines. This study will flag out impediments to attainment of the right to health.

Article 11(1) of the CoK recognizes culture as the cornerstone of the nation and as the cumulative civilization of the Kenyan people and nation. Article 11(2) mandatorily obligates the state to do three things. First, to enhance every form of national and cultural expression through literature, the arts, traditional celebrations, science, communication, information, mass media, publications, libraries and other cultural heritage. Secondly, to recognize the role of science and indigenous technologies in the national development. Lastly, to promote the intellectual property rights of the people of Kenya. Article 11(3) (b) of the CoK empowers the legislature to enact a law to recognize and protect the ownership of indigenous seeds and plant varieties, their genetic and diverse characteristics and their use by the Kenyan communities.

While legislation is expected to facilitate access to quality and affordable drugs, certain legislations that will be highlighted have impeded access to quality and affordable drugs. According to the

[2] Section 3 of the Judicature Act, Chapter 8, Laws of Kenya.
[3] Article 2(6) of the Constitution of Kenya, 2010.

WHO, Traditional medicine (TRM) plays an important role in the health care of a substantial proportion of the population living in poor nations, with statistics indicating that up to 80% of Africans – or more than a half billion people – seek some or all of their medical care from traditional healers.

This study shall therefore have an in-depth examination of the current legal framework in Kenya that facilitate putting in place various determinants that enhance accessibility of medicines and promote the right to health realization like lowering prices of medicine, universal health coverage, enhancing the use of traditional medicine and proper alignment of relevant legislations with WHO global strategy and plan of action on public health, innovation and intellectual property.

1.3 Statement of the Problem

CoK provides a constitutional underpinning of the advancement and attainment of the highest attainable standards of health by Kenyans. Accessing medicines is a critical component of right to health. Alternative medicine is an essential element of basic healthcare in Kenya since the national healthcare infrastructure is insufficient for meeting the needs of the entire population's medical needs. [4] Medicines used by majority of the vulnerable in rural areas are a cacophony of several various substances of biological origins and due to absence of regulation, quacks have a field day in the practice.

While the Health Act[5] now integrates traditional medicine into the mainstream conventional health care system, the same has not been fully utilized to the chagrin of many poor Kenyans who cannot financially access conventional medicine. A comprehensive legislation governing the practice of traditional medicine has not been enacted in Kenya. This has compromised access to medicines by the most vulnerable and marginalized groups in the society. This study seeks to find out the significance of utilization of traditional medicine as a way of promoting access to quality and acceptable medicine for the sake of right to health realization. It also explores the existing

[4] Okumu, M, Ochola, F, Onyango , A, Mbaria, J, Gakuya, D, Kanja, L, Kiama, S, Onyango, M, (2017), *The legislative and regulatory framework governing herbal medicine use and practice in Kenya: a review,* http://wwww.*panafrican-med-journal.com/content/article/28/232/full/ Accessed 5 December 2020.*

[5] The Health Act, Act No. 21 of 2017, Laws of Kenya.

challenges that has impeded free utilization of traditional medicine and how the challenge can be unlocked.

Kenya has responded positively to the WHO global strategy on public health, innovation, and intellectual property, which is a movement toward eliciting human rights practices in all systems in order to make sure that all countries take a human rights approach to their executive, legislative, and judicial activities. It has enacted several legislations in response to various elements of the strategy but the problem of access to medicines has persisted. This study seeks to find out Kenya's response to WHO's strategy and lapses in legislative interventions that has hindered accessibility of medicines and right to health realization.

1.4 Justification and significance of the study

The promulgation of the 2010 CoK ushered in a new constitutional order that recognizes socio-economic rights and the right to highest attainable standard of health in particular. The implementation of the CoK and relevant legislations to breathe life to this right is still underway. While the CoK acknowledges and gives anchorage of traditional knowledge, crucial legislation that regulates the practice of traditional medicine and knowledge on which it is based is yet to be enacted 10 years down the line. This has hindered Kenyans from attaining and enjoying the right to health by hampering access to medicines by majority of the vulnerable and marginalized groups in the society who cannot afford conventional medicine. The country has an enormous responsibility for respecting, fulfilling as well as protecting right to health

Currently, there is a global trend toward mainstreaming human rights practices into all institutions in order to make sure that the executive, legislative, and judicial branches of government in all countries take a human rights-based approach to their actions. The country is thus, at the moment, a fertile ground for comprehensive research and scholarly outlook on the issues which are likely to be affected by the current Constitution like the execution of socio-economic rights and the right to health in particular.

Of particular import is the interpretation of Article 20(5) in terms of what amounts to the

responsibility of the State to fulfil the right to health and how it should be done, the import of priority in resource allocation and robust approach by the Judiciary in pushing the state to fulfill its obligations.

This study shall highlight the normative justification of socio- economic rights and especially right to health and ensue a further step in examining how this right needs to be enforced and to some extent, legislative amendments and interventions and the policy implementations by the state that promotes the right to health.

Various research has been conducted in this field and there are various texts and scholarly articles highlighting the right to health in Kenya but a few analyze legislative interventions in Kenya which have been made after the Constitution 2010 enactment. In major cases, these studies are merely thematic and majorly envisioned on declaring a specific perspective.

Another significant justification is that a few, if none, of the studies reviews or analyze legislative or policy measures formulated by the government in response to WHO global strategy and plan of action on public health, innovation and intellectual property in terms of developing sound policies and legislations that are in sync with the various elements of strategy and plan of action to facilitate better right to health realization. This study will also highlight the lapses in several legislations enacted by Kenya in response to various elements of the strategy that hinders access to medicines and by extension the right to health realization.

While WHO has highlighted the significance of traditional knowledge in medicine as vital strategy in promoting access to medicines by the majority of Kenyans and by extension enhancement of the attainment of the right to health Kenya is yet to pass any legislative intervention to ensure proper incorporation of traditional knowledge in medicine into conventional health care system. This study will even go a step further to scrutinize steps taken in other jurisdictions like South Africa to make such crucial incorporation of Traditional Knowledge (TK) into the conventional health care system.

This study concedes that the research cannot convincingly aim at covering all these aspects within the limits of this thesis. It is envisaged that the discourse will create a background for further future research that will expansively cover this area.

Poor implementation of crucial policies in the health sector remains a challenge in realization of the right aforesaid in Kenya. It is difficult to implement policies however comprehensive they are unless requisite legislative measures are made. Lacuna or short coming in policies cannot be addressed by the judiciary. This is evident where the Courts have been reluctant to enforce claims presented by various Kenyans ostensibly for fear of the Judiciary playing the role of policy making of the government. A good illustration is the case of *Luco Njagi & 21 Others V The Ministry of Health & 2 Others*[6].

The discussion that culminates in the finding and recommendations at the tail end of this study would be significant to legal practitioners, academia, policy-makers, state officials and law reforms agencies in illuminating the path towards effective and satisfactory right to health realization.

1.5 Objectives of the Study

The following are the objectives of this study: -

1. To explore the role and obligations of the state and the legal framework in promoting the right to heath in Kenya.

2. To explore the place of traditional knowledge in medicine and traditional medicine in the conventional health care system in Kenya and its efficacy in promoting the right to health.

[6] Luco Njagi & 21 Others V The Ministry of Health & 2 Others [2015]eKLR. In this case the Petitioners, who were all suffering from a renal failure, sought to Orders to compel the Ministry of Health to meet the cost of medical dialysis on their behalf at eight private medical facilities or to subsidize the cost of medical dialysis at the rate equivalent to the one of Kenyatta National Hospital, a public hospital. The Court observed that it would issue orders in vain since that prayers sought was akin to the Court being asked to attempt to tell the state that it must have certain number of dialysis machines at a certain period in time or that it must ensure access to these machines in private institution when the court cannot determine the availability of resources. The Court clearly abdicated its responsibility of putting the state to task in fulfilling its responsibility of the State to show that the resources are not available and what resources have been budgeted to fulfill right to health. To be fair to court, the court sent a signal that issues of formulation of policy is not within the realms of the judiciary.

3. To explore the efficacy of the policy and legislative measures that have been put in place by the Government of Kenya in response to the WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

4. To make recommendation of the policy and legislative reforms that are needed in Kenya to facilitate full realization of the right to health.

1.6 Research Questions

The research questions in this study are:

1. What is the role and obligations of the state and the legal framework in promoting the right to heath in Kenya?

2. What is the place of traditional knowledge in medicine and traditional medicine in the conventional health care system in Kenya and how efficacious is it in stimulating the right to health?

3. What is the efficacy of the legislative measures that have been put in place by the Government of Kenya in response to WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property in enhancing access to medicine and promoting the right to health?

4. What are the policy and legislative reforms that are needed in Kenya to facilitate full realization of the right to health?

1.7 Hypotheses

This study is based on the following assumptions that will be subjected to test in the rest of the chapters. The hypothesis for the purposes of this study are:

1. The state has a critical role in facilitating Kenyan's access to medicines to improve realization of the right to health but is yet to fully address myriad of challenges that impedes access to medicine.
2. There are inadequate policies and lapses in legal framework that impedes access to medicine and realization of the right to heath in Kenya.
3. There is no proper legal framework for the practice of traditional knowledge in medicine in Kenya to the detriment of realization of right to health.
4. While the Government of Kenya has made positive progress in response to the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, there are serious lapses in the legislative measures that that stifle and hinder realization of the right to health.

1.8 Theoretical framework

This study shall deploy three theories, namely: John Rawl's theory of justice, John Locke's Natural Law theory and Jeremy Bentham's Legal Positivism theory.

Rawls offers a concrete image of the ideally just, but nonetheless earthly society.[7] Rawls' Theory of Justice was a response to an intellectual tradition utilitarianism and intuitionism where in machiavellian utilitarianism the sacrifice of minorities was justified as being a necessary step towards ultimate wellbeing of the majority. Rawls arrive at a theory of justice that is the basic structure and institutional organization of the society that is committed to representative democracy, liberal individualism and the rule of law centered upon an idea of human rights.

In identifying two fundamental principles of justice, he posits that the justice principles should be selected from behind a veil of ignorance to make sure that no one is disadvantaged or benefited in the selection of principles as a result of natural chance or the unpredictability of social conditions.[8] The first principle defines and secures the framework of basic liberties and the second concerns questions of distribution, the regulation of social and economic inequalities. Rawls indicate that

[7] Coyle, S. *Modern Jurisprudence: A Philosophical Guide* (2014).
[8] Ibid.

basic liberties include political liberty, freedom of speech and assembly, liberty of conscience and thought, freedom of the person along with the right to hold (personal) property), and freedom from arbitrary arrest and seizure.

He argues that all citizens of a just society should have an equal enjoyment of liberties since justice require them to have the same basic rights. Rawls' second principle deals with distributive justice. It holds that: Social and economic inequalities are to be arranged so that they are both; to the greatest benefit of the least advantaged, consistent with the just savings principle, and attached to offices and positions open to all under conditions of fair equality of opportunity. Rawls conception of justice is called "justice as fairness".

This theory is important for establishing the priority and appropriateness of the right to the greatest possible standards of health, as well as for determining the level of satisfaction with that right. It is also useful in guiding the state in formulating sound policies and securing legal framework that aids it in its fundamental duty for observing, respecting, promoting as well as fulfilling right to the highest achievable standard of health in Kenya.

The other significant and relevant aspect of Rawl's theory of justice in Kenya is its focus upon the "basic structure" of the community from which entitlements and obligations derive. Advocating for equal enjoyment of basic liberties is also a basis to advance full realization of right to highest achievable standards of health in Kenya.

According to the natural law theory, the law needs to conform to the laws which are renowned in nature. Unjust law is not law. John Locke, one of the key proponents, speaks of a state of nature where men and women are free and equal, and at liberty to do as they wish but only "within the bounds of the law of nature"[9]. That state triggered hardships and oppression and they formed a society and entered into a "social contract" with the Government which was obliged to guarantee everyone protection of life, property and to a certain extent liberty.

[9]John Locke, *The Second Treatise Government* (N19T5 2).

This theory places the full responsibility of the realization and protection of the right, *interalia*, to health on the Government in sync with the provision of Article 43 of the CoK as read with Articles 21 and 20(5) of the Constitution and Section 4 of The Health Act. This theory has been criticized as being exclusively self-interested since human beings were pursuing what they perceive to be in their individual interests yet they expect the government headed by men and women from the same society to be self-less in advancing their interests.

It has also been criticized as vague as any conflict with regards to property always lead to havoc in any society. Such state of havoc have sanctions after all. It is the duty of the government to put in place legal rules to punish aggressors and restore order. Some questions would be, can the laws formulated by the state which are unjust to a larger society prevail? How can full attainment of right to health be achieved? What is the highest attainable standards of health? Can proper legislative measures and policies by the state promote full right to health realization? In the course of attempting to answer this questions, it will be discerned that this school of thought is very relevant to this study.

Bentham, a legal positivist, was of the view that a significant component of law is what it is a command of the sovereign backed by sanctions[10]. He views law as it is and not what it ought to be. This theory has been criticized that Bentham never talked about concept of a legal system which is prevalent all over the world today. Critics contend that the theory contradicts common usage by denying the term 'law' to principles that are usually considered to be legal, such as those of customary and international law. These rules do not originate from a sovereign command but through customary usage and state practice.

In the case of *P.A.O & 2 Others v Attorney General*[11], the Court was able to declare that the provision alongside section 32 and 34 of the Anti-Counterfeit Act is unconstitutional for the simple reason that it offended, *interalia*, Article 40 of the supreme law of Kenya- CoK. Had there been no provision of the Constitution that guarantees right to health, the Court would have been reluctant

[10] Bentham,J, *Of Laws in General* (HLA, ed London Press, 1970)1.
[11] P.A.O & 2 Others v Attorney General [2012] eKLR.

to do so. The court therefore upheld the sovereignty of the Constitution whose sanction of violation is to be declared a nullity. This study will rely on this theory to make recommendation for amendments of various legislations to avert impeding stimulation of the attainment of the right to health in case of existing provisions and to safeguard the right in case of non-existent law.

1.9 Literature Review

After the promulgation of the CoK, 2010, Kenya is still on the path towards establishing a sound legal framework that promotes realization of this right. This section identifies some literature dependent on in undertaking this research with a view to identify gaps that needs attention and also reveals how literature links with the study objectives.

Halstead[12] analyzes the provisions of the European Convention on Human Rights (ECHR) and the Human Rights Act (HRA). He discusses in detail the paramount human rights contained in the two legislations which includes: right to life, right to liberty and security, prohibition against slavery, prohibition against torture, freedom of expression etc.

Halstead's publication does not make reference to Kenyan situation. It does not examine legal regime that promotes or hinders an attainment of the right to health. It does not look at Kenya's response to global strategy to promote the right to health. The current study will enrich itself with the literature in this book and gets an impetus to analyze current situation in Kenya.

Munyi and Lewis-Lettington discusses the sources of supply and pricing/accessibility trends of medicines Kenya. [13] They explore the existing legislation in Kenya and practice in terms of drug registration and regulation of pharmaceutical manufacturers. The paper also looks at future access scenarios of medicines. This paper looks at those issues identified, relevant to this study, from the intellectual property perspective and does not go deep to analyzing emerging issues in legislations that regulates pharmaceutical industry in Kenya. It does not look at emerging issues in Pharmacy

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[12] Halstead, P, *Unlocking Human Rights,* (2009) Hoder Education

[13] Lewis-Lettington, R, and Munyi, P, *"Willingness and Ability to Use TRIPs Flexibilities: Kenya Case Study (2004)*", *www.who.int/hiv/amds/countries/ken_UseTRIPsFlexibilitiesDFID.pdf accessed 1 May 2020.*

and Poisons Act like clinical trials and traditional medicine which are crucial areas in global strategy and plan of action on public health, innovation and intellectual property.

The paper does not for instance look at other legislations like Kenya Medical Supplies Authority (KEMSA) Act[14], that have provisions that affect pharmaceutical industry and hinder realization of right to health which this study covers.

The dynamics on the right to health has changed after the promulgation of the Constitution 2010. This paper will explore such dynamics and policy issues needed as strategies to enhance access to affordable drugs and to stimulate local manufacturing of pharmaceuticals which will thus promote the right to health.

This study shall also explore right to health commitments in Kenya which is not captured by the paper. It will look at regional and global instruments utilized to safeguard right to health.

Mbicha[15]. The paper talks about conceptualization of rights of health in Kenya and captures state obligations. It focuses on judicial enforcement of the right to health. It also discusses the challenges Kenyan courts face or may face in adjudicating the right to health. Unlike this study Mbicha does not explore in depth international and regional instruments that set out states obligations in promoting right to health. This is a very resourceful material in guiding this study but it does not capture crucial issues that promotes right to health which are an integral component of this study.

Unlike this study, Mbicha's paper does not discuss traditional knowledge on medicine as a crucial area that promotes right to health. Finally, the paper does not various elements of WHO's global strategy and plan of action on public health, innovation and intellectual property geared to promote, *interalia*, right to health realization in many countries. This paper believes that

[14] Kenya Medical Supplies Authority Act, Act No. 20 of 2013, Laws of Kenya.
[15] Mbicha, EA 'J*udicial enforcement of the right to health under the new Constitution of Kenya'* unpublished LLM Thesis, University of Nairobi, (2014).

with a broad spectrum of local and international legal instruments that protects right to health, court's lethargy in enforcement of this crucial right should be a thing of the past.

Maleche, A, Were, N, and Dulo, C [16] in their case study alalyzes state commitments on the right to health from 1963 to 2010 and post 2010. It looks at the responsibility of courts in right to health realization and the existing challenges. The paper is very beneficial in enriching the debate of the evolution of right to health. It does not however give prominence to the various legal instruments which enhances and affects the right to health. It does not address traditional knowledge in health and global strategies that promotes right to health realization which are covered in this study.

1.10 Methodology

This study will be largely conducted through desk-based review of available and pertinent literature.

This study will utilize both primary and secondary sources of data. Primary sources utilized shall include analysis of the existing international, regional and domestic legal instruments governing the area under study.

Secondary Sources will include textbooks, journals, law reports and Internet Publications.

1.11 Scope and limitation of the study

The key limitation of this study is that due to limitation of resources and time constraints, it will be unable to conduct personal interview with several players on the various areas under study. The greatest limitation of this study is the outbreak of a novel virus known as COVID-19 that triggered

[16] Maleche, A, Were, N, and Dulo, C, Mapping the constitutional provisions on the right to health and the mechanisms for implementation in Kenya Case study report (2018) https://www.equinetafrica.org/sites/default/files/uploads/documents/KELIN%20Kenya%20rights%20case%20study%202018.pdf Accessed on 6 May 2020.

the government to impose partial lockdown. Time constraints ad limitation of space will not permit exhaustive analysis of all the elements of strategy of the WHO's global strategy on, *interalia*, public health.

The study makes recommendations to provoke further intellectual discourse on the challenges acknowledged in the legal and policy framework on execution of the right to health. The recommendations are made to inform and persuade future legislative amendments.

1.12 Chapter breakdown

Chapter One is the introduction part that covers the background of the problem, justification for the study, theoretical framework, hypotheses, research questions, objectives-both general and specific objectives, research methodology, literature review and chapter breakdown.

Chapter two will look at the evolution of the right to health in Kenya. It will explore the role of state in promoting right to health. It will discuss the normative content of the right to health. It will highlight domestic, regional and international instruments that form the legal framework for the establishment and advancement of access to medicines and thus promote right to health. It will interrogate the health commitments vi-a-vis the obligation of state under General Comment 14 in advancing the realization of the right to health.

Chapter 3 will comprehensively discuss the question of protection of traditional knowledge based medicine as a way of promoting right to health. This chapter will explore various challenges of the legislative framework of TK in medicine in Kenya at domestic, regional and international level. It will make a case for an integration TK in medicine into the conventional health care system to facilitate access to medicines hence promote the right to health. It shall analyze challenges of non-protection of TK bases medicine and test the sufficiency of the *Sui Generis* system of protection of TK in Kenya.

Chapter 4 will discuss various elements of WHO's global strategy and plan of action on public health, innovation and intellectual property to promote, *interalia*, realization of the right to

health. It will discuss a plethora of legislative measures formulated by the government in response to various plan of action of diverse elements of global strategy discussed to facilitate effective attainment of the right to health and demonstrate how some legislative provisions stifle access to medicine and thus hinder an attainment of the right to health.

Chapter five is the conclusive part that gives study summary, findings and recommendations for both policy and legislative reforms.

CHAPTER TWO

2 THE ROLE OF STATE AND THE LEGAL FRAMEWORK IN PROMOTING RIGHT TO HEALTH IN KENYA

2.1 INTRODUCTION

This chapter will briefly capture how the right to health has evolved in Kenya. It will explore the role of state in promoting right to health. Normative content of the right to health shall be discussed. It will highlight domestic, regional and international instruments that form the legal framework for the establishment and advancement of access to medicines and thus promote right to health. It will interrogate the health commitments vi-a-vis the obligation of state under General Comment 14 in advancing an attainment of the right to health.

2.2 RIGHT TO HEALTH DEFINED

The Constitution of the WHO defines health in a broad manner. It defines it as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.[17] The Constitution underscores the importance of right to health, *interalia*, as critical to achieving peace and security, and uneven development in various countries in terms of health promotion and disease prevention, particularly communicable disease, is a shared threat.

According to General Comment Number 14[18] right to health is a cornerstone of human rights that is crucial for the exercise of other human rights. The human right to health is recognized in

[17] The Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States (*Off. Rec. Wld Hlth Org*., 2, 100), and entered into force on 7 April 1948. Amendments adopted by the Twenty-sixth, Twenty-ninth, Thirty-ninth and Fifty-first World Health Assemblies (resolutions WHA26.37, WHA29.38, WHA39.6 and WHA51.23) came into force on 3 February 1977, 20 January 1984, 11 July 1994 and 15 September 2005 respectively and are incorporated in the present text. See https://www.who.int/governance/eb/who_constitution_en.pdf accessed 5 December 2020.

[18] United Nations on International Covenant on Economic, Social & Cultural Rights, General Comment 14: The Right to the Highest Attainable Standard of Health, 20th Session. 12 U.N. Doc E/C. 12/2000/4 (2000). General Comments of the Committee do not have legally binding effect but they are considered authoritative guidance on clarifying the contents of rights and obligations enshrined in the ICESCR.

numerous international instruments[19]. Article 25(1) of the Universal Declaration of Human Rights affirms that,

> "Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services."

The core provision on the right to health in international human rights law is embodied in Article 12 (1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) which establishes that the States Parties to the Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. It also goes ahead and gives steps to be taken by the States Parties to the present Covenant to achieve the full realization of the right to health.[20]

General Comment Number 14 issued by the United Nation's Committee on Economic, Social and Cultural Rights (ESCR)[21] clarifies the term right to health that it should not be understood as a right to be healthy but comprises of both freedoms and entitlements.

Freedoms included the right to regulate one's health and body, notably reproductive and sexual freedom, as well as the right to be free from interference, like the right to be free from torture. Entitlements include the right to a health-care system that ensures that everyone has an equal opportunity to achieve the best possible degree of physical and mental health. Importantly, the Committee states that the right to health is an inclusive right. It is not just about access to health care services but also the underlying broader determinants of health including safe drinking water, adequate sanitation, and an adequate supply of safe and nutritious food and healthy occupational and environmental conditions etc. The Committee goes a notch higher to set out the key elements of the right to health. It states that health care and underlying determinants must be available,

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[19] Examples of these instruments referred in this study are: Universal Declaration of Human Rights, International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families, International Covenant on Social, Economic and Cultural Rights, Convention on Elimination of all Forms of Discrimination against Women, among others.

[20] Article 12(2) of the International Covenant on Social, Economic and Cultural Rights.

[21] This is a body of independent experts that monitors implementation of the ICESCR by its State Parties. It was established in 1985. The Committee makes interpretations of the ICESCR known as General Comment and publishes the same. See http://www.ohchr.org/EN/HRBodies/CESCR/Pages/CESCRIntro.aspx. Accessed 10 April 2020

accessible, acceptable and of good quality, paying particular attention to the most vulnerable and marginalized groups in society.[22]

Right to health is also included in a slew of regional instruments, which generally establish both the right to adequate health care in the event of illness and the obligation to take public health steps to prevent epidemic and endemic diseases.[23] For instance, article 16 of the Banjul Charter sets out the right of every individual to enjoy the "best attainable state of physical and mental health" and declares that states parties shall take "the necessary measures to protect the health of their people."[24]

2.3 A Brief Outline of the Evolution of the Right to Health

The historical origin of the right to health is traced in the context of social economic rights. The historical background of the latter is less certain. The emergence of the right to health happened at the same time with the emergence of the rest of contemporary international law as an after-effect of the World War II.[25] The Universal Declaration of Human Rights recognizes two sets of human rights: the 'traditional' civil and political rights, as well as economic, social and cultural rights.[26]

Commands expressed in different religious traditions to care for the vulnerable is where origins of social economic rights has drawn its strength. Papal encyclicals in Catholicism have promoted the usefulness of the right to live with dignity. Other sources include philosophical writings and political theory from socialist philosophers such as Thomas Paine, Karl Marx, Immanuel Kant and John Rawls that gained prominence in the 19th century.[27]

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[22] Helena Nygren-Krug, Health and Human Rights – a Historical Perspective <http://www.iahm.org/journal/vol_8/num_3/text/vol8n3p34.htm> accessed 22 June 2018.
[23] Yamin, A, *Not Just a Tragedy: Access to Medications as a Right Under International Law*, 21 B.U. Int'l L.J. 325 (2003).
[24] Ibid.
[25] Supra Note 23. Page 36.
[26] Henry J. Steiner, Philip Alston and Ryan Goodman (eds), *International Human Rights in Context: Law, Politics Morals* (3rdedn, Oxford University Press 2007).
[27] Ibid.

The establishment of the International Labour Organization (ILO) has been argued as the starting point for the conception of the ideas about the socio-economic rights in international human rights law[28]. Workers had suffered an injustice and degrading treatment and the Treaty of Versailles was put in place in 1919 to abolish such injustice and to guarantee fair, just and humane conditions of labour. Western Countries championed for the Treaty same in response to the ideologies of Russian Communist and Socialist after the Russian Revolution[29].

During the period of war, the ILO adopted international minimum standards in relation to a raft of matters which are within the realm of economic and social rights such as the right to organize trade unions, minimum working age, hours of work, weekly rest, forced labour etc[30].

After the World War II various instruments were adopted like UN Charter and Universal Declaration of Human Rights (UDHR) in 1948 and the journey to translate the rights recognized in the latter into binding treaty obligations begun.

Article 25 (1) of the UDHR recognize right to health as a socio-economic right. Despite UDHR being a non-binding instrument as it is a declaration it occupies a special place today as the normative foundation of international human rights movement.

ICESCR was eventually passed by the UN General Assembly in the year 1966. This is a crucial instrument in the international foundation of right to health.

By virtue of Article 12 (1) ICESCR recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health as a human right. Article 12 (2) of ICESCR provide steps to be undertaken by the State Parties to attain full right to health realization.

Subsequently, there have been steps taken at international level by the UN to give meaning and effect to the right to health as a fundamental human right.

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[28] Supra Note 26. Page 269

[29] J T Shotwell, 'The International Labour Organization as an Alternative to Violent Revolution', 166, The Annals of the American Academy of Political and Social Science (1933) 18. The Treaty of Versailles was the peace settlement signed after World War 1 had ended in 1918 and in the shadow of the Russian Revolution and other events in Russia. The treaty was signed at the vast Versailles Palace near Paris – hence its title – between Germany and the Allies. For more details on the treaty see http://www.historylearningsite.co.uk/modern-world-history-1918-to-1980/the-treaty-of-versailles/ accessed 15 June 2018.

[30] Supra Note 26. Page 269.

In the year 2000 the UN Committee on ESCR, a body which monitors States Parties' compliance with the ICESCR, set out its interpretation of the right to health.

In the year 2002, the UN Commission on Human Rights (now replaced by the UN Human Rights Council) appointed a UN Special Rapporteur on the Right to the enjoyment of the highest attainable standard of physical and mental health – an independent expert tasked with monitoring and reporting on the enjoyment of the right to health globally.[31]

Their mandate on the right to health includes: submitting annual reports to the Human Rights Council and the General Assembly on the actions and research carried out in support of the mandate's execution; to monitor the global status of the right to health by detecting global trends in the right to health and conducting country visits to collect firsthand information on the situation of the right to health in a particular country; communicate with States and other interested parties regarding reported instances of health-related rights breaches; as well as advocating for the full implementation of the right to health through communication with key stakeholders through participation in seminars, conferences, and professional meetings.[32]

It is only until 2010 in Kenya, pursuant to the promulgation of the CoK 2010, that Article 43 now recognizes right to health as a social and economic right and thus justiciable. Article 21(2) of the CoK obligates the state in mandatory terms to take legislative, policy and other measures, including the setting standards, to attaining the progressive rights realization assured under Article 43 of the said CoK.

2.4 Normative Content of the Right to Health

General Comment No. 14 posits that the right to health in all its forms and at all levels contains four interrelated and essential elements, whose precise application will depend on the conditions prevailing in a particular State Party. These include:-

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[31] Office of the High Commissioner for Human Rights, _Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' UN Doc E/C /4 Res 31/2002.

[32] United Nations Human Right, _Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health <http://www.ohchr.org/EN/Issues/Health/Pages/SRRightHealthIndex.aspx>accessed 22 June 2018.

2.4.1 Availability

This encompasses a functioning public health and individual health-care facilities within the State party. Goods and services, as well as programmes, have to be available in sufficient quantity.[33] The nature of the facilities, goods and services varies and is determined by the level of development of a state party. State parties should ensure there is safe drinking water and enough sanitation facilities, hospitals, clinics and other health-related buildings, trained medical and professional personnel receiving competitive remuneration and availability of essential drugs.[34]

2.4.2 Accessibility.

Goods and services have to be accessible to all devoid of discrimination within the jurisdiction of the State party.[35] Accessibility entails four key elements, namely: non-discrimination, physical accessibility, economic accessibility and information accessibility.[36] Health care facilities must be affordable. Water and sanitation facilities must be within physical safe reach. Governments shall make sure that everyone has the right to access, receive, and give health information that is treated confidentially.

2.4.3 Acceptability

Health facilities must respect medical ethics and culture of diverse individuals and communities of those concerned. It should be developed in such a way that confidentiality is maintained and the health status of individuals involved is improved.[37]

2.4.4 Quality

Health facilities, goods and services needs to be scientifically and medically suitable. It should be of good quality and culturally acceptable.[38]

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[33] General Comment No. 14. Para12(a).
[34] Ibid. Essential Drugs envisaged are those defined by WHO Action Programme on Essential Drugs.[34]
[35] Ibid. Para 12(b)
[36] Ibid.
[37] Ibid.Para12(c).
[38] Ibid. Para 12(d).

Medical personnel should possess requisite skills. Medicine administered should be unexpired and scientifically approved. Hospital equipment must be scientifically approved. Water should be safe and sanitation mist be adequate.[39]

2.5 Right to health commitments in Kenya

The promulgation of the CoK, 2010 provided the much-needed impetus in the journey towards attainment of the right to health as per the standards set out under the CoK. Health care is typically delivered through a variety of governmental and commercial organizations. Although the state is responsible for public health, policies and programs that are issued, implemented, and enforced by the state or with the backing of the state are the primary means by which this responsibility is carried out.[40]

This study questions an superficial mainstreaming of traditional medicine in the Health Act and makes a case of an enactment of independent legislation to govern practice of traditional medicine in Kenya to promote access to medicines and to ensure that traditional healers possess requisite skills, to facilitate punish of errand traditional healers and to generally promote access to medicine which is the ultimate component of full realization of the right to health in Kenya.

As the study critically examines the assorted health commitments in Kenya vi-a-vis WHO global strategy and plan of action of public health, innovation and intellectual property, it shall point out flaws in such legislations that undermines access to medicine and by extension stifle attainment of the right to health.

[39] Ibid.
[40] Jonathan M. Mann and others (eds), *Health and Human Rights* (Routledge 1999).

2.5.1 National Instruments

The cornerstone of the right to health in Kenya is Article 43 (1) of the CoK which guarantees every person, *inter alia,* to the highest attainable standard of health, which includes the right to health care services, including reproductive health care.

Article 2(6) of the CoK recognizes any treaty or convention ratified by Kenya as components of the law of Kenya. The Constitutional dispensation is a great success on the area of right to health. This provision has made it easy for the courts to adjudicate and give life to realization of this right as seen in cases cited in Chapter 4.

Article 21(2) of the CoK obligates the state in mandatory terms to take legislative, policy and other measures, including the setting standards, to achieve the progressive realization of the rights guaranteed under Article 43 of the said CoK.

Significant health legislative interventions in Kenya have been preceded by policy framework. It is crucial to highlight them.

The Kenya National Drug Policy (NDP) of 1994[41], Vision 2030 blueprint, Kenya Health Policy 2014-2030 are some of the key policy instruments that are meant to streamline health sector and to promote access to medicine by Kenyans and by extension to facilitate right to health realization.

The Kenya National Drug Policy (NDP) is a policy document that addresses important issues impacting pharmaceutical services. Its aim is utilizing available resources to design pharmaceutical services for meeting the requirements of every Kenyan in preventing, diagnosing and treating diseases using efficacious, high quality, safe and cost−effective pharmaceutical products.[42]

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[41] The goal of the National Drug Policy (NDP) is to use available resources to develop pharmaceutical services to meet the requirements of all Kenyans in the prevention, diagnosis and treatment of diseases using efficacious, high quality, safe and cost-effective pharmaceutical products. http://collections.infocollections.org/whocountry/en/d/Jh4332e/3.1.html Accessed 4 March 2020.

[42] http://apps.who.int/medicinedocs/documents/s16443e/s16443e.pdf accessed on 23 June 2018.

Another significant objective of the NDP is to provide drugs through the government, private, and non- government sectors at affordable prices. Traditionally-based medicine was recognized by the NDP as an important part of Kenyan culture and as such, it needed to be integrated into the country's primary health care system. No legislative intervention has been made until the promulgation of the CoK, 2010 and the recent enactment of the Health Act[43]. The Act has not made comprehensive provisions or subsidiary legislation that governs the practice of traditional medicine in the country. NDP also targeted access to affordable medicine through pricing policies. To date majority of Kenyans cannot afford medicine.

Kenya Health Policy 2014-2030 espouses two key obligations of health. First, realization of fundamental human rights including the right to health as enshrined in the CoK, 2010. Second, contribution to economic development as envisioned in Vision 2030. It focuses on ensuring equity, people centeredness and a participatory approach, efficiency, a multi-sectoral approach, and social accountability in the delivery of healthcare services.[44] Its objective, *inter alia*, is to eliminate communicable diseases, provide essential health care like access to emergency care and to reinforce partnership with private and other sectors which have an impact on health.[45]

Vision 2030 blueprint[46] is another crucial document which highlighted health sector under one of the pillars, "Social Strategy: Investing in the People of Kenya" and one of the flagship projects being the creation of National Health Insurance Scheme in order to promote equity in Kenyan's health care financing. It also advocates for de-linking of the Ministry of Health from service delivery in order to improve management of the country's health institutions primarily by devolution of health management to communities and health-care experts at district, provincial

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[43] Supra Note 5.

[44] http://publications.universalhealth2030.org/uploads/kenya_health_policy_2014_to_2030.pdf Accessed 5 December 2020.

[45] http://www.afidep.org/?wpfb_dl=80 accessed on 23 June 2018.

[46] Kenya Vision 2030 is the long-term development blueprint for the country and is motivated by a collective aspiration for a better society by the year 2030. The aim of Kenya Vision 2030 is to create a globally competitive and prosperous country with a high quality of life by 2030. It aims to transform Kenya into a newly-industrialising, middle income country providing a high quality of life to all its citizens in a clean and secure environment. http://vision2030.go.ke/inc/uploads/2018/05/Vision-2030-Popular-Version.pdf Accessed 5 December 2020.

and national hospitals[47]. Kenya is yet to establish universal health coverage scheme to the chagrin of many Kenyans who are unable to access medicine. Despite devolution of health functions, health workers are constantly on strike. Lives of Kenyans seeking medical services are at risk.

Policies however flowery provisions they contain without sound legislative interventions shall remain a mirage in realization of access to affordable medicine and right to health realization. The enactment of a principal legislation in health sector known as The Health Act[48] is a significant step in right to health realization. This is the law enacted for creation of a unified health system, for coordination of the inter-linkage between the national and county government health systems, for provision of regulation of health care services and their providers, health products and health technologies and for connected purposes.

There are five key objects of the law. First, is to establish a national health system which encompasses public and private institutions and providers of health services at the national and county levels and facilitate in a progressive and equitable manner, the highest attainable standard of health services. Second, is to protect, respect, promote and fulfill the health rights of all persons in Kenya to the progressive realization of their right to the highest attainable standard of health, including reproductive health care and the right to emergency medical treatment. Third, is to protect, respect, promote and fulfill the rights of children to basic nutrition and health care services contemplated in Articles 43(1) (c) and 53(l) (c) of the CoK. Fourth, is to protect, respect, promote and fulfill the rights of vulnerable groups as defined in Article 21 of the Constitution in all matters regarding health. Lastly, is to recognize the role of health regulatory bodies established under any written law and to distinguish their regulatory role from the policy making function of the national government.[49]

[47] Ibid.
[48] Ibid.
[49] Ibid, Section 3.

Section 86 of The Health Act empowers the department of health to ensure that progressive financial access to universal health coverage is attained by taking measures that include, *inter alia,* developing policies and strategies that ensure realization of universal health coverage.

The Health Act does not give a provision for a comprehensive compulsory health insurance scheme for every citizen including the unemployed, the elderly, children, persons with disabilities and other vulnerable, underprivileged and disregarded people and groups. The greatest challenge here is the weak purchasing power due to high levels of poverty

The Act does not make it compulsory for the employers to provide health insurance covers for the employees. It can be an opportunity to provide for utilization of certain percentage of premiums collected by insurance companies on healthcare services and health care quality improvement.

The Act does not provide for setting up a fund that can be used by the state to purchase essential medicines for ease of access by the citizens.

Another crucial Act is the HIV and AIDS Prevention and Control Act[50]. Section 19(2) of Act provides for accessibility to health care services like access to crucial medicines at cheap prices by persons with HIV/AIDS and those exposed to the HIV infection risk. This act lacks a provision to expressly exclude generic drugs from counterfeit goods. This will pose that emerged earlier by anti-counterfeit legislation.

Related to the HIV and AIDS Prevention and Control Act is the provision of section 2 of the Anti-Counterfeit Act[51] defines counterfeit goods to include the "manufacture, production…or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods." This was successfully argued by the Petitioners in the case of *P.A.O & 2 Others*

[50] HIV and AIDS Prevention and Control Act ,Act No. 14 of 2006, Laws of Kenya.
[51] The Anti-Counterfeit Act, Act No. 13 of 2008, Laws of Kenya.

v Attorney General[52] that this provision alongside section 32 and 34 of the Anti-Counterfeit Act is unconstitutional and if enforced will have a serious adverse impact on the availability, affordability and accessibility of low-cost, high-quality medicines by persons living with HIV/AIDS who uses generic drugs and thus affect their constitutional rights to have access to the highest achievable standard of health.

The Cancer Prevention and Control Act[53] was enacted to provide for the prevention, treatment and control of cancer. Section 3 provides that this law will promote access to quality and affordable diagnostic and treatment services for persons with cancer. This is a crucial legislation coming at a time which cancer has become a major killer in Kenya and only one public hospital, Kenyatta National Hospital, offers cancer treatment.

Section 4 of this Act establishes a body known as National Cancer Institute of Kenya [hereinafter termed as "the institute"]. The Act is silent and no powers is given to the institute to make annual disbursements to cancer centres in all the counties to subsidize charges and treatment costs for the cancer patients.

The Act does not empower the institute to facilitate training of cancer experts. An ambitious scholarship programme should be rolled out to aspiring doctors so that we have enough human resource in future to work on the cancer centres. The Act does not make a provision for registering cancer foundations which will source funds from donors to widen access to cancer facilities by patients.

Section 15 of the Act indicates source of funds of the institute. It does not specify how much a Parliament can appropriate to it. The Act also uses the word "may" making any appropriation by the Parliament discretional. It leaves it to the discretion of Parliament. Leaving funding to such an important institute at the mercy of the Parliament is not healthy. Other legislations like the National

[52] Supra Note 11.
[53] The Cancer Prevention and Control Act, Act No 15 of 2012, Laws of Kenya.

Government Constituencies Development Act[54] establishes a specific fund with a specific formulae for allocation of such funds to various sub-counties as follows, "a national government fund consisting of monies of an amount of not less than 2.5% (two and half percentum) of all the national government's share of revenue as divided by the annual Division of Revenue Act enacted pursuant to Article 218 of the Constitution".

The Pharmacy and Poisons Act[55] is a law enacted to make better provision for the control of the profession of pharmacy and the trade in drugs and poisons. At the moment, parallel importation takes place in a none structured way and only based on individual orders[56]. For example, If a hospital or doctor indicates a need for a specific drug that cannot be obtained locally or that is available but at an exorbitant cost, a licensed importer would submit an application to the Pharmacy Poisons Board (PPB) and a decision to support importation would be made by the PPB to bring in just enough quantity to meet that particular hospital need[57].

The act requires a framework that will allow the importation on a wider scale to serve the needs of many potential users and to facilitate the protection of right to health.

In a nutshell, as indicated earlier in this study, this act does not have rules to facilitate regulations on parallel importation and control of illegal trade in pharmaceuticals through the process of drug registration, inspectorate powers, post market surveillance and publishing medicines information to the public so as to maintain affordable prices and/or to encourage competition hence competitive prices.

Food, Drugs and Chemical Substances Act.[58] It is the law that makes provision for the prevention of adulteration of food, drugs and chemical substances and for matters incidental thereto and connected therewith. It prohibits sale of adulterated food, chemical substances and drugs that are

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[54] The National Government Constituencies Development Act, Act No. 30 of 2015, Laws of Kenya.
[55] Pharmacy and Poisons Act, Chapter 244, Laws of Kenya.
[56] http://pharmacyboardkenya.org/blog/2017/12/parallel-importation-of-drugs-to-lower-cost-of-medication > accessed on 1 August 2018.
[57] Ibid.
[58] Food, Drugs and Chemical Substances Act, Chapter 254, Laws of Kenya.

harmful to health. It also prohibits sale of cosmetics and devices that are harmful to health. Public Health (Standards) Board is established to enforce the act. The composition of the board is not broad enough. There is only one representative of municipal council which is now an equivalent county government. The Board entrusted with a tremendous responsibility does not have countrywide offices. Source of their funding is also not clearly spelt out in the act and with the influx of adulterated and counterfeit products in the market, this hampers their work and threaten right to health.

This act still makes reference to obsolete terms as "municipal council" and there is need to align it with the present terminology.

Radiation Protection Act.[59] This law provides for the protection of the public and radiation workers from the dangers arising from the use of devices or material capable of producing ionizing radiation and for connected purposes.

The penalty provision under Section 16(2) of this act provides for a lenient penalty to an offender. It provides that a person who contravenes any of the provision of this Act relating to or in connection with the importation, possession, transportation, use or disposal of irradiating devices, radioactive materials or any other sources of ionizing radiation without being in possession of a valid license shall be guilty of an offence and shall be liable to imprisonment for a term not exceeding two years.

The above provision means that a person who exposes Kenyans to dangers of radiation devices can cool their heels in prison for even one day since that is within the penalty provision.

Those who obstruct the Chief Radiation Protection Officer under section 16(1) from say confiscating radioactive materials can only pay a fine of Kenya Shillings Twenty Thousand only (Kshs. 20,000/=) or imprisonment for a term not exceeding one year or both.

[59] Radiation Protection Act, Chapter 243, Laws of Kenya.

Public Health Act[60]. This law provides for securing and maintaining health. It establishes Central Board of Health with its seat in Nairobi to advise the Minister upon all matters affecting the public health and other incidental activities. This law makes mentions of obsolete terms as "district", "local authority", "municipal council" etc which means it cries for review.

The Board has a broad-spectrum that covers diverse areas, which includes, prevention of spread of leprosy and smallpox management of cemetery, handling of foodstuff, health concerns at ports and inland waters, matters sanitation and housing etc. That the board only sits in Nairobi does not augur well with the wide mandate. There should be seating in all the 47 counties.

Narcotic Drugs and Psychotropic Substances (Control) Act[61]**.** This is a law to make provision with respect to the control of the possession of, and trafficking in, narcotic drugs and psychotropic substances and cultivation of certain plants; to provide for the forfeiture of property derived from, or used in, illicit traffic in narcotic drugs and psychotrophic substances and for connected purposes.

Of relevance to this study is section 3(3) of this act which provides an exemption from possession of narcotic drug or psychotrophic substance. It permits, *interalia*, a medical practitioner, dentist, veterinary surgeon or registered pharmacist who is in possession of a narcotic drug or psychotropic substance for any medical purpose and a person who possesses the narcotic drug or psychotropic substance for medical purposes from, or pursuant to a prescription of, a medical practitioner, dentist or veterinary surgeon.

Science, Technology and Innovation Act[62]. This law facilitates the promotion, co-ordination and regulation of the progress of science, technology and innovation of the country; to assign priority to the development of science, technology and innovation; to entrench science, technology and innovation into the national production system and for connected purposes. This one is in sync

[60] Public Health Act, Chapter 242, Laws of Kenya.
[61] Narcotic Drugs and Psychotropic Substances (Control)Act, Chapter 245, Laws of Kenya.
[62] Science, Technology and Innovation Act, Act No. 28 of 2013, Laws of Kenya.

with element 2 of the WHO global strategy that focus on promoting research and development by way of, *interalia*, promoting access to knowledge and technology. This is discussed in depth in Chapter 4.

2.5.2 Regional Instruments

Kenya has ratified the African Charter on Human and Peoples' Rights (also known as the Banjul Charter). This is a significant human rights instrument that is meant to promote and safeguard human rights and basic freedoms throughout the African continent while taking into account the political and legal cultures of African governments as well as maintaining African custom and identity.

The obligations of African states stems from Article 16 (1) and 16(2) of the Banjul Charter which provides as follows: -

> "Every individual shall have the right to enjoy the best attainable state of physical and mental health.
> States parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick".

Article 14 of the African Charter on the Rights and Welfare of the Child provides that every child shall have the right to enjoy the best attainable state of physical, mental and spiritual health.

Article 14 of the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa obligates the state to ensure that the right to health of women, including sexual and reproductive health is respected and promoted.

Kenya has also ratified a Protocol to the African Charter on Human and Peoples` Rights on the Establishment of an African Court on Human and Peoples` Rights. The Court has jurisdiction on all cases and disputes submitted to it concerning the interpretation and application of the Charter, the Protocol and any other relevant Human Rights instrument ratified by the States concerned.

The Court can entertain cases of human rights violations which have even gone to the highest courts at national level and where a party feels justice has not been done.

Access to health services by migrant workers is also taken care of. Article 43(1)(e) of the International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families provides that migrant worker shall enjoy equality of treatment with nationals of the State of employment in relation to access to social and health services, provided that the requirements for participation in the respective schemes are met.

2.5.3 Global Instruments

UDHR is a starting point for any discourse on human rights at global level.

The UDHR was a solemn resolution of the UN General Assembly, which organ cannot adopt binding decisions, and the Declaration was intended to be an inspiration for a binding international treaty, as many times later declarations of the General Assembly have prepared the way to international human rights treaties.

It has been argued that after the World War II several cases that redressed massive human rights violations made reference to "principles" enunciated in the UDHR and therefore the same has attained customary law status.[63] A case in point is *Hostages Case* (US V Iran) where the International Court of Justice referred directly to the Universal Declaration of Human Rights and found in its principles proof of the existence of universal human rights in that: -

> "Wrongfully to deprive human beings of their freedom and to subject them to physical constraint in conditions of hardship is in itself manifestly incompatible with the principles of the Charter of the United Nations, as well as with the fundamental principles enunciated in the Universal Declaration of Human Rights".[64]

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[63] V Dimitrijevic 'Customary law as an instrument for the protection of human rights' (ISPI working paper 7, 2006) 8, <www.**ispionline.it/it/documents/wp_7_2006.pdf**> accessed 24 June 2018.

[64] ICJ, *United States v. Iran*, ICJ Reports, 1980, para. 42.

Article 25(1) of the UDHR provides that:-

> "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control".

Article 12 of the ICESCR is a legally binding treaty that safeguards right to health.

Article 2(1) of the ICESCR has been described as the fulcrum of the Covenant[65]. It obligates the state to "take steps ... to the maximum of available resources, with a view to achieving progressively the full realization of the rights recognized in the Convention by all appropriate means including particularly the adoption of legislative measures".

The UN Committee on Economic, Social and Cultural Rights (CESCR) in its General Comment No. 3 expounds in detail the imports of the phrases used in Article 2.

Although Kenya has ratified the ICESCR it is yet to ratify the Optional Protocol to the ICESCR[66] The Optional Protocol to the ICESCR entered into force in the year 2013 after receiving its tenth instrument of ratification. Its goal is to address violations of socio-economic rights, which have received less attention than civil and political rights in recent years. Specifically, it accomplishes this by granting an individual locus standi before the Committee, allowing the Committee to inquire directly into whether a state has violated the ICESCR. The delay by the government in

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[65] M Craven *'The International Covenant on Economic, Social and Cultural Rights: A perspective on its development'*(1995) 106.

[66] Adopted through the General Assembly resolution A/RES/63/117 on 10 December 2008. See the following link for details of the protocol, <http://www.ohchr.org/EN/ProfessionalInterest/Pages/OPCESCR.aspx> Accessed on 22 June 2018.

ratifying it will thus be denying people the right to present communications before the CESCR for action[67].

General Comment No. 9 of the United Nations Committee on CESCR emphasizes that it is up to states how they give effect to the rights contained in the ICESCR, including the right to health, but whatever arrangements they choose, they must be effective. This instrument was quoted by the Petitioners in the case of *Luco Njagi & 21 others v Ministry of Health & 2 others*.[68] The petitioners argued that they were not able to realize their right to health as they did not have access to essential haemodialysis at the Kenyatta National Hospital as it is ill-equipped to cater for all the patients who need dialysis**.** They thus sought to compel the Ministry of Health to meet the cost of medical dialysis on their behalf at eight private medical facilities.

The court quoted with approval a South Africa decision that made a finding in a suit that echoed that of the Petitioners that:

> "Courts are ill-suited to adjudicate upon issues where court orders could have multiple social and economic consequences for the community. The Constitution contemplates rather a restrained and focused role for the courts, namely, to require the state to take measures to meet its constitutional obligations and to subject the reasonableness of these measures to evaluation. Such determinations of reasonableness may in fact have budgetary implications, but are not in themselves directed at rearranging budgets. In this way the judicial, legislative and executive functions achieve appropriate constitutional balance."

Justice Mumbi thus found that it cannot issue orders in vain for the court to attempt to tell the state that it must have a certain number of dialysis machines at a certain period in time or that it must ensure access to these machines in private institution when the court cannot determine the

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[67] Kenya National Commission on Human Rights (KNCHR) & Kenya UPR Stakeholders Coalition 'Universal Periodic Review (UPR) annual progress report 22nd September 2010-21st September 2011: An assessment by stakeholders of government's performance in implementation of UPR recommendations' (September 2011) 30. , <http://www.knchr.org/LinkClick.aspx?fileticket=EDsk95op-cM%3D&tabid=159&portalid=0&mid=586> Accessed on 22 June 2018.

[68] Supra Note 6.

availability of resources, or what impact the diversion of resources to meet the petitioners' individual demands would have.

The Court in arriving at its finding in dismissing the petition appeared to have been largely guided by the principles under Article 20 (5) of the Constitution which gives guiding principles to the courts while applying Article 43 of the Constitution and one of the principles is that it is the obligation of the state to illustrate that resources are not available. It was demonstrated by the state that over time they have installed dialysis machines which are very expensive and the court was satisfied by such measures. The grave danger with this approach by the court appears to give a huge leeway to the state to ensure such rights are realized at its mercy. A bolder and proactive approach by the courts would suffice.

The Treaty Making and Ratification Act[69] has now been enacted to give effect to Articles 2(5), 2(6) and 94(5) of the CoK which can now provide a clear procedure for ratification if treaties.

It is therefore crucial for the government to ratify the Option Protocol to the ICESCR to facilitate better realization of those rights enshrined in the ICESCR. It will also offer an appropriate checks and balance and thus foster accountability on the part of the government.

Article 12 of the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), and Article 24 of the Convention on the Rights of the Child are other crucial instruments at global level.

2.6 Tripartite typology of obligations of the State towards realization of the right to health

The State plays a great duty in the full attainment of the right to health. Article 21 of the CoK provides that it is a fundamental duty of the State and every State organ to observe, respect, protect, promote and fulfill the rights and fundamental freedoms in the Bill of Rights.

[69] The Treaty Making and Ratification, Act No. 45 of 2012, Laws of Kenya.

Article 21 (2) goes ahead to provide that the State shall take legislative, policy and other measures, including the setting of standards, to achieve the progressive realization of the rights guaranteed under Article 43 of the CoK.

The above provisions of the CoK are also echoed under Section 4 of The Health Act which provides that, "it is a fundamental duty of the State to observe, respect, promote and fulfill right to the highest attainable standard of health including reproductive health care and emergency medical treatment."

The principle of progressive realization is premised on the understanding that states might not have adequate resources to instantly take all the needed steps towards social and economic rights realization. The Supreme Court has had an occasion to elaborate its understanding of the word 'progressive realization' in the Advisory Opinion No. 2 of 2012 in the matter of *the Principle of Gender Representation in the National Assembly and the Senate*[70]

> *"*...We believe that the expression "progressive realization" is neither a stand-alone nor a technical phrase. It simply refers to the gradual or phased-out attainment of a goal-a human rights goal by its very nature, cannot be achieved on its own, unless first, a certain set of supportive measures are taken by the State. The exact shape of such measures will vary, depending on the nature of the right in question, as well as the prevailing social, economic, cultural and political environment. Such supportive measures may involve legislative, policy or programme initiatives including affirmative action."

UN Committee on ICESCR gives comprehensive examples of obligations of States under General Comment No. 14.

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[70] Advisory Opinion No. 2 of 2012 in the matter of *the Principle of Gender Representation in the National Assembly and the Senate* [2012]eKLR. Paragraph 53. Although the case had nothing to do with enforcement or determination of an issue revolving around social and economic rights, the definition of the concept of progressive realization is relevant.

2.6.1 Obligation to respect.

This duty obliges state from directly or indirectly interfering with the enjoyment right to health. It has been argued that the same is negative in character[71]. UN Committee on ICESCR in General Comment No. 14 gives a long list of obligations to respect for instance States is obliged to refrain from limiting equal access for all persons to preventive, curative and palliative health services. The persons include prisoners, detainees, minorities, asylum seekers and illegal immigrants among others. It also obliges the state to refrain from prohibiting traditional preventive care and medicines.

A state is said to violate its obligation to respect when it repeals or suspends a law necessary for the continued enjoyment of the right or when it adopts legislation or policies that are manifestly incompatible with pre-existing domestic or international legal obligations relating to the right to health.[72] For instance, laws and regulations that would restrict access to medications by increasing prices—thereby decreasing access—would presumptively constitute a violation of the state party's obligations under the ICESCR.[73] Continued enactment of legislations highlighted above is an example of states commitment to respect the enjoyment of right to health.

With respect to the obligation of the state to respect the rights of detainees, Kenyan courts have defined inhuman treatment to mean physical or mental cruelty so severe that it endangers life or health.

In affirming, *interalia*, protection of right to heath, the High Court in the case of *Republic -v- Minister for Home Affairs and Others ex parte Sitamze*[74] in which Justice Nyamu, after citing various authorities, stated as follows:

> "The provisions of section 74(1) of the Constitution of Kenya are echoed in article 7 of the International Covenant on Civil and Political Rights, 1966, (ICCPR) which states that no one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment.

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[71] Mchangama, J, '*Health as Human Right: The Wrong Prescription'* International Policy Network 2009.
[72] United Nation Committee on Economic, Social & Cultural Rights., General Comment 14.
[73] Ibid. Paragraph 47.
[74] Republic -v- Minister For Home Affairs and Others ex parte Sitamze Nairobi HCCC NO, 1652 OF 2004 120081 2 EA 323

> Torture means 'infliction of intense pain to the body or mind; to punish, to extract a confession or information or to obtain sadistic pleasure. It means infliction of physically founded suffering or the threat to immediately inflict it, where such infliction or threat is intended to elicit or such infliction is incidental to means adopted to illicit, matter of intelligence or forensic proof and the motive is one of military, civic or ecclesiastical interest It is a deliberate inhuman treatment causing very serious and cruel suffering. "Inhuman treatment" is physical or mental cruelty so severe that it endangers life or health. It is an intentional act which, judged objectively, is deliberate and not accidental, which causes serious mental or physical suffering or injury or constitutes a serious attack on human dignity." Emphasis added.

The court in the case of *Koigi Wamwere V Attorney General*[75] in a case where the Petitioner, detainee during Moi era, sued the Attorney General for acts of unlawful detention and solitary confinement by the state. The Petitioner argued that while on while under the unlawful detention and solitary confinement, his torture was enhanced with bad, half-cooked ugali and electricity dried, hard and impossible to chew beans that wreaked havoc to his health. The Petitioner pleaded that they asked authorities for better food, the diet was never changed under the claim that, as african detainees, they were only entitled to food scale A for Africans and not food Scales B,C or D that were meant for Non-African detainees.

Justice Mumbi Ngugi found that the respondent did not contest the charges of torture made by the Petitioner during his detention at Nyayo House, and instead limited himself to stating that they could have been committed by individuals other than state agents during the period in question. The Court awarded a sum of Two Million Five Hundred Thousand Shillings as a compensation for such violations by the state.

The finding of the court thus confirms that the state has an obligation to respect the right of health, among others, of the detainees during confinement. But considering the ordeal that the petitioner went through the compensation should be more enhanced to deter future actions.

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[75] Koigi Wamwere V Attorney General[2012]eKLR

2.6.2 Obligation to protect.

This duty obliges the States to avert third parties from prying with the enjoyment of human rights and provide adequate redress.

Under General Comment No. 14 the 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. It also include an obligation to make sure that privatization of the health sector does not create a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services.[76] Again the plethora of legislative measures that the government has taken is in tandem with this obligation. Radiation Protection Act[77] , as a legislative measure, ensures that third parties do not expose public to health hazards of devices and materials capable of producing ionizing radiation.

The state is required to regulate the marketing of medical equipment and medications by third parties, as well as to guarantee that medical practitioners and other health professionals fulfill adequate educational, skill, and ethical criteria.[78] States should also ensure that third parties do not limit people's access to health-related information and services.[79]

The state has put in place the Medical Practitioners and Dentists Act[80] which was enacted to consolidate and amend the law to make provision for the registration of medical practitioners and dentists. It establishes a Board known as the Medical Practitioners and Dentists Board whose role is to punish errant medical practitioners and dentists.

Section 24 of this act provides that a prosecution of an offence under it shall require written consent of the Attorney General. This is unconstitutional. If prosecution proceeds under this provision, it

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[76] General Comment Number 14, <http://www.nesri.org/resources/general-comment-no-14-the-right-to-the-highest-attainable-standard-of-health> accessed 26 June 2018.
[77] Supra Note 59.
[78] Ibid.
[79] Ibid.
[80] Medical Practitioners and Dentist Act, Chapter 253, Laws of Kenya.

can easily be challenged. Article 157 of the CoK empowers the office of the Director of Public Prosecution (DPP) to commence or take over criminal proceedings. Article 157(11) of the CoK expresses in mandatory terms that the DPP does not need consent or direction of any person in exercising its powers.

At the height of severe acute respiratory syndrome Coronavirus 2 (COVID-19) pandemic, the state has put in a raft of legislative interventions to protect its citizens and to slow the transmission of virus. One such measure is the Legal Notice No. 36, The Public Order (State Curfew) Order, 2020 under the Public Order Act[81]. The Order put a curfew period between seven o'clock in the evening and five o'clock in the morning with effect from the 27th March, 2020 for a period of 30 days. The Order bars public gatherings, processions or movement either alone or as a group during the period of the curfew except as shall be permitted, in writing, by a police officer in charge of the police in a county or a police officer in charge of a police division.

An attempt by the Law Society of Kenya (LSK) to have the curfew order declared unconstitutional in the case of *Law Society of Kenya v Hillary Mutyambai Inspector General National Police Service & 4 others; Kenya National Commission on Human Rights & 3 others (Interested Parties)* [82] was resisted by the Court on grounds that the Curfew Order seeks to contain the novel corona virus which is a life threatening pandemic. This is a classical case where the court decided to validate the states' measure to protect the right to health.

The state, in response to the COVID-19 pandemic, has also made rules under Section 36 of the Public Health Act vide Legal Notice No. 46 of 2020, The Public Health (Prevention, Control and Suppression of Covid-19) Rules, 2020, published on 3rd April,2020 in Kenya Gazette Supplement No. 39. It makes provisions for handling, prevention, control and suppression of COVID-19 cases and give penalties for violations. In formulating this, the state was acting in sync with its obligation to protect its citizens by managing the spread of COVID-19 pandemic.

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[81] Public Order Act, Chapter 56, Laws of Kenya.

[82] Law Society of Kenya v Hillary Mutyambai Inspector General National Police Service & 4 others ; Kenya National Commission on Human Rights & 3 others (Interested Parties) [2020] eKLR.

2.6.3 Obligation to fulfill.

This is the most far reaching obligation. It needs the states to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health.[83] This obligation resonates well with provisions of the CoK which has, *inter alia,* informed the enactment of The Cancer Prevention & Treatment Act which is a significant milestone in the realization of the right to health. One of the provisions is about setting up centers to combat cancer, an ailment that requires palliative care. Distribution of free anti-retroviral drugs in many health facilities in the country also resonates with this obligation.

It is possible that states will be held responsible for a wide range of acts and omissions without being able to predict which acts and omissions will constitute prospective violations of the Covenant.[84]

The obligation to *fulfill (facilitate)* requires States *inter alia* to take positive measures that enable and assist individuals and communities to enjoy the right to health. States parties are also obliged to *fulfil (provide)* a specific right contained in the Covenant when individuals or a group are unable, for reasons beyond their control, to realize that right themselves by the means at their disposal[85].

This obligation can be deciphered in the case of *Luco Njagi & 21 others v Ministry of Health & 2 others*[86] cited earlier, where the court was satisfied with the positive administrative measures taken by the state to avail dialysis machines at Kenyatta National Hospital in finding there was no violation of right to health of the Petitioners. In other words, the state was on the right path to facilitate enjoyment of the right to health. The Judiciary failed in its role to do proper justice to the Petitioners by failing to ask the state to table hard facts on the budgetary allocation towards promotion of right to health in Kenya in order to make arrive at a sound judgment.

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[83] Ibid.
[84] As above 58.
[85] As above 59.Para 37.
[86] Supra Note 6.

The three state's obligations was aptly put in practical perspective in the case of *Mitu-Bell Welfare Society v. The Hon. Attorney General and 2 Others*[87] where Justice Mumbi Ngugi observed that with respect to social economic rights, the state, as a signatory to the ICECS, was aware, or should have been aware well before the promulgation of the Constitution, of its obligation, as now enunciated in Article 21 and 43, to observe, respect, protect, promote and fulfil the social economic rights of citizens. The Court directed the parties report back on the progress made towards a resolution of the petitioners' grievances within 90 days. It also directed the state, one of the respondents, furnish copies of such policies and programmes to the petitioners to aid in resolution of the matter.

It is thus clear that state has a critical role in ensuring that right to health is attained. It can be achieved through legislative, policy and other measures including the setting of standards. The legislation should meet international standards of protection of social and economic rights and particular realization of right to health.

The Judiciary in instances where there socio-economic right has been violated should give instant redress rather than leave litigants at the mercy of the aggressor, third parties, like in the *Mitu-Bell Welfare Society Case.* More time given to the parties after the delivery of judgment is tantamount to a delayed justice. Justice delayed is justice denied.

Infact on an appeal against the above cited case, the Court of Appeal found that the High Court Judge made a grave error by issuing "interim" Judgment and allowing parties to file pleadings post-judgment, an act that violates *functus officio* doctrine.[88] The Court also found that it was wrong for the court to compel state to formulate policies. The Court of Appeal set aside the Judgment in its entirety. This reinforce the argument advanced by this study that legislative safeguards are proper mechanisms to safeguard right to health through access to medicine and in streamlining other health determinants.

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[87] Mitu-Bell Welfare Society v Attorney General & 2 others [2013] eKLR.

[88] Kenya Airports Authority v Mitu-Bell Welfare Society & 2 others [2016] eKLR.

2.7 Conclusion

This chapter has outlined evolution of the right to health in Kenya. It has explored in detail the three crucial roles of state in promoting right to health. It has laid down the normative content of the right to health. It has highlighted domestic, regional and international instruments that form the legal framework for the establishment and advancement of access to medicines and thus promote right to health. It has answered the question as to the role and obligation of the state in promoting the right to health. It has examined a number of legislations meant to promote full attainment of the right to health and inherent weaknesses in those legislations that hampers right to health realization. The next chapter shall explore the place of traditional medicine in promoting right to health. It shall make a discussion whether there is a sound legal framework regulating the practice of traditional medicine in Kenya.

CHAPTER 3

3 A CASE FOR UTILIZATION OF TRADITIONAL KNOWLEDGE IN MEDICINE IN KENYA TO ENHANCE ACCESS TO MEDICINE AND RIGHT TO HEALTH

3.1 INTRODUCTION

This Chapter will comprehensively discuss the question of protection of traditional knowledge-based medicine as a way of stimulating access to medicine by Kenyans and by extension enhancement of the right to health. It shall explore the significance of traditional medicine and a case for mainstreaming its practice into conventional health care system through a sound regulatory framework. This chapter will explore various challenges of the existing legislative framework of TK based medicine in Kenya and lapses therein. It shall explore regional and international instruments that offers protection of traditional knowledge. It will highlight legislative measures put in place by South Africa to integrate TK based medicine into the conventional health care system. It shall analyze challenges of non-protection of TK bases medicine and test the sufficiency of the *Sui Generis* system of protection of TK based medicine in Kenya.

Articles 11, 40 and 69(1) (c) of the Constitution 2010 lays down constitutional basis for protection of traditional knowledge. It recognizes culture as the foundation of nation. It obligates the state, *interalia*, to recognize the role of science and indigenous technologies in the development of a nation. It obligates parliament to recognize and protect the ownership of indigenous seeds and plant varieties, their genetic characteristics and their use by the communities in Kenya. Article 40 of the Constitution allows ownership of property by a group of people in any part of the country.

Article 69(1) (c) of the Constitution obligates the State to protect and enhance intellectual property in, and indigenous knowledge of, biodiversity and the genetic resources of the communities.

This chapter will to answer the question as to whether we have sound policies and legal framework for the practice of traditional medicine in Kenya.

3.2 Traditional Knowledge in Medicine Defined.

TK is knowledge, expertise, skills and practices which are produced, perpetuated and passed on from one generation to another within a society, often forming part of its traditional or moral identity[89].

Traditional Knowledge based medicines also described as non-conventional medicines (NCMs) has several definitions but the WHO definition is the most widely used and only adopted here. It describes NCMs as "different practices, methods, knowledge and beliefs in health which imply the utilization for medical purposes of plants, animal parts and minerals, spiritual therapies, techniques and manual exercises, applied either individually or in combination to look at, to diagnose and to prevent the diseases or to protect the health."[90]

The Constitution of Kenya does not define traditional knowledge but is an anchorage that provides for an enactment of the legislation to safeguard the same.

Protection of Traditional Knowledge and Cultural Expressions Act[91] defines traditional knowledge to include medical knowledge as follows:-

> traditional knowledge means any knowledge—
>
> (a) "Originating from an individual, local or traditional community that is the result of intellectual activity and insight in a traditional context, including know-how, skills, innovations, practices and learning, embodied in the traditional lifestyle of a community"; or
>
> (b) "Contained in the codified knowledge systems passed on from one generation to another including agricultural, environmental or medical knowledge, knowledge associated with genetic resources or other components of

[89] https://www.wipo.int/tk/en/tk/, accessed 26 March 2020.
[90] WHO, *General guidelines for methodologies on research and evaluation of traditional medicine* (Geneva: WHO, 2000). See https://www.hhrjournal.org/2013/10/traditionalalternative-medicines-and-the-right-to-health-key-elements-for-a-convention-on-global-health/, accessed 26 March 2020.
[91] Protection of Traditional Knowledge and Cultural Expressions Act, Act No. 33 of 2016, Laws of Kenya.

biological diversity, and know-how of traditional architecture, construction technologies, designs, marks and indications."

Section 2 of the Science, Technology and Innovation Act[92] defines traditional knowledge "as the wisdom developed over generations of holistic traditional scientific utilization of the lands, natural resources, and environment."

3.3 The link between the right to health and access to essential medicines

Right to health is critical cornerstone and gateway for the exercise of other rights. Critical component of this right is access to medicines without discrimination.

According to WHO, essential drugs are those that are required to meet the population's highest priority health care demands. They are chosen with proper consideration given to their significance to public health, evidence of efficacy and safety, and comparative cost-effectiveness.[93] WHO posits that crucial elements of essential medicines within the context of a functioning health system are: availability at all times in adequate amounts, and in the appropriate dosage forms; assured quality and adequate information, affordability in terms of a price the individual and the community can afford[94].

As captured under General Comment number 14[95] realizing the rights to access to medicines is contingent upon the realization of four interrelated elements that is: availability, accessibility, acceptability and quality ("AAAQ" framework). Integration of traditional medicine will make it easier for the government to ensure that the medicine meets the "AAAQ" framework. There is an emphasis on equality of access to health care and health services especially to the most vulnerable and marginalized sections of the society.

[92] Science, Technology and Innovation Act, Act No. 28 of 2013, Laws of Kenya.
[93] https://www.who.int/topics/essential_medicines/en/ Accessed 5 December 2020.
[94] Ibid.
[95] Supra Note 18

3.4 Significance of Traditional Knowledge based medicine and challenges of non-protection.

More than 60 per cent of the population of the world used Traditional Knowledge based medicines. Rural masses use them for their primary health care in developing countries. They are also used in developed countries where the dominant medicines is the modern one.[96] According to the UK Commission Report of 2001, knowledge has always been generated, refined and passed by generations to successive generations by human communities[97]. Such traditional knowledge is often an integral part of their cultural identities.

Traditional knowledge (TK) has played, and continues to play, an important role in the daily lives of the vast majority of people throughout history and throughout the world[98]. Traditional knowledge is essential to the food security and health of millions of people in the developing world[99].

Traditional Medicine (TRM) play a key role in health care for a substantial portion of the people living in developing countries. As per the WHO,

> "…up to 80 per cent of Africans –or more than a half billion people- visit traditional healers for some or all of their medical care. In Africa and in many developing nations, medical services are limited or unobtainable for the majority of the population. It is the traditional healers and birth attendants in rural and urban areas that have historically provided and continue to provide primary healthcare. They are the vital link to supplying the needed services in their communities, and yet their efforts must continue

[96] https://phrg.padovauniversitypress.it/system/files/papers/2018_3_3.pdf, accessed 26 March 2020.
[97] http://www.iprcommission.org/papers/pdfs/final_report/Ch4final.pdf, accessed 26 March 2020.
[98] Ibid.
[99] Ibid.

to expand as populations grow, and health concerns continue to increase in complexity and case numbers" (Nelson-Harrison et al, 2002, p. 283).[100]

Appreciating the significance of traditional system of medicine, WHO passed resolution in 1989 advocating for the use of traditional medicine in health care system[101]. It resolved that member states should explore ways in which traditional practitioners may be used to extend the coverage of primary health care system. It also urged members to encourage collaboration between universities, health services, training institutions and relevant international organizations in the scientific appraisal of modern forms of medical treatment and their application in the modern health care.

WHO reckons that proper use of traditional medicine can contribute to the efforts of the Member States in achieving the goal of Health for all. It further reckons that where modern health care services cannot be fully provided at the primary health care level, the majority of the people living in rural areas would continue to rely on traditional remedies, as in the past in promotion of their health.[102] Universal Health Care coverage in Kenya has been elusive owing to limited resources.

Munyi et al aptly highlight the significance of TK in medicine in the world of science today. They posit that although the TK systems and indigenous innovations have contributed significantly to the present body of knowledge possessed by scientists (e.g. ethnobotanists, ethnopharmacologists, agriculturists, foresters and food technologists) and conservationists, recognition, reciprocation and appreciation by policy decision processes has not been satisfactory[103].

Gakuya et al asserts that Alternative medicine is an important component of basic healthcare in Kenya since the country's health-care infrastructure is insufficient to meet the needs of the entire

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[100] Correa, C *'Protection and Promotion of Traditional Medicine: Implications for Public Health in Developing Countries* (2002), see https://apps.who.int/medicinedocs/pdf/s4917e/s4917e.pdf accessed 29 March 2020.

[101] https://apps.who.int/iris/bitstream/handle/10665/127565/SEA_HMM_Meet_17.5.Pdf?sequence=1&isAllowed=y Accessed 8 December 2020.

[102] Ibid.

[103] Ongugo, P, Mutta, D, Pakia, M, and Munyi, P, (2012), *Protecting Health Knowledge in Kenya: The Role of Customary Laws and Practises. https://pubs.iied.org/pdfs/G03443.pdf Accessed 6 May 2020.*

population's medical needs.[104] Medicines used by majority of the vulnerable in rural areas are a cacophony of several different substances of biological origin and due to absence of regulation, quacks have a field day in the practice. With regulation of practice of such medicine the marginalized shall be able to access with ease affordable quality medicine that is readily available and acceptable hence satisfying crucial component of the right to health.

Janska et all argues that majority of the population in many developing countries depends on traditional medicine to meet its primary healthcare needs for the reason that they are affordable, accessible and acceptable due to efficacy of its treatment[105]. The only challenge is quality and side effects since they are not subjected to rigorous tests and surveillance like conventional medicine. The other challenge is ignorance on appropriate dosages which can be highly risky.

It has also been argued that one of the reasons "given for the reliance of traditional medicine is the fact that traditional healers are often available due to the fact that they tend to reside in the same neighborhood as their patients and share the same language as the community as the patients[106].

Proper protection of TK based medicine should start with a comprehensive recognition by the law and a comprehensive definition. Most statutes do not define with precision TK based medicine. This is a serious lapse. Thorough protective mechanisms start with precise recognition and definition. The only trouble is charlatan healers hence the need to make a formal regulation of the practice.

The majority of pharmaceutical medicines produced and utilized in poor nations are derived from biological components that are sourced through traditional medical practices. Plant and algae extracts, as well as chemicals obtained from microbial sources and animals, are examples of this type of substance. The pharmaceutical industry relies heavily on plants, in particular.[107]

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[104] Supra Note 4.
[105] Janska, E, Serbulea, M, and Tobin, B, (2005), *The Importance of Traditional Knowledge for Meeting Public Health Needs in Developing Countries.*
[106] Ibid.
[107] Ibid.

It has been argued that TK is difficult to protect under the current intellectual property system, which normally offers protection for a limited amount of time to inventions and unique works created by named people or firms.

The use of traditional medicine also implicates various human rights, including, *interalia*, the right to health by access to diverse therapies where they have demonstrated their therapeutic efficacy[108].

There are myriad of challenges that will arise if the practice of traditional medicine and knowledge on which it is based are not regulated. First, the challenge of quality and possible toxicity. Products made with poor quality plants may constitute a serious threat to the safety of patients[109]. The law does not protect users of traditional medicine against malpractise of poor hygiene, toxicity and low quality products.

Secondly, the issue of sustainability, bio-prospecting, and bio-piracy if bio-prospecting can be understood as the "exploration, extraction and screening of biological diversity and indigenous knowledge for commercial value," bio-piracy consists of the exploration of and the use for commercial purposes of genetic and biological resources, as well as traditional knowledge, without adequately compensating the local communities and states from which these resources arise[110]. This practice needs to be controlled to avert prospect of extinction of endangered species and destruction of resources and natural environments and by extension violation of human rights. The penalty for bio-prospecting is not deterrent enough to protect locals from those utilizing medicinal plants for commercial value.

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[108]https://sites.sph.harvard.edu/hhrjournal/2013/10/traditionalalternative-medicines-and-the-right-to-health-key-elements-for-a-convention-on-global-health/, accessed 27 March 2020.
[109]Segar, J, "Complementary and alternative medicine: Exploring the gap between evidence and usage," *Health: An Interdisciplinary Journal for the Social Study of Health, Illness and Medicine* 16/4 (2012), pp. 366-381. See https://www.hhrjournal.org/2013/10/traditionalalternative-medicines-and-the-right-to-health-key-elements-for-a-convention-on-global-health/ , accessed 29 March 2020.
[110] Ibid.

It has been correctly established that biopiracy has a negative impact on the ecosystem. Little animals and plants that co-exist with the plant that is being 'stealthily' harvested are vulnerable to destruction, resulting in an even greater degradation of the ecosystem as a result[111]. There is an urgent need to establish effective and acceptable methods of combating biopiracy while also guaranteeing that humankind can profit from the medical potential of plants found in its environment. This will undoubtedly promote the right to health.

Thirdly, valuing, training, promotion, and research in traditional medicine remains a big challenge. Traditional health knowledge has not been given the value it deserves. Under our laws no funds have been established for research purposes. There are no training institutions on traditional medicines. In other jurisdictions like South Korea 85% of medical schools offered instruction on complementary or alternative medicines between 2007 and 2010[112]. Kenyan legislation does not provide for training of medical students or pharmacy students on traditional medicine.

TRM's commercial value may derive from different activities, such as cultivation of medicinal plants for sale or production and distribution of TRM. Legislation should make a provision for funding of those who possess the knowledge to enable them plant more medicinal plants for sustainability purpose. TRM can also be a signpost for the screening of natural products for therapeutic benefit.[113] Proper legislative measures will ensure that screening exercise happens in all the counties in Kenya. The much that has been done is to only obligate county governments to maintain a register carrying data on TK.

Fourthly, the challenge of the national and international recognition. Apart from locals, TK has also been acquired and employed by foreign entities, including foreign individuals, research academics, and multinational companies[114]. The globalized nature of modern TK use highlights

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[111] Supra Note 5. P 286.
[112] D. Y. Kim, W. B. Park, H. C. Kang, et al., "Complementary and alternative medicine in the undergraduate medical curriculum: A survey of Korean medical schools," *Journal of Alternative and Complementary Medicine* 18/9 (2012), pp. 870-874. See https://www.hhrjournal.org/2013/10/traditionalalternative-medicines-and-the-right-to-health-key-elements-for-a-convention-on-global-health/ , accessed 29 March 2020.
[113] Supra Note 10.
[114]Supra Note 83.

the necessity for legal frameworks to govern such transnational operations, not only through national agencies, but also through international mechanisms like the World Intellectual Property Organization[115].

International institutions have neither come up with a comprehensive treaty on obligations of various states nor formulated enforcement mechanisms to ensure national implementation of treaty. An international legal instrument can provide for a minimum of basic level of protection or a strict universally applied requirement.

3.5 Challenges in the legislative framework of the protection of traditional medical knowledge in Kenya

Kenya is not short of policies as far as the question of protection of TK is concerned. The National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, 2009 was developed in response to a growing need to address three main challenges facing the country then. First, accelerating technological development. Second, integration of the world economic. Third, ecological, cultural, trading and information systems and the growing relevance of intellectual property rights to these areas of activity.[116] According to the policymaker, the three core areas have a significant impact on traditional knowledge, genetic resources, and folklore, which are the primary topics of this policy statement. In recognition of the fact that traditional knowledge and traditional cultural expressions are not acknowledged in many national policy and legal systems, the policy notes that This policy had a significant role in the passage of the Protection of Traditional Knowledge and Cultural Expressions Act, which was passed in 2016. The shortcoming is that there is yet to be a robust legislation on the regulation of practice of traditional medicine in Kenya.

National Drug Policy, 1994, has acknowledged traditional medicine as a key component of Kenya's culture and thus the need to mainstream it into the primary health care system as discussed

[115] Ibid.
[116] https://www.wipo.int/edocs/lexdocs/laws/en/ke/ke022en.pdf Accessed 5 December 2020.

in chapter two is to that effect. Despite that and as it will be seen later, recognition of traditional medicine and acceptance into the mainstream conventional health care system has been at a snail's pace.

Under the Kenya Health Policy 2014-2030, the national government is obligated to ensure a review of the health sector legal and regulatory frameworks and align them to the policy and CoK[117]. It advises the ministry responsible for health to put in place measures to regulate traditional and complementary medicines. It also defines the private health sector to include Private-Not-For-Profit (PNFP), Private Health Provides (PHP), Faith Based Organizations (FBO) and Traditional and Complimentary Medicine Providers (TCMP). It advocates for collaboration with the public health sector through an establishment of an appropriate legislative framework and guidelines to facilitate and regulate private sector in line with existing laws and regulations and also development of Public Private Partnership Policy framework. This is recognition of state obligation to protect, promote and respect the right to health composed of access to traditional medicine. Plethora of policies is not a solution to lapses in the existing legal framework.

No legislative intervention has been made until the promulgation of the CoK, 2010 and the recent enactment of the Health Act[118]. The Act has not made comprehensive provisions or subsidiary legislation that governs the practice of traditional medicine in the country. NDP also targeted access to affordable medicine through pricing policies. To date majority of Kenyans cannot afford medicine.

It is thus crucial to see various scattered pieces that attempts to recognize TK and the challenge of protection.

The Environmental Management and Coordination Act (EMCA)[119] regulates access to all genetic resources.[120] This was the position before promulgation of the 2020 constitution.

[117] Supra Note 43.
[118] Supra Note 3.
[119] Environmental Management and Coordination Act, Act No. 8 of 1999, Laws of Kenya.
[120] Wekesa, M An overview of the Intellectual Property rights (IPRS) regime in Kenya in M Wekesa & B Sihanya (eds) (2009) *Intellectual Property Rights in Kenya* Konrad Adenauer Stiftung Sportslink Authors.

EMCA is administered by the National Environment Management Authority (NEMA) which has the mandate to identify and codify all genetic resources in Kenya.

Section 53 of the EMCA empowers the Cabinet Secretary on the recommendation of the NEMA to issue guidelines and prescribe measures for sustainable management and utilization of genetic resources of Kenya for the benefit of the people of Kenya.

Environmental Management and Co-Ordination (Conservation of Biological Diversity And Resources, Access To Genetic Resources And Benefit Sharing) Regulations, 2006 has been formulated and now in force.

Under the guidelines NEMA requires a Materials Transfer Agreement (MTA) after prior informed consent. The MTA is needed to show the ways of sharing the benefits. In relation to traditional medicine (TM), EMCA does not go far enough to offer comprehensive protection to local communities[121].

Contravention of the guidelines shall constitute an offence whose penalty is a jail term not exceeding 18 months or a fine not exceeding Kenya Shillings Three Hundred and Fifty Thousand (Kshs 350,000). A person who has exploited genetic resource for economic value to the detriment of locals will find this penalty non-deterrent at all. From the foregoing it is discernable that NEMA is ill-equipped to protect TK at the local level.

It is crucial to have a substantive law with an associated institution for protecting TK. The law that has been enacted empowers County Governments to maintain a register carrying data on TK. A body to give protection is needed. There is a risk of manipulation of data at the county level to the detriment of the locals.

Science, Technology and Innovation Act is a general legislation that establishes research institutions like Kenya Medical Research Institute (KEMRI) as a national body responsible for carrying out health research in Kenya. The act does not pay a lot of attention on the critical aspect

[121] Ibid.

of traditional medicine. KEMRI has only less than 5 regional offices. This is not sufficient to serve 47 counties in Kenya. Apart from the mention of TK in the interpretation section, there is no mention of TK based medicine anywhere in the statute. This falls on the face of one of the mandates that KEMRI prides itself in appearing on its website. It gives its mandate, *interalia*:-

> "Rationalization of traditional medicines in collaboration with traditional healers; evaluation of plant drugs using medicinal Phytochemistry, pharmacology and toxicology and, formulation of herbal remedies…"[122]

It is as a result of the above that parliament in 2016 enacted the Protection of Traditional Knowledge and Cultural Expressions Act, 2016 [the Act] to provide for a framework for the protection and promotion of traditional knowledge and cultural expression.

Section 8 of the Act mandates County Government to establish and maintain a register which shall contain information relating to traditional knowledge collected and documented by the county government during the registration process. This study has discovered after sampling officers of three County Governments that they are not aware of the existence of the Act, leave alone creation of a register.

The Act does not specify what happens if County Governments do not establish or maintain registers carrying data on traditional knowledge. It also does not provide time frames within which such registers are to be established. The data on those registers are supposed to form basis of maintaining Traditional Knowledge Digital Repository by the national government. Failure to create a record at the county level will affect record of data on the national level.

The fine for exploitation of traditional knowledge without consent of the owner is not deterrent enough. A few examples of such sanctions and remedies are highlighted in the following paragraphs.

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[122] https://www.kemri.org/centre-for-traditional-medicine-and-drug-research-ctmdr-nairobi/ accessed 30 March 2020.

Section 37(1) (f) of the Act provides that a person who in any manner develops any goods or service using unauthorized traditional knowledge or cultural expressions in the course of trade, commits an offence and is liable on conviction to imprisonment for a maximum term of five years, or to a fine of not exceeding five hundred thousand shillings in respect of each article or item involved or to imprisonment for a term not exceeding ten years or to a fine not exceeding one million shillings.

Section 37(2) of the Act provides that a person who without authorization makes a non-customary use of traditional knowledge or cultural expressions whether or not such use is of a commercial or industrial nature, commits an offence and is liable, on conviction, to a fine not exceeding one million shillings or imprisonment for a term not exceeding five years or both.

Section 37(6) of the Act provides that a person who without authorization acquires and exercises intellectual property rights over protected traditional knowledge or cultural expressions commits an offence and is liable, on conviction, to a fine not exceeding two million shillings or imprisonment for a term not exceeding ten years or both.

The use of the word liable means that the judicial officer is given discretion to impose any fine as long as it does not exceed the amount given. This is not deterrent at all.

The law does not provide for mechanisms of mass generation of medicines extracted from the medicinal plants and that brings into fore the question of sustainability of the use of traditional medicine on enhancing the protection of right to health.

3.6 Regional and International Instruments of protection of traditional medicine.

The significance of international protection of traditional knowledge cannot be gain said. There are efforts to protect TK within intellectual property context. Ouma argues that municipal and

regional laws that protect traditional knowledge a limited impact[123]. This is because they have legal force in the countries in which they have been enacted or ratified. She correctly argues that It is necessary to broaden the scope of the protection they provide by forming bilateral or multilateral agreements between states which have a shared interest in conserving traditional knowledge and have national laws that are similar.[124] The biggest challenge of protection of use of international intellectual property regime to protect TK is that TK values practice from one generation to the other rather than originality.

The preamble of the Swakopmund Protocol on the Protection of Traditional Knowledge and Traditional Cultural Expressions talks about the recognition of the right of holders and custodians of traditional knowledge and expressions of folklore to effective and efficient protection against all acts of misuse, unlawful exploitation or misappropriation of their knowledge and expressions of folklore[125]. This protocol gives a wide definition of traditional knowledge to include medical knowledge.[126] The Protocol lays a legal framework that protects traditional knowledge holders by way of fair and equitable sharing of benefits that arises from the commercial use of their knowledge. The protocol does not however make a comprehensive legal framework for the practice of traditional medicine in member states.

African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources of 2000 provides for , *interalia,* the protection of their traditional knowledge relevant to plant and animal genetic resources.

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[123] Ouma, M, "Traditional knowledge: the challenges facing international lawmakers (2017)". See https://www.wipo.int/wipo_magazine/en/2017/01/article_0003.html Accessed 5 December 2020.

[124] Ibid.

[125] Ibid. Swakopmund Protocol on the Protection of Traditional Knowledge and Traditional Cultural Expressions was adopted in 2010 by the 19 member states of the African Regional Intellectual Property Organization (ARIPO).

[126] "Traditional knowledge shall refer to any knowledge originating from a local or traditional com-munity that is the result of intellectual activity and insight in a traditional context, including know-how, skills, innovations, practices and learning, where the knowledge is embodied in the traditional lifestyle of a community, or contained in the codified knowledge systems passed on from one generation to another. The term shall not be limited to a specific technical field, and may include agricultural, environmental or medical knowledge, and knowledge associated with genetic resources." See https://www.wipo.int/edocs/lexdocs/treaties/en/ap010/trt_ap010.pdf Accessed 5 December 2020.

Article 8(j) of the 1992 Convention on Biological Diversity provides that contracting parties shall respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization if such knowledge, innovations and practices. The nitty-gritty of the implementation of this provision is left to the contracting parties.

Article 31 of the UN Declaration on the Rights of Indigenous Peoples provides for the rights of indigenous peoples to maintain, control, protect and develop, among other things, their traditional knowledge and genetic resources as well as their IP over such knowledge.

Convention on International Trade in Endangered Species of Wild Fauna and Flora was adopted against the backdrop of the belief that international co-operation is essential for the protection of certain species of wild fauna and flora against over-exploitation through international trade. This regulates trade in specimens of the endangered species by giving powers to the management authority of a contracting party to issue export and import permit. Protection ensures preservation of certain species of wild fauna and flora which may be of essential medicinal value.

Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an instrument that is concerned about, *interalia*, protection of medicine in the intellectual property sense-unauthorized use by third parties. According to the World Intellectual Property Organization (WIPO), in order to obtain a patent, those who possess traditional medical knowledge must overcome significant obstacles such as proving novelty and inventiveness, which can be difficult because many traditional medicines are in use for generations, are widely disseminated, and are documented in widely accessible sources. Absence of novelty will disqualify it from patent protection.[127]

[127] https://www.wipo.int/export/sites/www/tk/en/documents/pdf/background_briefs-e-n6-web.pdf Accessed 6 December 2020.

The above international conventions and protocols need to be adopted locally to take care of critical issues like sustainable use and utilization of medicinal plants as a resource and conservation efforts to enable most Kenyans to have access of affordable essential medicines.

3.7 Is *Sui generis* system of protection of traditional knowledge sufficient to protect right to health?

This refers to a special form of protection regime outside the mundane legal framework.[128] Intellectual property rights (IPRs) the term refers to a special form of protection regime outside the known framework.[129]

IPRs systems are inadequate to protect TK because of the following major features.

First, is the concept of property ownership. IPRs main focus is protection of individual rights. On one hand modern IPRs regimes recognize individual ownership based on time and labour utilized in coming up with the new invention while on the other hand TK is passed on from generation to generation. There is no novelty. "Community rights" is an alien in the arena of the modern IPRs. TK therefore cannot find solace of protection in the arena of IPRs. It is knowledge confined to certain communities or families.

Second, is the criteria for patenting an invention. Inventive step, novelty, and the patent's commercial viability. For a patent to be issued, an invention must fulfil all the three tests. TK does not pass the three tests because the knowledge under TK is not new, has no inventive step and the restriction of ownership within families or certain communities does not make it commercially viable.[130] It is therefore clear that traditional medicine persons are unable to use patents to protect their knowledge.

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[128] Supra Note 115. *Sui generis* is a Latin term meaning "a special kind".
[129] Ibid.
[130] Moni Wekesa, What is *sui generis* system of intellectual property protection? See https://atpsnet.org/wp-content/uploads/2017/05/technopolicy_brief_series_13.pdf Accessed 31 March 2020.

Third, TK is trans-generational, which is a legal booby trap in identifying an innovator or creator for the purpose of rewarding their creativity.[131] This raises also problem of duration of protection since intellectual property rights are protected for a limited duration. The reward theory underlying IP policy is not apt in justifying protection of existing knowledge like TK[132].

In the international context, a number of countries eg Costa Rica, Peru, Thailand and Venezuela have put *sui generis* regimes in place. Costa Rica has a law on biodiversity, Biodiversity Law of 1998, under which TK is acknowledged. Article 82 provides:

> "The State expressly recognizes and protects, under the common denomination of sui generis community intellectual rights, the knowledge, practices and innovations of indigenous peoples and local communities related to the use of components of biodiversity and associated knowledge. This right exists and is legally recognized by the mere existence of the cultural practice or knowledge related to genetic resources and biochemicals; it does not require prior declaration, explicit recognition nor official registration; therefore it can include practices which in future acquire such status…"

The 1987 Constitution of the Philippines recognizes traditional knowledge. Section 17 Article XIV provides: -

> "The State shall recognize, respect and protect the rights of the indigenous cultural communities to preserve and develop their cultures, traditions and institutions"

Sui generis system does not contain an elaborate regulations on the practice of traditional knowledge in Kenya. The *sui generis system* as demonstrated above is a replica of recognition of TK knowledge under Constitution 2010 but it is not enough, we need to have in place a robust system of protection

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[131] Djims Milius, 'Justifying Intellectual Property in Traditional Knowledge' (2009) 2 IPQ 185, 193-194.
[132] Paull J. Heald, 'The Rhetoric of Biopiracy' (2003) 11 Cardozo Journal of International and Comparative Law, 519-546.

of TK based medicine and a specialized regulatory institution that manages the same and license the practitioners of traditional medicine, introduction of training curriculum in higher learning institutions, more research on healing plants in various communities within the republic and sustainability of TRM to safeguard citizenry's right to health.

3.8 Conclusion

This Chapter has discussed the significance of traditional knowledge in enabling Kenyans access medicines owing to the challenges of access of the conventional healthcare infrastructure. It has highlighted the scattered nature of legislations defining traditional knowledge. It has highlighted various domestic, regional and international legal instruments that protects traditional knowledge. It has also discussed the effects of non-protection of traditional knowledge and made a case for regulation of the practice of traditional healers. It has done an assessment of how *sui generis* system of protection is not efficient way to protect traditional knowledge. It has answered the question about the place of traditional knowledge in medicine in the conventional healthcare system and how efficacious in promoting right to health. It has made a case of the need for sound regime for the practice of traditional medicine in Kenya. The next chapter shall embark on Kenya's response to WHO global strategy and plan of action on public health, innovation and intellectual property. It will highlight lapses in the legal framework that hinders full attainment of the right to health.

CHAPTER FOUR

4 GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY

4.1 INTRODUCTION

This Chapter will discuss various components of global strategy and plan of action on public health, innovation and intellectual property advanced by the WHO to promote, *interalia*, attainment of the right to health. It will discuss a plethora of legislative measures formulated by the government in response to various plan of action of diverse elements of global strategy discussed to facilitate effective right to health realization. It also highlight how some of the legislative interventions by the government has created monopolies in supply of medicine which will stifled access to medicines in terms of affordability by majority of Kenyans.

The global strategy on public health, innovation and intellectual property aims to promote new thinking on innovation and access to medicines and, based on the recommendations of the report of the Commission on Intellectual Property Rights, Innovation and Public Health, provide a medium-term framework for securing an enhanced and sustainable basis for needs-driven essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area[133].

The elements discussed in this chapter will go towards promoting access to medicines and by extension promote right to health realization.

[133] https://www.who.int/phi/implementation/phi_globstat_action/en/ accessed on 6 April 2020.

4.2 The elements of the global strategy

According to the WHO, there are eight elements of the global strategy which are designed to promote innovation, build capacity, improve access and mobilize resources. First, prioritizing research and development needs.[134]

Second, promoting research and development. Third, building and improving innovative capacity. Fourth, transfer of technology. Fifth, application and management of intellectual property to contribute to innovation and promote public health. Sixth, improving delivery and access. Seventh, promoting sustainable financing mechanisms. Lastly, establishing and monitoring reporting systems.[135]

4.2.1 Element 1. Prioritizing research and development needs

WHO has proposed a number of actions to be taken to actualize prioritizing research and development needs? These include: mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries, formulating explicit prioritized strategies for research and development at country and regional and interregional levels and encouraging research and development in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples.

As illustrated earlier in Chapter 3, Kenya has formulated a raft of legislations to encourage research and development in traditional medicine but there are still numerous loose ends as highlighted earlier that impedes success in that area.

The CoK 2010 makes an indirect recognition of traditional knowledge. A thorough legislative enactment is needed to align the country with the recommended action to actualize research and development needs.

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[134] Ibid.
[135] Ibid.

Research priorities in traditional medicines have not been set in Kenya.

4.2.2 Element 2. Promoting research and development

The actions to be taken for promoting research and development include: support for national health research program development and improvement, as well as the establishment of strategic research networks when appropriate, in order for players in this field to work together more effectively; assisting poor countries in their research and product development efforts; promoting health and biomedical research and development cooperation, involvement, and coordination; fostering increased access to knowledge and technologies necessary to satisfy public health demands of emerging nations and developing and enhancing national and regional coordinating entities on research and development.

Greater access to knowledge technology entails promotion of the Creating and developing public health libraries in underdeveloped nations so as to increase the availability and utilization of relevant publications by universities, institutes, and technical centers.

Article 11(2) (b) of the CoK obligates the state to recognize the role of science and indigenous technologies in the development of the nation.

Article 11(3) of the CoK obligates the legislature to enact legislation to achieve twin objectives. First, is to make sure that communities receive compensation or royalties for the use of their cultures and cultural heritage. Second, to recognise and protect the ownership of indigenous seeds and plant varieties, their genetic and diverse characteristics and their use by the communities of Kenya.

To this end and flowing from the above, Kenya has enacted Science, Technology and Innovation Act[136]. This law facilitates the promotion, co-ordination and regulation of the

[136] Science, Technology and Innovation Act, Act No. 28 of 2013, Laws of Kenya.

progress of science, technology and innovation of the country; to assign priority to the development of science, technology and innovation; to entrench science, technology and innovation into the national production system and for connected purposes.

Under this Act, it is now open for any person to establish a research institution. All one needs under section 17 is to apply for a licence from the Nation Commission on Science, Technology and Innovation.

The Act focuses much on research institutes and does not even give attention to institution of higher learning such as universities as centres of innovation and research. Whereas a National Research Fund is established source of funding is, *interalia*, a sum of money amounting to two per cent of the country's gross domestic product. This is negligible. A country that values science and research to promote health should increase funding.

The Act also does not provide for funding of innovators and researchers in private or public universities.

In the year 2019 Cabinet Secretary for the Ministry of Information, Communications and Technology (ICT) announced that the government would support innovations through funding.

> "…Mr. Mucheru said the government would support the innovations by funding the developments and facilitating in commercialization.
> The Cabinet Secretary, who made the remarks at the University of Nairobi today when he presided over the Nairobi Innovation Week, said that the Ministry of ICT has established the white box where innovators can deposit their innovation. He said if it is establishes that the innovative ideas were viable and could be adopted by government to facilitate deliverable of services, the government will protect and fund the innovation…"[137]

[137] https://ict.go.ke/about-the-ministry/, accessed on 13 April 2020.

Proper and sustainable funding of innovators required a proper legal framework. Depositing innovation in a whitebox does not properly safeguard the rights of innovators. It does not protect innovation as well from theft. There are two main financial instruments for financing innovations. First, private funding of innovative firms through retained earnings, microcredit, crowdfunding, angel investors, value chain investment, stock markets, loan from commercial banks etc[138].

The next financial instrument for innovation is direct public funding. Direct public funding of Science, Technology and Innovation (STI) and Research and Development (R &D) is a common policy aimed at improving the innovation performance of firms, industries and national economy.[139] Technology or Innovation Funds are major instruments for the public funding of innovation. This one has been provided for under the Science, Technology and Innovation Act but with no elaborate mechanisms to fund innovators. Public (government) credit guarantees can also be used to facilitate access to external funding, especially for SMEs. This will offset reluctance by banks to loan Small- and medium-sized enterprises (SMEs). This one has not been legislated upon by the government of Kenya. Other instruments are repayable grants, subsidized credits and see financing.[140] The government of Ireland issues innovation vouchers for those who develop a new product and to support innovations.[141] This can be innovation in any area including area of medicine that by extension will promote right to health.

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[138] https://unctad.org/en/PublicationsLibrary/dtlstictinf2019d2_en.pdf, accessed on 13 April 2020.
Crowdfunding is a recent phenomenon that is emerging in some developed countries as a means of accessing early-stage financing. It operates by using the Internet to link investors with enterprises searching for investment financing. Retained earnings is the surplus after profits are distributed. Angel Investors are wealthy individuals, often with entrepreneurial experience, who invest in small companies in these early stages. In addition to finance they usually provide technical, managerial and business expertise and networking service. Venture capital (VC) financing happens when an entity called a venture capital fund acquires an ownership stake by direct investment in emerging firms and outside the capital market.2 VC typically invests for relatively long periods during the early growth stages of firm development and after angel have already invested.

[139] Ibid.

[140] Ibid.

[141] https://www.enterprise-ireland.com/en/Research-Innovation/Companies/Collaborate-with-companies-research-institutes/Innovation-Voucher.shortcut.html, accessed on 13 April 2020. The Innovation Voucher initiative was developed to build links between Ireland's public knowledge providers (i.e. higher education institutes, public research bodies) and small businesses. Innovation Vouchers worth €5,000 are available to assist a company or companies to explore a business opportunity or problem with a registered knowledge provider.

The Science, Technology and Innovation Act is silent on an action needed to promote research and development that entails support the creation of voluntary open databases and compound libraries, including voluntary provision of access to drug leads identified through the screening of such compound libraries. No such libraries is established under the Act in line with WHO recommendation.

4.2.3 Elements 3 & 6: Building and improving innovative capacity & Improving delivery and Access

Under these two elements, there are similar plans of action. Issues of good manufacturing practices and clinical trials apply to both elements. That is why this study has considered discussing them together. This study shall start with element 3.

The strategy here entails framing, developing and supporting efficient policies which promotes the development of capacities in underdeveloped countries associated with health innovation.

Key areas for investment are capacities relating to science and technology, local production of pharmaceuticals, clinical trials, regulation, intellectual property and traditional medicine.[142]

South Africa as a way of recognizing traditional medicine as a means of facilitating right to health enacted Traditional Health Practitioners Act (the South Africa Act).[143] Many prefer traditional health practice as opposed to conventional health practice because it is generally affordable and has therapeutic qualities. The South Africa Act gives formal recognition to traditional practitioners and establishes Traditional Healers Practitioner's Council of South Africa with wide powers to ensure that health care services are efficient, safe and of a high quality.

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[142] Ibid.

[143] https://www.researchgate.net/publication/228265738_Institutionalisation_of_African_Traditional_Medicine_in_South_Africa_Healing_Powers_of_the_Law, accessed 14 April 2020.

If Kenya can enact such legislation as in South Africa, the same can provide for model code of ethics for traditional health practitioners, training centres, funding of those pursuing that line of study, disciplinary organ/council governing licensing procedures and conduct of practice of traditional health practitioners.

As response to this element of the global strategy by the WHO, in 2014, The Traditional Health Practitioners Bill, 2014 was formulated to be introduced in Parliament with a view to have it enacted. The passage of Health Act attempted to incorporate traditional medicine into the conventional health care system but leave out crucial issues that can only be provided for by an independent law similar to the one that has been enacted in South Africa.

The Bill seeks to establish the Traditional Health Practitioner Council of Kenya with powers to , *interalia*, approve institutions other than those established or accredited under the Universities Act,2013 for the training of traditional health healers and to establish, approve and accredit programs for continuing professional educational programs, to publish in the Kenya Gazette the names of all registered traditional healers every calendar year and more significantly to enhance traditional health practices that adhere to universally accepted health care standards and values with the goal of improving patients' and the general public's quality of life.

Regulation of practice of traditional medicine would demystify traditional healing. It will also provide protection for the practitioners and their patients. It would also ensure that traditional medicine is subjected to the same rigorous testing, standards as allopathic medicines so as to make it safer.

Despite the significant role of traditional practitioners, there is little discussion or debate about integrating them in the country's healthcare system. The deafening silence is curious given the enactment of the Health Act in 2017 that opened the door to the integration of traditional medicine into the healthcare system. While the Health Act requires the Ministry of Health to set procedures

for patient referrals between conventional and complementary healthcare practitioners and directs Parliament to establish a regulatory body to oversee the practice of complementary medicine, little progress has been made to date.

The Health Act lays a critical road map and foundation for recognition and enactment of a law to govern conduct of practice of traditional medicine in Kenya. For example, it defines “alternative medicine” means complementary medicine and includes a broad set of health care practices that are not part of Kenya's tradition and are not integrated into dominant health care system. This can be understood as traditional medicine.

Section 74 of the Health Act mandates the national government department of health shall formulate policies to guide the practice of traditional and alternative medicine. It also mandates the county executive department for health to ensure implementation of any policies thereto.

Section 75 of the Health Act envisages mandatory establishment of a regulatory body by an Act of Parliament, to regulate the practice of traditional medicine and alternative medicine and knowledge on which it is based. It requires the regulatory agency to keep a registry on a national and county level at the time of implementation. It requires that the regulating authority, in cooperation with the National government's department of health, establish the minimum standards of practice for traditional medicine and complementary and alternative medicine practitioners. It obligates the regulatory body in mandatory terms to be responsible to register, licence and ensure there is standards compliance of practice in traditional and alternative medicine.

How the country appears to have gone into a lull over this crucial issue remains an enduring legal conundrum.

The Bill is substantially similar to South Africa’s law save that the latter provides for an investigating officer to investigate complaints under the act with powers, under the approval of the Council, to enter and search premises of business other than dwelling premises and report to the Registrar who will in turn report to the Council for further action.

The other key sub-element of building and improving innovative capacity is local production of pharmaceuticals.

Kenya introduced the Kenya National Drug Policy in 1994. It was hardly implemented due to lack of an enabling legislative and institutional framework.

The second edition which forms the basis of Sessional Paper No.4 of 2012 on Kenya National Pharmaceutical Policy (KNPP) is an integral part of Kenya Health Policy 2012-2030 that endeavors to advance universal access of essential medicines by promoting local production and Vision 2030, the long term development plan for Kenya.[144]

The Pharmacy and Poisons Board (PPB) which is established under the Pharmacy and Poisons Act[145] is the regulatory body for the pharmaceutical sector in Kenya. It licenses persons to manufacture medicinal substances and also to ensure there is compliance with good manufacturing practice. The Act also establishes the National Drug Quality Control Laboratory used, *interalia*, as a facility for testing, at the request of the Board and on behalf of the Government, of locally manufactured and imported drugs or medicinal substances with a view to determining whether such drugs or medicinal substances comply with the requirements under the Act or existing rules.

The PPB is also tasked to perform regular inspections of local and foreign pharmaceutical manufacturers to ensure compliance with Current Good Manufacturing Practices (cGMP) standard that govern pharmaceutical production.

There is however a challenge in the prices of the locally produced pharmaceutical products. The prices are still high. Local pharmaceutical production was disadvantaged due to importation of

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[144] Vugigi, S,'Assessment of The Pharmaceutical Manufacturing Industry In Kenya to Forecast Local Production Sufficiency' unpublished M.PHARM thesis, University of Nairobi, (2013).
[145] Pharmacy and Poisons Act, Chapter 244, Laws of Kenya.

most pharmaceutical inputs and the small production capacity[146]. A report titled 'Why manufacturers exit Kenya' stated that the high cost of manufacturing locally and bureaucracy were among the causative factors for relocation of multinationals.[147] There is need for the government to consider lowering taxation charges for the pharmaceutical inputs imported to facilitated local manufacturing. This will lower the costs of medicine and increase access to essential medicines by Kenyans.

Section 19 of the Pharmacy and Poison Act that outlines general restrictions to unregistered persons is a controversial provision. Section 19(5) allows any person to sell non-poisonous drugs as long as such drug is sold in its original condition as received by the seller or to require such person to be registered as a pharmacist. This provision appears to give a window of opportunity to owners of shops, kiosks and other street vendors to sell drugs and medicines. The act however categorically and in mandatory terms bars persons other than those authorized to import, possess, distribute, sell or purchase part I poisons under the Act from importing, possessing, distributing, selling or purchasing any drug.

Greater access to medicines to enhance right to health realization can be attained if pricing of drugs are checked to avert going beyond the reach of many Kenyans. "While there is much focus and control of drugs' entry and distribution in Kenya, healthcare providers are left free to establish their own prices.

There are no requirements for in-service training and refresher training in order to update the skills of pharmacists. This goes against the spirit of the law that is to control the profession of pharmacy and trade in drugs.

The pharmacy and poisons board is empowered to issue and renew licenses every year to, *interalia*, those who sell part II poisons, those who manufacture medicinal substances, dealers of part I poisons. An amendment to the Pharmacy and Poisons Act was made in the year 2019

[146] Supra Note 119. P105.
[147] Ibid.

for re-licensure every year to be subject to a pharmacist or pharmaceutical technologist undertaking appropriate continuous professional development program (CPD) as prescribed by the board.

The board has not made regulations governing such continuous professional development programs yet. In jurisdiction like United States of America, Continuing pharmacy education (CPE) an equivalent of CPD has served as the standard for maintaining professional competence and health of patients for many years. Pharmacy knowledge of most practitioners may not be up-to-date due to lack of a legal requirement for continuous updating and maintaining professional knowledge and skills.

An organized educational activity shall "support the continuing development of pharmacists, pharmacy technicians or technologists in order to improve and maintain their competence. With the advent of new ailments, a practitioner may easily become confined in their application of new diagnostic and treatment procedures and revert to outdated medical technologies, resulting in errors and risking patient health. The Pharmacy and Poisons Board hence have to formulate regulations for evidence of continuous training as a requirement for pharmacist re-licensure every year as required now under section 9F of the Pharmacy and Poisons Act.

Several countries including Australia, Canada, New Zealand, and the United Kingdom have incorporated the Continuous Professional Development (CPD) approach as a requirement for pharmacist re-licensure.[148]

Practice in pharmacy in Kenya appears to be treated as a non-medical service. However, the role of pharmacists in diagnosing and prescribing treatment appears to be rising rapidly[149]. Pharmacists are providing both health consultation and advise to patients[150]. It is unclear from

[148] Tran et al, *" US and international health professions' requirements for continuing professional development*" *Am J Pharm Educ*. 2014;78(6) Article 129
[149] Muthaka David I. et al, "A review of the Regulatory Framework for Healthcare Services in Kenya", KIPPRA Discussion Paper No. 35 of 2004"
[150] Ibid.

a legal standpoint if they are permitted to participate in clinical practices. To ensure the safety of patients and their health, the legal void regarding the duty of consulting pharmacists should be filled.

Another hazard to consumers of medicinal drugs in the medical practice is an amendment to the Pharmacy and Poisons Act that creates a new phenomenon known as pharmaceutical technologists. They are equivalent of clinical officers registered under the Ministry of Health. The Pharmacy and Poisons Board has only formulated guidelines for evaluation and assessment for enrolment as a pharmaceutical technologist in the year 2013 but there are currently no rules governing this practice, despite the fact that pharmacists employ these technicians and even operate independent pharmacies and chemists. Without clear regulations governing this industry, consumers are exposed to danger due to negligence and misconduct on the part of these healthcare providers. This hampers realization to right to health.

The recent changes in the law puts diploma and degree in pharmacy at the same level of recognition since pharmacists and pharmaceutical technologists are now registered under one role and that has sparked fury from the Pharmaceutical Society of Kenya (PSK). Such amendments with no clarity on the role of the technologists may expose consumers of drugs and medicinal substances. PSK argues that such legislative changes also the entrance level of pharmacy practice in Kenya has been lowered to diploma level, as has the greatest sense of responsibility in pharmaceutical care.

The strategy under element 6 envisages that the strengthening and backing for health systems is critical to the strategy's success, as is competition stimulation and the adoption of appropriate pricing and tax policies for health products. Mechanisms that monitor the safety, quality, and efficacy of medications and other health goods, as well as adherence to good manufacturing practices and effective supply chain management, are essential components of a well-functioning health system.

Some of the plan of action is to support the use of pooled procurement arrangements for health products and medical devices.

The government under the KEMSA Act[151] has bestowed KEMSA with power to enter into partnership with or establish frameworks with County Governments for purposes of providing services in procurement, warehousing, distributing of drugs and medical supplies.

KEMSA Act vide an amendment contained in the Health Laws (Amendment) Act now makes it mandatory for national and county public hospitals to obtain drugs and medical equipment from KEMSA. The monopoly of supply created by this law will eliminate competition and will even make prices expensive affecting access to drugs and endangering right to health. Council of Governors (CoG) have challenged this law in Court. The CoG is concerned that KEMSA has been jeopardizing health services at the grassroots due to delays or failure to deliver drugs and equipment[152]. This undermines the NDP of 1994 that advocates for pricing policies that improves access to essential medicine.

COG also argues that the provision of the law is a threat to independence of the County Governments and by extension a threat to devolution.

This provision also hampers WHO's strategy to promote pharmaceutical production since the market of supply of many pharmaceutical suppliers is limited since 47 County Governments are barred from sourcing drugs competitively.

Section 4(3) of the KEMSA Act vide the said amendment contained in the Health Laws (Amendment) Act[153] assented to on 13th May, 2019 makes drugs and medical supplies procured and distributed should the standards of quality and are efficacious as authorized by the board.

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[151] Supra Note 14.
[152] https://www.nation.co.ke/news/3-NGOs-join-Kemsa-monopoly-case/1056-5484476-w0i4tb/index.html, accessed on 19 April 2020.
[153] Health Laws (Amendment) Act, Act No. 9 of 2019, Laws of Kenya.

Section 4(4) of the KEMSA Act that provides for a penalty for contravention of section 4(3) states that a convict will be liable to a fine not exceeding Two Million shillings or imprisonment for a term not exceeding five years. This does not deter an unscrupulous supplier from engaging in procurement and supply of poor quality drugs and simply paying a minimal fine. The word liable means that the judicial officer has discretion to give non-custodial sentence and to even impose a low fine. This poses serious threat to right to health of consumers of such poor quality drugs.

Another plan of action is establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices. This is expected to be accomplished by *,interalia,* promoting ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines and supporting regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for evaluation and approval of medicines.

Courtesy of the this strategy and plan of action, an amendment has now been made by introducing section 3B after section 3 of the Pharmacy and Poisons Act that authorizes the Pharmacy and Poisons Board to grant or withdraw authorization for conducting clinical trials of medical products. It gives it the authority to approve the use of an unregistered medicinal substance for the purposes of clinical trials. It gives it the authority to approve and regulate clinical trials involving medicinal substances.

Section 25A bars pharmaceutical products from clinical trials unless the boards approve it with the approval of the relevant ethics body. Once is expected to present a study protocol and a robust quality assurance system to ensure that the clinical trial is carried out to ensure the integrity of data generated, the safety and well-being of study participants. This is a good entry point for clinical trials that promote right to health.

Robust clinical trials guidelines should be put in place to ensure that Kenyans do not risk being used as guinea pigs in the testing of unproved drugs of local and foreign origin. United Kingdom has put in place comprehensive clinical Trial Regulation. There is Clinical Trials Information System (CTIS) that contains centralized European Union (EU) portal and database for clinical trials[154]. There is no such provision in the Pharmacy and Poisons Act in Kenya and there is risk of duplication of clinical trials or repetition of unsuccessful trials.

4.2.4 Element 7: promoting sustainable financing mechanisms

WHO acknowledges under this element that donors have supplied significant additional funding to make health items available in poor nations through innovative financing structure. The report also notes the fact that additional funding has been gained for research and development activities that are relevant to the control of illnesses covered by the global plan. WHO is working towards identifying and analyzing the most serious gaps in financing for health products and research and development covered by the global strategy.

WHO recommends two major actions to be taken to promote sustainable financing mechanisms. First, endeavoring to secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries.

The first mechanism is expected to be achieved by establishing a results-oriented and time-limited expert working group under the auspices of WHO and linking up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate research and development related to Type II and Type III diseases and the specific research and

[154] https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation, accessed 19 April 2020

development needs of developing countries in relation to Type I diseases[155]. The other major action is to consider channeling additional funds to health-oriented research organizations, as appropriate, in both the private and public sector of developing countries and promote good financial management to maximize its effectiveness, as recommended by resolution WHA58.34. Lastly is to create a database of possible sources of financing for research and development.

The second major action is making the best use of, and supplementing as necessary, existing financing, including that provided through public–private and product development partnerships, in order to develop and deliver safe, effective, and affordable health products and medical devices, by documenting and disseminating best practices from public–private and product development partnerships; developing methods for evaluating the efficacy of public–private and product development partnerships on a periodic basis; promoting public–private and product development collaborations, as well as other acceptable research and development projects in underdeveloped nations.

It is thus clear that while the WHO elements of strategy has guided Kenyan government and has resulted in making the necessary legislative measures by way of amendments and enacting new legislations in order to improve the right to health, there is still a raft of legislative measures, interventions and amendments to facilitate full realization of this right which is an integral component of social and economic rights as enshrined in the Constitution of Kenya.

[155] https://www.who.int/phi/3-background_cewg_agenda_item5_disease_types_final.pdf, accessed 18 April 2020. Type I diseases are incident in both rich and poor countries, with large numbers of vulnerable populations in each. Cancer is an example. Type II diseases are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. Tuberculosis and AIDs are examples. Type III diseases are those that are overwhelmingly or exclusively incident in developing countries. Examples are infectious tropical diseases eg malaria.

4.3 Conclusion

This Chapter has highlighted various elements of strategy under WHO global strategy and plan of action on public health, innovation and intellectual property. It highlights various legislations and legislative amendments that have been enacted by the government of Kenya in response to the global movement. It pointed out with precision how despite traditional medicine being promoted, the government has not enacted a comprehensive law governing the practice of traditional medicine. It also pointed out how measures like directing county governments under KEMSA Act will create a monopoly of supply of drugs hence eliminate competition and will even make prices expensive affecting access to drugs and endangering right to health. The study therefore answers the question about the efficacy of the legislative measures that have been put in place by Kenya in response to the global strategy spearheaded by WHO. The lapses shall be addressed in the next chapter and recommendation on the way forward given.

CHAPTER FIVE

5 FINDINGS AND RECOMMENDATIONS

5.1 INTRODUCTION

This is the final chapter of this study. It gives summary of the study and recommendations for both policy and legislative reforms that can promote access to medicines and realization of the right to health.

5.2 FINDINGS

Chapter 2 has given a brief outline of how the right to health evolved in Kenya, the role of state in promoting right to health. It laid down the normative content of the right to health and highlighted domestic, regional and international instruments that form the legal framework for the establishment and advancement of access to medicines and thus promote right to health. It found that there are a number of legislations meant to promote attainment of right to health but have weaknesses that hampers realization of the right to health.

Chapter 3 found that whereas the government has put in place health policy framework and enacted a raft of legislations and measures in line with the various elements of the global strategies propagated by the WHO as well as to align them to international standards in realization of the right to health, there are several lapses in numerous post 2010 legislations that will curtail full realization of the right to health aforesaid.

Chapter 4 discussed the place of traditional knowledge in our legal system, significance of complete mainstreaming of the traditional knowledge based medicine in the legal system, the effects of non-protection of traditional knowledge and made a case for regulation of the practice of traditional medicine and knowledge. It found that *sui generis* system of protection is not efficient way to protect traditional knowledge on which it is based in Kenya. It found that there is no sound and comprehensive legislation in Kenya that regulate the practice of traditional medicine and knowledge on which it is based which would otherwise ensure there is proper safeguards of majority of the vulnerable and marginalized section of the society that depends

on traditional medicine. It found that there are lapses in the legal framework that is an impediment to realization of the right to health. The study found that there are sound policies already in place that can promote access to medicine like NDP of 1994 that was to, *interalia*, address price of drugs and that calls for protection of traditional medicine but poor adoption and lack of implementation of the same hampers access to medicine and right to health.

The study found that Kenya Health Policy 2014-2030 recommends making of more policies like Public Private Partnership Policy without sound adoption and implementation of the said policy and others. It is therefore the finding of this study that the problem in terms of policy in this country is not shortage of the same but adoption and implementation.

5.3 RECOMMENDATIONS

It is against the backdrop of the critical analysis and scrutiny of the Kenya's policy and legislative framework of facilitating realization of the right to health, utilization of traditional medicine to promote right to health and global strategy and plan of action on public health, innovation and intellectual property that the study recommends the following:

1. The definition of traditional knowledge that includes medical knowledge is scattered in different legislations. A comprehensive independent law that promotes the practice of traditional knowledge in Kenya should be enacted that should provide for, *interalia*, a regulatory body, registration of traditional medicine practitioners, disciplinary mechanisms, quality control of traditional medicine, mechanisms of mass generation of medicines extracted from the medicinal plants for it to be sustainable.

2. There are progressive policies that promote access to medicines and that promote equity in healthcare delivery services for example NDP on need to make drugs affordable as well encourage local production of medicine through tax remissions. This study recommends sound adoption of the existing policies

3. Some policies like Kenya Health Policy 2014-2030 recommends making of more

policies like Public Private Partnership Policy. Policies however flowery provisions they contain without sound legislative interventions and/or framework and without being adopted shall remain a mirage in realization of access to affordable medicine and realization of the right to health. It is the recommendation of this study that the state should focus on sound regulatory framework to improve access to medicines by Kenyans and equity in healthcare service delivery. The state should also focus on sound adoption of the existing policies to enhance equity in healthcare service delivery and to promote access to medicines.

4. In terms of gaps within the existing legal framework that prevents medicines and drugs from meeting the "AAAQ" framework and gaps which stifle access to medicines, this study proposes amendments of provisions of various legislations as captured in the paragraphs below.

5. It is recommended that Section 74 of the Health Act that provides that the national government department of health shall formulate policies to guide the practise of traditional and alternative medicine should amended by deleting the same and a watertight framework be provided for in the comprehensive statute that is recommended to be enacted.

6. The controversial provision, being section 19(5) of the Pharmacy and Poisons Act, that gives a window of opportunity to owners of shops, kiosks and other street vendors to sell drugs and medicines should be amended to avoid watering down the provision of section 19 (1) of the Act which prohibits any person apart from a registered pharmacist to carry on, either on his own behalf, or on behalf of another, the business of a pharmacist and in the course of business , prepare, mix, compound or dispense any drug.

7. In order to encourage pharmaceutical production in Kenya and to ensure affordability of drugs and access by majority of Kenyans the Cabinet Secretary can consider as a way of legislative measures to reduce taxes for imported pharmaceutical inputs so as to reduce the costs of production and ultimate prices of

drugs.

8. Section 25A of the Pharmacy and Poisons Act should be amended to provide for the establishment of the Clinical Trials Information System in Kenya that contains centralized portal and database for clinical trials in different counties to avoid duplication and unsuccessful repetition of clinical trials just like it is in the European Union. Successful clinical trials will enhance right to health.

9. The Health Act should be amended to give a provision for a comprehensive compulsory health insurance scheme for every citizen including the unemployed, the elderly, children, persons with disabilities and other vulnerable, disadvantaged and marginalized individuals and groups.

10. Section 19(2) of the HIV and AIDS Prevention and Control Act of Act that provides for the access to health care services including access to essential medicines at affordable prices by persons with HIV or AIDS and those exposed to the risk of HIV infection should be amended to expressly exclude generic drugs from counterfeit goods.

11. Section 4 of The Cancer Prevention and Control Act should be modified to empower the National Cancer Institute of Kenya to make annual disbursements to cancer centres in all the 47 counties to subsidize charges and treatment costs for the cancer patients.

12. The Cancer Prevention and Control Act should be amended to widen the powers of the National Cancer Institute of Kenya to facilitate training of cancer experts by way of rolling out an ambitious scholarship programme to aspiring doctors so that we have enough human resource in future to work on the cancer centres. The Act should also be amended to make a provision for registering cancer foundations which will source funds from donors to widen access to cancer facilities by patients.

13. Section 15 (1) (d) of the Cancer Prevention and Control Act that identifies one source of the funds for the National Cancer Institute as discretional appropriation

by parliament should be amended by replacing the word "may" with the word "shall" and specifying a minimum amount to be annually allocated being at least 3% (three percentum) of all the country's gross domestic product. I have borrowed this formulae from the one that has been adopted under National Government Constituencies Development Act. The Science, Technology and Innovation Act as well provides for a sum of money amounting to two per cent of the country's gross domestic product. An allocation should even be more than this since the mandate of the national government is limited to the development of national health policy and the administration of national referral hospital while it still maintain a relatively bloated budget compared to what is allocated to the County Governments.

14. Regulations on parallel importation and control of illegal trade in pharmaceuticals through the process of drug registration, inspectorate powers, post market surveillance and publishing medicines information to the public so as to maintain affordable prices and/or to encourage competition hence competitive prices should be enacted under the Pharmacy and Poisons Act to give a framework that will allow the importation on a wider scale to serve the needs of many potential users and to facilitate the protection of right to health.

15. The penalty provision under section 16(2) of the Radiation Protection Act that provides that a person who contravenes any of the provision of the Act relating to or in connection with the importation, possession, transportation, use or disposal of irradiating devices, radioactive materials or any other sources of ionizing radiation without being in possession of a valid licence shall be guilty of an offence and shall be liable to imprisonment for a maximum term of two years should be amended and enhanced to a period of 10 years.

16. The penalty for a person who obstructs the Chief Radiation Protection Officer from confiscating radioactive materials is a fine of Kenya Shillings Twenty Thousand only (Kshs. 20,000/=) or imprisonment for a term not exceeding one year or both under Section 16(1) (a) of the Radiation Protection Act. This provision should be

enhanced to a sum of Kenya Shillings Five Hundred Thousand (Kshs. 500,000) to make it deterrent.

17. The Public Health Act should be amended so that the Central Board of Health which advise the Minister on matters revolving around the public health and other incidental activities which currently has its seat in Nairobi only can also have presence in all the 47 counties.

18. Environmental Management and Co-Ordination (Conservation Of Biological Diversity And Resources, Access To Genetic Resources And Benefit Sharing) Regulations, 2006 should be amended by enhancing penalty for contravention of the guidelines to a minimum period of 18 months and a minimum fine Kenya Shillings Three Hundred and Fifty Thousand (Kshs 350,000) to deter persons from exploiting genetic resource for economic value to the detriment of locals.

19. Section 8 of the Protection of Traditional Knowledge and Cultural Expressions Act that mandates County Government to establish and maintain a register which shall contain information relating to traditional knowledge collected and to document the same during the registration process should be amended to specify what happens if County Governments do not establish or maintain registers carrying data on traditional knowledge. It should also be amended to provide time frames within which such registers are to be established.

20. The penalty provisions under Section 37(1)(f) of the Protection of Traditional Knowledge and Cultural Expressions Act imposed on, *interalia*, any person who develops any goods or service using unauthorized traditional knowledge or cultural expressions in the course of trade is not deterrent enough, a wide discretion given to judicial officers can easily be abused. I propose that the same be enhanced to protect the rights of members of the communities with such knowledge.

21. Science, Technology and Innovation Act should be amended to give attention to institution of higher learning such as universities as centres of innovation and

research. It should also be amended to include provision for funding of innovators and researchers.

22. Section 4(4) of the KEMSA Act that provides for a penalty for contravention of section 4(3) as being liable to a fine not exceeding Two Million shillings or imprisonment for a term not exceeding five years should be amended by enhancing the sentence to deter unscrupulous suppliers from engaging in procurement and supply of poor-quality drugs and getting away by paying nominal fine at the expense of jealously safeguarding sacrosanct right to health.

23. Kenya should comprehensively internalize the WHO global strategy and plan of action on public health, innovation and intellectual property and develop sound policies and legislations that are in sync with the various elements of strategy and plan of action to facilitate better realization of the right to health.

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