International Human Rights and Access to Medicines

A Thesis Submitted for the Degree of Doctor of Philosophy

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Abstract

The issue of access to medicines has been widely discussed under the international human rights law regarding patients without medicines. Through critical analysis of relevant documentary material of the international human rights law, this thesis examines the status of access to medicines as a human right. To explore the status of access to medicines as a human right, this study examines the available sources of international human rights law. Benefiting from the indivisibility of human rights, the study presents the scope of interpreting access to medicines as a human right under the right to life and health. The thesis argues for the status of access to medicines as a human right instead of considering it a mere ethical or moral demand.

The recent outbreak of Coronavirus (COVID-19) pandemic is not only a test for human advancement in medical sciences but is also a reality-check for human rights in general and access to medicines in particular. The study systematically argues that treating the issue of access to medicines as an ethical or moral demand, instead of treating it as a human right, has affected the response to pandemics and epidemics. The Access to Medicines Index Report 2018 concludes that almost 2 billion people face several issues accessing the required medicines. The deprivation causes pain, fear, and violation of human right to life and health.

To establish access to medicines as a human right, it is imperative to develop the human rights framework for access to medicines under the international human rights law. The arguments will progressively analyse the status of access to medicines as a human right. For developing the human rights framework, the study will analyse the norm-creation process of the international human rights law, the status of access to medicines as a legal norm, the obligations of state parties, limitations to recognise and enforce access to medicines as a legal norm, and the ways to elevate the standing of access to medicines as a human right.

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Declaration

This thesis, submitted for the Degree of Doctor of Philosophy, is an original work of my own and has not been submitted before for any other degree.

This thesis is dedicated:

To that moment, a parent feels the agony of her sick child denied of medicines…

Acknowledgment

The doctoral research journey has been a unique quest in my life. During my time at Brunel University London, I have learned the art of perseverance, dedication, and refining an immature academic idea into a practical research project. Therefore, I acknowledge the contribution of Brunel University London towards my academic life. Moreover, I feel proud to complete this research with the help of the Punjab Higher Education Commission of Pakistan. I will always feel my honest gratitude for the commission throughout my life.

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List of Abbreviations

ACHPR	African Charter on Human and Peoples' Rights
ACHR	American Convention on Human Rights
ADRD	American Declaration on the Rights and Duties of Man
Berne Convention	Berne Convention for the Protection of Literary and Artistic Works
CESCR	Committee on Economic, Social and Cultural Rights
ESCR	Economic, Social, and Cultural Rights
CPR	Civil and Political Rights
CRC	Convention on the Rights of the Child
Doha Declaration	Doha Declaration on the TRIPS Agreement and Public Health
ECHR	European Convention on Human Rights (European Convention for the Protection of Human Rights and Fundamental Freedoms)
ECtHR	European Court of Human Rights
GA	UN General Assembly
GATT	General Agreement on Tariffs and Trade
HIF	Health Impact Fund
ICC	International Criminal Court
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICJ	International Court of Justice
ILC	International Law Commission
MDG	Millennium Development Goals
MPP	Medicines Patent Pool
Right to Health	Right of Everyone to the Enjoyment of the Highest Attainable

	Standard of Physical and Mental Health (Article 12 of ICESCR)
Right to Life	Every human being has the inherent right to life (Article 6 of ICCPR)
TB	Tuberculosis
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNSC	United Nations Security Council
VCLT	Vienna Convention on the Law of Treaties
WHA	World Health Assembly
WHO	World Health Organization
WTO	World Trade Organization

Chapter 1: Introduction and Methodology

1.1 Introduction

This study analyses the status of access to medicines under international human rights law. The debates on the issue of access to medicines often rely on treating access to medicines as a moral demand. On ethical grounds, the argument for human rights focuses on its broad natural law perspective. Amartya Sen notes, "Human rights can be seen as ethical demands… Like other ethical claims that demand acceptance, there is an implicit presumption in making a pronouncement on human rights that the underlying ethical claim will service open and informed scrutiny."[1] This approach remained pivotal to research conducted on the issue during the last two decades.[2] However, the recent outbreak of Coronavirus (COVID-19) as a pandemic[3] and anticipated vaccine calls for changing the perspective on the status of access to medicines. Recently, some experts suggested studying the issue of access to medicine as an international legal right with a positive law perspective.[4] Therefore, to contribute towards existing academic literature, this research will focus on identifying the prospects for the effective realisation of access to medicines as a human right.

Treating the issue of access to medicines as a moral or ethical demand has been less effective in solving this challenge. The Access to Medicines Index Report 2018 finds that almost 2 billion people around the globe cannot access the medicines they need.[5] During the year 2015, almost 5.9

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[1] Amartya Sen, 'Elements of a Theory of Human Rights' (2004) 32 (4) Philosophy & Public Affairs 315-356, 320. Stephan P. Marks, *Human Rights; A Brief Introduction* (Harvard University, 2016) 2

[2] Laurence Helfer, 'Human Rights and Intellectual Property: Conflict or Coexistence?' (2003) 5 (1) *Minnesota Intellectual Property Review* 47-61

[3] World Health Organisation (WHO), 'WHO Director-General's opening remarks at the media briefing on COVID-19' (11 March 2020) < https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020 > accessed 11 March 2020

[4] Ruth L. Okediji, 'Does Intellectual Property Need Human Rights?' (2018) 15 (1) *Journal of International Law and Politics* 2-62

[5] Access to Medicine Foundation, Access to Medicine Index 2018

million children died from preventable diseases around the world.[6] For instance, the antiretroviral drugs (ARVs), a treatment that helps to the HIV/AIDS infected people living their normal life, was introduced during the 90s. However, millions of people lose their lives for the want of availability, accessibility, and affordability of medicines for the treatment.[7] In this regard, the developing and less-developed countries spend almost 40 percent of their health spending on procuring medicines that cuts the overall efficiency of health care systems.[8] As highlighted from pandemics such as the COVID-19, HIV/AIDS, TB, and malaria, the issue of access to medicines significantly affects the right to health in general and the right to life in particular. One of the studies on the topic finds that the issue, "forces us to face the momentous suffering and loss of life that is occurring in developing countries due to HIV/AIDS, tuberculosis, malaria and other diseases as not just a tragedy; it forces us to recognise it as a horrific injustice".[9] A critical analysis of Access to medicines Index Report reveals that the issue of access to medicines is getting more serious.[10] Not only the issue of access to medicines is becoming earnest, but it is also becoming complex in its legal treatment. Many factors are affecting the issue of access to medicines in the world such as poverty, lack of scientific and technological progress, backward health care systems, patent monopolies of medicines, and not treating access to medicines as a human right.

Therefore, it is vital to examine the status of access to medicines under international human rights law. The elements of access to medicines-related human rights obligations can be deduced from a range of international legal documents and international customs as part of human rights. Access to medicine mainly stems from Article 25 of the Universal Declaration of Human Rights (UDHR). The text of the article states, "Everyone has the right to a standard of living adequate for the health

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[6] Report by UN Inter-Agency Group for Child Mortality Estimation, 'Levels and Trends in Child Mortality' (2015) < https://childmortality.org/files_v20/download/IGME%20Report%202015_9_3%20LR%20Web.p> accessed on 28 May 2019; Siva Thambisetty, 'Improving Access to Patented medicines: Are Human Rights Getting in the Way?' (2018) *LSE Law,* Society and Economy Working Papers *3/2018* 2

[7] Joint United Nations Program on HIV/AIDS (UNAIDS), 'Global Report: UNAIDS on the Global AIDS Epidemic (2013) 4-6; Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to medicines* (Ashgate, 2015) 121

[8] Ibid.

[9] Alicia Yamin, 'Not Just a Tragedy: Access to Medications as a Right under International Law' (2003) *Boston University International Law Journal* 325-71, 370

[10] Access to Medicine Foundation, Access to Medicine Index 2018

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."[11]However, the UDHR does not have binding force for being declaration but some authorities consider it part of customary international law for its a uniform practice accepted as law.[12] The access to medicine-related human rights obligations are included in various provisions of the International Bill of Rights. Access to medicines-related human rights obligations may mainly form part of the human right to health and in case of life-threatening diseases; it can be traced under the domain of the right to life.[13] Article 6(1) of ICCPR confers the right to life as an inherent right of everyone. The text of the article mentions, "Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life."[14] The right to life is the most fundamental of all human rights for the realisation of all other human rights. The Human Rights Committee (HRC) calls for wider interpretations of the right to life that includes access to medicines in pandemics, reducing infant mortality, and increasing life expectancy.[15] This may encompass the enforcement of access to medicines under the scope of the

[11] Universal Declaration of Human Rights (adopted 10 December 1948 UNGA Res 217 A(III) (UDHR) Article 25

[12] Ian Brownlie, *Principles of Public International Law* (Oxford University Press 2008) 559-560.

[13] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicine* (Oxford University Press, 2008) 116

[14] International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171, Article 2 (1)

[15] United Nations Human Rights Committee, General Comment No. 36 on Article 6 of the International Covenant on Civil and Political Rights – Right to life, para 26 "The duty to protect life also implies that States parties should take appropriate measures to address the general conditions in society that may give rise to direct threats to life or prevent individuals from enjoying their right to life with dignity. These general conditions may include … the prevalence of life threatening diseases, such as AIDS, tuberculosis or malaria, extensive substance abuse, widespread hunger and malnutrition and extreme poverty and homelessness. The measures called for addressing adequate conditions for protecting the right to life include, where necessary, measures designed to ensure access without delay by individuals to essential goods and services such as food, water, shelter, health-care, electricity and sanitation, and other measures designed to promote and facilitate adequate general conditions such as the bolstering of effective emergency health services, emergency response operations (including fire-fighters, ambulances and police forces) and social housing programs. States parties should also develop strategic plans for advancing the enjoyment of the right to life, which may comprise measures to fight the stigmatization associated with disabilities and diseases, including sexually transmitted diseases, which hamper access to medical care; detailed plans to promote education to non-violence; and campaigns for raising awareness of gender-based violence and harmful practices, and for improving access to medical examinations and treatments designed to reduce maternal and infant mortality. Furthermore, States

right to life. Creating the scope of enforcing access to medicines under the right to life can help solving the issue effectively and forming an international consensus. Apart from life-threatening diseases, access to medicines broadly falls under the Right to Health of the ICESCR, a binding international human rights document. The covenant obligates state parties to work individually and through international cooperation for realisation of rights mentioned under the covenant.[16] Access to medicine also forms a part of the human right to health under Article 12(1) of the ICESCR. The article mentions that:

"The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; (b) The improvement of all aspects of environmental and industrial hygiene; (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness."[17]

Likewise, Access to medicines related to human rights obligations may also find space under domain and scope of article 15 of the ICESCR that binds state parties to recognise the right of everyone to enjoy the benefits of scientific progress and its application. In this way, access to medicines may become part of enjoying the benefits of scientific progress. Apart from the International Bill of Rights, access to medicines related human rights obligations are found in various international and regional treaties.[18] Among fundamental characteristics of human rights is their invisibility. The thesis benefits from the idea of the indivisibility of human rights.

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parties should also develop, when necessary, contingency plans and disaster management plans designed to increase preparedness and address natural and man-made disasters, which may adversely affect enjoyment of the right to life, such as hurricanes, tsunamis, earthquakes, radio-active accidents and massive cyberattacks resulting in disruption of essential services."; UN Human Rights Committee (HRC), *CCPR General Comment No. 6: Article 6 (Right to Life)*, 30 April 1982 <https://www.refworld.org/docid/45388400a.html> accessed 16 September 2019; HRCee, General Comment No. 6. The Right to Life (Article 6 of the International Covenant on Civil and Political Rights) (UN Doc. HRC/GC/6; 1982) 5

[16] Holger Hestermeyer (n-13) 116

[17] International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, Article 16

[18] The European Convention on Human Rights (ECHR); African Charter on Human and Peoples' Rights American Declaration of the Rights and Duties of Man

For developing the arguments on substantial legal grounds, the issue of access to medicines can be argued from primary and secondary sources of international human rights laws. The constitution of the World Health Organisation (WHO) includes the right to health and access to medicine by mentioning, "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being".[19] The UN Development Group interprets access to medicine as "having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes of the population".[20] The Commission on Human Rights recognised the issue of access to medicine by adopting the resolution in 2001 stating that "access to medication in the context of pandemics such as HIV/AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health".[21] The Committee on Economic, Social, and Cultural Rights in General Comment No. 14 explained states' duties towards the right to health such as obligations to respect, protect, and fulfil towards realisation of the right to health and access to medicine. Moreover, the issue of the right to healthe has been scrutinised by most UN Special Rapporteurs on the right to health. Paul Hunt, one of the former UN Special Rapporteurs on the highest attainable standards of health, has criticised inequitable gap of access to medicine in various parts of the world. Paul Hunt has contributed both academically and internationally stressing states to optimise the realisation of the right to health using all necessary legislative and financial resources.[22] On the same issue of access to medicine, John Ruggie, the UN Special Representative of the Secretary-General further stresses the need of solving the issue of access to medicine stating, "Companies need to adopt a human rights policy. Broad aspirational language may be used to describe respect for human rights, but more detailed guidance in specific functional areas is necessary to give those commitments meaning."[23] It is evident from various empirical evidence that access to medicine is one of the primary elements for the realisation of the right to health guaranteed by various international

[19] Constitution Of The World Health Organization, Preemble.

[20] MDG Gap Task Force, Millennium Development Goal 8: Delivering on the Global Partnership for Achieving the Millennium Development Goals: MDG Gap Task Force Report 2008, (United Nations 2008) 35.

[21] Joo-young Lee, Paul Hunt, 'Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicine' (2012) *Journal of Law Medicine, and Ethics* 220-223

[22] Ibid.

[23] Ibid.

human rights instruments.[24] These multiple sources of conceptualising access to medicines related human rights obligations included in the primary and secondary sources of international human rights law make the research practical.

Recently, academic research has focused on developing the human rights framework for the issue of access to medicines. The literature does not deny the existence of the issue of access to medicines.[25] However, the focus remains on creating space for access to medicines as a concession from the patent protection of medicines.[26] In the same line of arguments, former UN Special Rapporteur on Right to Health suggests solutions in creating and enforcing human rights responsibilities of pharmaceutical companies towards access to medicines.[27] It has been found that bargaining the issue of access to medicines as a moral or ethical demand has not been effective.[28] Therefore, the researchers demand to develop a human rights framework for access to medicines as a legal right under the international human rights law.[29] The development of the human rights framework will strengthen the demand for access to medicines as an entitlement protected by the laws. Therefore, the discussion in this research will broaden the scope of the debate of access to medicines under international human rights law.

Therefore, the thesis aims at establising that access to medicines related to human rights obligations are entitlements included in the international human rights law as a matter of right, not as a mere ethical or moral demand. Moreover, the research embarks on developing a human rights framework for facilitating respect, promotion, and fulfilment of access to medicines related human

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[24] Ibid.

[25] Thomas Pogge, 'Montréal Statement on the Human Right to medicines' (2007) 16 *Cambridge Quarterly of Healthcare Ethics* 97–108.

[26] Duncan Mathews, 'The Right to Health and Patents' in C. Geiger (ed.) *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar Publishing, 2015) 496-512; Holger Hestermeyer (n-11) 288; Carlos M. Correa, 'Flexibilities provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights' (2018) 96 (3) *Bulletin World Health Organisation* 148; Ellen FM 't Hoen et, al. 'Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016' (2018) 96 Bulletin World Health Organisation *185-192*

[27] Joo-young Lee, Paul Hunt (n-21) 220-223

[28] Siva Thambisetty (n-6)

[29] Ruth L. Okediji (n-4) 2-62

rights obligations. The human rights approach for the issue of access to medicines can help to understand the domain of the issue of access to medicine by highlighting its status in the international human rights framework, introducing interpretative scope, and finding enforcement potentials.

1.2 The Research Question

The issue of access to medicines has been highlighted after the outbreak of the COVID-19, HIV/AIDS, Ebola, and other contagious diseases. The demand for access to medicines in the cases of pandemics and endemics has been treated as moral or ethical bias, and the approach has not been effective. Therefore, this study makes the case for access to medicines as a fundamental human right under the international human rights law. The development of the human rights framework for access to medicines will provide theoretical legal analysis for helping legislation, interpretation, and enforcement of access to medicines related human rights obligations. This study analyses the issue from a human rights perspective. Examining the issue from human rights is likely to help to evolve the status of access to medicines as a legal entitlement under the international human rights law.[30] The fundamental question in this research is:

Does international human rights law guarantee access to medicine as a human right?

To find the answer, the research will suggest studying the issue by examining the issue of access to medicines as a right under the international human rights law, hindrances in the way of achieving effective enforcement, and the ways of recognising it as a legal right. Moreover, it focuses on finding ways to uplift effective enforcement of access to medicines as a human right.

1.3 Research Methodology

The research uses the documentary and textual legal analysis to answer the research question. The study predominantly benefits from doctrinal and comparative research methods. Adopting the black letter approach will help to analyse and evaluate the scopes and issues related to the

[30] Susan K. Sell, 'Trips and the Access to medicines Campaign' (2002) 20 *Wisconsin Journal of International Law* 481-522, 482

realisation of access to medicines as a part of human rights under the international human rights law. Doctrinal legal analysis approach seems appropriate for the objective of the research to examine the status of access to medicines, nature of obligations, enforcement standards, issues in the way of implementation, and the ways for guaranteeing access to medicines as a part of human rights under the international human rights law in an efficient manner. For achieving the objective, the research will provide a systematic exposition of the rules relating access to medicines, analysing the relationship between access to medicines and the international human rights framework, and explaining how to raise the status of access to medicines as a legal entitlement.

This research explores the issue of access to medicines as an entitlement guaranteed by law as a positive right.[31] The legal positivist approach can help in understanding access to medicines as an entitlement stemming from the formal norm-creating process.[32] This can elevate human rights as enforceable and binding on national or international societies. The distinction between the positivist theory of rights and naturalist approach is that the former links law with the formal legal or political authority while the later may attributes itself to nature or divine.[33] Moreover, positivist rights are open to change, derogation, and flexibility, and natural rights are often interpreted as absolute, permanent, and inalienable rights.[34] The right of access to medicines may confirm with the positivist approach of defining human rights as it stems from an international legal authority and norm-creating process. The positivist approach accordingly helps in developing arguments for the positivist notion of access to medicines under the international human rights law.

As mentioned earlier, the research uses the textual analysis that is closely related to the doctrinal research method. The structure of doctrinal research mainly follows the two-stage process. In the first stage, it locates sources of law, and the second stage analyses and interprets the text of relevant laws. To find the answer to the primary question in this thesis, the researcher identifies laws

[31]Stephan P. Marks notes, "Legal positivists" regard human rights as resulting from a formal norm-creating process, by which we mean an authoritative formulation of the rules by which a society (national or international) is governed. While "natural rights" derive from natural order or divine origin, and are inalienable, immutable, and absolute, rights based on "positive law" are recognized through a political and legal process that results in a declaration, law, treaty, or other normative instrument". The research analyses the concept of access to medicines related human rights obligations as a positive right.

[32] Stephan P. Marks, *Human Rights; A Brief Introduction* (Harvard University, 2016) 2

[33] Ibid. 3

[34] Ibid.

relevant to establishing access to medicines as part of the international human rights law. This part will be expository that may form *lex lata* in its basic nature. In this regard, the International Bill of Rights is landmark development towards establishing a modern framework of the international human rights law. The bill stands as a universal manifestation of international human rights. Among the International Bill of Rights, the UDHR is a declaration with non-binding status. The declaration includes the right to life as well as health that may accommodate access to medicine as an integral part of both rights. Article 25 of the UDHR specifically focuses on access to medicine under the right to health. As mentioned in the introduction, the right of access to medicines may fall broadly under Article 12 of ICESCR. Moreover, in case of life-threatening diseases such as the COVID-19, HIV/AIDS, malaria, and tuberculosis, Article 6(1) of ICCPR may bear relevance in its role as a pivotal primary source of international human rights to solve the issue of access to medicines. In the second stage of the research, the study includes case laws that includes the trends of interpreting access to medicine under national laws and the international human rights. It will help to substantiate the status of the right to access to medicine at national and international judicial and quasi-judicial forums. Samuel explains the second stage in a question that 'Can legal reasoning be demystified?'[35] In the second stage, the arguments may be termed as *lex ferenda*. To substantiate the argument, the study interprets available international legal documents and available literature. This involves the interpretation of the law in a systematic way to find the answer to the question in the research. At this stage, interpretation of primary documents is presented coherently to substantiate arguments on the issue. Apart from interpreting available laws on the subject, this research will benefit from economic and financial studies presenting the empirical perspective to substantiate the argument of protecting access to medicines as a human right.

The study also uses comparative methods to analyse interpretation of access to medicines as a human right in developing and least-developed countries. The research benefits from case laws decided by the courts from Argentina, Brazil, Columbia, and other developing countries jurisdictions. This part will mainly aim at highlighting how courts, in different countries ,have relied on various provisions of the international human rights law mentioning access to medicines. This selection of the countries bases on the criteria that these countries are affected by the issue of access to medicine and are persistently quoted in literature on the subject. In this way, the research will establish consistency in interpreting access to medicines related human rights obligations under various provisions of human rights.

[35] Geoffrey Samuel, 'Can Legal Reasoning Be Demystified?' (2009) 29(2) *Legal Studies* 18; Terry Hutchinson, Nigel Duncan, 'Defining and Describing What We Do: Doctrinal Legal Research' (2012) 17 *Deakin Law Review* 110

The fundamental nature of research in law does not require the study of statistical data. One of the researchers notes that "[l]aw is not a datum; it is in constant evolution, developing in ways that are sometimes startling and endlessly inventive".[36] However, legal research ought to be more neutral, objective, and near to positive orientation. Therefore, this research does not apply empirical research design to argue the issue of access to medicine. However, empirical data from secondary researches will appear throughout the research to highlight the issue of access to medicine. The most significant are statistics from the Access to Medicines Index[37], WHO based statistics, UNICEF, UNITAID, access to medicine statistics from health establishments in various jurisdictions, and from academic work conducted by distinguished researches.

1.4 Significance and Aim of the Study

The demand for access to medicines has been a matter of debate on academic and social levels where the treatment of access to medicines as moral or ethical rights have not been fruitful. Therefore, the significance of this study is to help to elevate the status of access to medicines and established positive legal rights on national and international forums. A through examination of access to medicines-related human rights obligations under international human rights law will help the state parties at legislative, judicial, and enforcement levels. The research will present a thorough analysis of interpreting access to medicines under the right to life and health. Moreover, the issue of access to medicines is very scarcely examined from international human rights perspective. Therefore, this research will contribute to the debate of treating access to medicines as a legal entitlement under the international human rights law.

The ongoing challenges to the issue of access to medicines directly challenge the credibility of human rights epitomes. The issue demands actions from both international and national levels. The crisis of the COVID-19, HIV/AIDS, Ebola, and other infectious diseases threat global commitments in the shape of various human rights incorporated in national and international legal frameworks. International forums report that the gap in health inequality is widening among

[36] Terry Hutchinson, Nigel Duncan, 'Defining and Describing What We Do: Doctrinal Legal Research' (2012) 17 *Deakin Law Review* 84

[37] Access to Medicine Foundation (n-10)

nations.[38] Low-income countries are finding it difficult to deal with issues of climate change, environmental catastrophes, and an outbreak of epidemics. Therefore, these global issues need both national and global efforts to deal with them. Especially, the case of access to medicines needs urgent attention from the global community. This study academically explores the scope of dealing with the issue of access to medicines using the international human rights framework.

This thesis aims to build an argument that access to medicine is a human right under the international human rights law. Furthermore, it highlights the potentials in the international human rights framework to uplift effective realisation of access to medicines. Previously, the issue of access to medicine has remained under debate on various academic, governmental, and non-governmental levels at both national and international circles and a good deal of literature is available on the subject.

1.5 A brief Overview of Thesis

The thesis forms of seven chapters in total. The first chapter introduces the issue in the research and related methodology. While seventh chapters conclude the discussion, and the rest of the five chapters systematically construct the arguments.

Chapter 1: The chapter introduces the research by explaining the overview of the topic, the primary question under the investigation, research methodology, limitations of the research, and the chapter break down.

Chapter 2: Since the research focuses on establishing access to medicines as a legal entitlement instead of moral or ethical demand, it is pertinent to understand how norms are established and enforced under the international human rights law. Therefore, the chapter will examine the norm creation and enforcement process under the international human rights law. The arguments will focus on the concept of right under the international human rights law, a significant part of International Law. This chapter critically examines the sources of International Law in general and the international human rights in particular with special reference to human rights. An examination

[38] World Health Organisation, 'Commission on the Social Determinants of Health, Closing the Gap in a Generation, Health Equity through Action on the Social Determinants of Health' (WHO, Geneva, 2008) < https://www.who.int/social_determinants/final_report/csdh_finalreport_2008.pdf > accessed 11 December 2018

of various sources of International Law will help in ascertaining the status of access to medicines as part of human rights.

Chapter 3: After discussion on norm creating process under the international human rights law, this chapter will find the pieces of evidence for tracing access to medicines related human rights obligations in international human rights instruments. This chapter will analyse of establishing access to medicines as a norm under the right to life, health, and other relevant provisions of international treaties, international legal documents, and interpretations of international institutions. The arguments explore if access to medicines is part of the international human rights law?

Chapter 4: The chapter will comprehensively examine the obligations of the state parties towards access to medicines as part of human rights. For thoroughly analysing the issue, the discussion will include the nature of obligations in relation to access to medicines under CPRs and ESCRs and other regional and international human rights treaties. The chapter aims at examining the obligations related to access to medicines within human rights to guide legislation and policy-making on the topic. Moreover, the research not only focuses on the obligations of the state parties but also analyses the obligation of pharmaceutical companies and other stakeholders vis-à-vis human rights.

Chapter 5: The chapter will critically examine the limitations to underline various challenges in establishing access to medicines as part of international human rights. The chapter will also help in developing a practical framework for the obligations of the state parties towards access to medicines and their practical application. The arguments will help to suggest a workable human rights framework for access to medicines in the coming chapter.

Chapter 6: This chapter suggests the human rights framework for access to medicines as a part of human rights. The arguments will focus on obligations of access to medicines under various human rights stemming from the International Bill of Rights, and the obligations under regional and the international human rights treaties. The research will endeavour to set the normative framework of access to medicines as part of human rights to enhance its better enforcement.

Chapter 7: The chapter will present the summary of suggestions and recommendations for recognising and enforcing access to medicines related human rights obligations as a matter of law, not a mere moral or ethical demand.

1.6 Limitations of the Research

The research limits itself to the arguments stemming from the international human rights law. Previously, the issue has been analysed from the social, economic, and moral grounds. The literature on the issue of access to medicines focus on finding flexibilities from patents on medicines. However, this research confines itself to arguing that access to medicines related human rights obligations can be found in the text of international and regional human rights instruments and the state parties should perform towards legislating, interpreting, and enforcing them as a matter of right.

The research does not examine the issue vis-à-vis poverty, underdeveloped health care system, scarcity of research and development, and ineffective states preparedness to meet the challenge of access to medicines against new diseases. As mentioned earlier, the issue of access to medicines may be studied in various perspectives such as access to medicines under flexibilities provided by TRIPS Agreement of WTO, investigating empirical evidence to highlight the issue of access to medicines, through the lenses of competition laws, equitable pricing mechanisms, issue of research and development on the neglected disease, and the international human rights law. However, this research limits its scope on arguments elevating the status of access to medicine under the international human rights standards.

While the research can help to elevate the status of access to medicines as legally enforceable demand in most of the states, this research limits itself to the challenges of access to medicines in low-income countries. The research benefit from the trends of incorporating access to medicines-related international human rights obligations in the national legal frameworks. Furthermore, the research mainly focuses on the role of states and international organisations towards harmonising their obligations towards ensuring access to medicines as part of the international human rights law for populations living in developing and least-developed countries.

Chapter 2: Development of the international human rights framework

2.1 Introduction

The chapter examines the norm-creating and enforcing processes under the international human rights law. The arguments will focus on the concept of right under the international human rights law, a significant part of international law.

The fundamental idea of enforcing rights and obligations vary in the national and international legal framework. The concept of rights and obligations emerge from the principles and rules of a certain legal system. The creation of rights and obligation as a product represents primary rules and the procedure of their making or input process as secondary rules.[1] At the domestic level, the primary rules may originate from constitutions, legislative enactments as well as judicial interpretations. While secondary rules define various state organs with the formal mandate to make or interpret laws.[2] In the case of International Law, the discussion on secondary rules does not form consensus for various reasons such as the absence of state-like legislative body similar to parliaments and effective judicial organs to systematically interpret the connotation of various rules of international law. The fundamental question in international dispute remains the status and recognition of existing rights or obligations. To recognise a claim as of right or obligations under International Law, the sources of International Law may serve the purpose of secondary rules.[3] The question in this chapter is to explain how a rule acquires a status of right or obligation under the international human rights law with specific reference to access to medicines.[4] Is access to medicines just a *lex ferenda* or *lex lata*? International human rights law is evolving regarding access to medicines related human rights obligations.

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[1] H.L.A. Hart, *The Concept of Law* (Oxford University Press 1997) 26.

[2] Ibid.

[3] Hugh Thirlway, 'The Sources of International Law' in Malcolm D. Evans (ed.) *International Law* (Oxford University Press 2010) 96.

[4] Ibid.

The international human rights law creates rights and obligations mainly through treaties and international customs. The domain of human rights is evolving in almost all aspects of their realisation such as adoption, interpretation, and enforcement of the human rights obligations at both national and international levels.[5] At the domestic legislative frameworks, both legislatures and judiciaries of the state parties set the idea of human rights. At international levels, human rights are of great concern for the UN and its compliance bodies. After the adoption of the UDHR during 1948, international consensus on the international human rights evolved every passing day. The adoption of the International Covenant on Civil and Political Rights (ICCPR) 1966 and International Covenant on Economic, Social, and Cultural Rights (ICESCR) 1966 further raised the standards of international human rights by their internationally binding status. The scope of access to medicine falls under both the right to life of ICCPR and the right to health of ICESCR. Therefore, this chapter provides background and development of the international human rights law that will help in understanding the relevance of access to medicine in the international human rights framework.

This chapter critically examines the sources of International Law in general and the international human rights in particular with special reference to human rights. An examination of various sources of International Law will help in ascertaining the status of access to medicines as part of human rights.

2.2 Norm Creating Process; a study of Sources of International Law

Modern concepts of the nation-state, sovereignty, and development of international law take root in the Pact of Westphalia 1648. The Westphalian model of the modern state is imperative in defining the sovereignty of state both at domestic and international levels.[6] The new idea of state sovereignty remains imperative in the norm-creation process both in national and international

[5] Thomas Buergenthal, ' International Human Rights in an Historical Perspective' in Janusz Symonides (ed.), *Human Rights: Concept and Standards* (Routledge, 2016) 9; Paul Gordon Lauren, *The evolution of International Human Rights: Visions seen* (University of Pennsylvania Press, 2011) 5.

[6] Stephane Beaulac, 'The Westphalian Model in Defining International Law: Challenging the Myth' (2004) 8 *Australian Journal of Legal History* 181-213

legal systems.[7] The Pact of Westphalia led to the development of the universal idea of human rights. The norm creating process in international law has been evolutionary. During the 19th century, the codification of International Law started by outlawing slavery and defining rights and obligations related to wounded and sick during wars.[8] The effects of the First and Second World War compelled the international community to reconstruct the framework of International Law on positive orientations with more effective enforcement mechanisms. In the aftermath of the two World Wars, the world agreed on the fundamental principles of International Law on 26 June 1945 in the shape of adopting the Charter of the United Nations. Among other principles, the charter included the dignity of humans and its indiscriminate protection of human rights through International Law. The preamble of the Charter broadens its scope by including a spectrum of human rights related to both protection of human life as well as its dignity and welfare.[9] The recent era has focused on codification and effective enforcement of international laws.

The status of human rights is also gaining strength through the adoption of effective treaties. Apart from principles and rules related to human rights in the Charter of the United Nations, the UDHR presented a consolidated document of international human rights. However, the concept of human rights is often confused with moral obligations rather than a positive legal obligation. This part will focus on examining the sources of International Law to highlight the codification-process of human rights and their status under International Law. This will be done with an aim to show that the norms under international human rights law are not moral rather are binding.To elaborate on the sources, Article 38 (1) of the Statutes of the International Court of Justice (ICJ) is significant. Under the article, the sources include international conventions, international customs, and general principles of law, judicial decisions, and teachings of the most highly qualified publicists.[10] The following discussion will analyse the binding status of various sources of International Law. In practice, treaties and international customs are more significant in defining binding rights and obligations of the states. Among treaties and conventions, the following argument will assess the status of various sources of International Law.

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[7] Ibid.

[8] A.H. Robertson, *Human Rights in the World* (Manchester University Press 1972)15-20.

[9] Article 1 (3) of the Charter of the United Nations, "To achieve international co-operation in solving international problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language, or religion".

[10] The Statutes of International Court of Justice, Article 38 (1)

International conventions or treaties are binding agreements setting rights and obligations between or among states.[11] To ascertain the rights and obligations between or among states on the specific subject matter, the treaties stand as a fundamental source for lawyers, judges, and the parties involved in the matter of rights or obligations. Article 2 (1) of the Vienna Convention on Law of Treaties (VCLT) defines a treaty as a written agreement between states with the legally binding force.[12] The question is why do the states observe international conventions or treaties? The answer is that the binding nature of the treaties is not parallel to domestic laws rather the principle of *pacta sunt servanda* that compels the state parties to abide by their treaty obligations under good faith.[13]The treaties set the rights and obligations of the state parties.[14] Classification of treaties may include general treaties among states, for example, setting tariffs and law-making treaties such as the ICCPR and the ICESCR. To define the binding scope of treaties, the principle of *Res inter alios acta, aliis nec nocet nec prodest* sets the same principle that a treaty cannot create rights or obligations for states not parties to the treaties without their consent.[15] Some treaties intend to create contractual obligations between two or more parties and do not include any general legal obligation and the example is the extradition treaty between two states. While others include general principles of international law such as Convention on Biological Diversity, United Nations Convention on the Law of the Sea, and the Vienna Convention on Diplomatic Relations.

In the case of the international human rights treaties, ICCPR and ICESCR are law-making treaties defining various rights and correlated obligations of the state parties. Moreover, the human rights covenants aim at effective enforcement of individual rights among the state parties through national legal systems. The human rights committees constantly monitor compliance of the covenants and these committees provide interpretative insight on various rights mentioned in the covenants. To supervise the enforcement of human rights treaties, the High Commissioner's office

[11] Hugh Thirlway (n-3)99.

[12] Vienna Convention on the Law of Treaties 1969, Article 53, Article 2 (1)

[13] Ibid.

[14] Hugh Thirlway (n-3) 100.

[15] Vienna Convention on the Law of Treaties 1969, Article 53, Article 34

monitors the enforcement of international human rights standards. There exist several bodies to monitor the compliance of treaties such as HRC, Committee against Torture (CAT), and others.

The second source of international law is customs. Within societies, various practices regulate the relationship among individuals. These practices evolved from the status of 'should' to 'must'. The same concept is relevant as a source of International Law in the shape of International Customs. International customs bind the states as they reflect continuously and settled practice along with the belief of the obligatory status of its existence under International Law.[16] To elevate a practice as an international custom, the first condition is the state practice. It includes positive actions of states as well as abstentions from certain activates.[17] In this regard, the *Asylum Case* sets the condition of uniformity of the states' practices to form a condition of International Customary status.[18]

The second condition for a practice to take the status of International Custom is subjective that requires the acceptance of the state of the legally binding status of the practice.[19] The concept is further elaborated in *Nicaragua v. the United States of America,* the decision of ICJ held that:

"The Court does not consider that, for a rule to be established as customary, the corresponding practice must be in absolutely rigorous conformity with the rule. In order to deduce the existence of customary rules, the Court deems it sufficient that the conduct of States should, in general, be consistent with such rules, and that instances of State conduct inconsistent with a given rule should generally have been treated as breaches of that rule, not as indications of the recognition of a new rule. If a State acts in a way prima facie incompatible with a recognized rule, but defends its conduct by appealing to exceptions or justifications contained within the rule itself, then whether or not the State's conduct is in fact justifiable on that basis, the significance of that attitude is to confirm rather than to weaken the rule"[20]

[16] *North Sea Continental Shelf cases, Judgment, ICJ Reports 1969*, p. 44; Javaid Rehman 22

[17] Javaid Rehman, *International Human Rights Law* (Pearson Education Ltd, 2010) 22.

[18] Ibid.

[19] Anthony D'Amato, 'The Concept of Special Custom in International Law' (1969) 63 *American Journal of International Law* 211-223

[20] Military and Paramilitary Activities in and against Nicaragua (Nicaragua v. United States of America), Merits, Judgment, ICJ Reports 1986, p. 98, para. 186

For instance, there exist several customary rules on the protection of the environment. These include several obligations to protect the environment such as the obligation to cooperate on the protection of the marine environment, not to dump radioactive waste in international seas, and the polluter pay principle.[21]

The recognition of practice as a legal obligation by the member states is termed as *opinion juris*. The requirement means that the practicing state must consider the practice as law. There should be necessary evidence that the state considers the practice as an obligation under the law.[22] This can be ascertained from various actions of the state such as acts of the legislature, policies of executive, and interpretation of relevant rules by the courts in a country. Moreover, the evidence of considering a practice as the law may be established through international treaties, statements form the state representatives, UNGA resolutions, and other international documents. Professor Javaid Rehman notes:

"A treaty provision could possess customary force if it fulfils the basic criteria relative to the establishment of custom; it could reflect customary law if its text declares or its travaux preparatoires state, with the requisite opinion juris, that its substance is as such declaratory of existing customary international law."[23]

In this way, the obligations under the UDHR may not attain the status of legally binding per se; however, the obligations enumerated under the declaration can fall under the customary international law. Moreover, human rights obligations under ICESCR and ICCPR are evolving to the level of International Customs and the states are gradually enhancing both practices as well as the requisite *opinion juris.*

Among the other sources of international law, the General Principles of Law mainly help in the interpretation of treaties and international customs.[24] The ICJ may consider the general principles of law, in cases where the law is not available from intentional customs and treaties on a certain subject matter. These principles stem from legal principles observed by the civilised states. The principles sharing the same legal basis among members of the international community may take the status of the general principle of international law. For instance, principles of bias, the binding

[21] SOAS University, 'International custom accepted as law' < https://www.soas.ac.uk/cedep-demos/000_P514_IEL_K3736-Demo/unit1/page_21.htm> accessed 30 April 2020

[22] *North Sea Continental Shelf cases, Judgment, ICJ Reports 1969*

[23] Javaid Rehman (n-17) 23.

[24] Ibid.

status of the agreements, principles of fairness, and double jeopardy may fall under the domain of the general principles of international law. Moreover, these principles may have roots in the practice of international law through various tribunals and the courts. The concept of the general principles of law may coincide with human rights in cases of free-trial and presumption of innocence for the accused.[25] Article 38 1(d) of the Statutes of the International Court of Justice included judicial decisions and the highly qualified publicists. In the case of human rights, judicial findings of the international court are very significant in understanding the fundamental nature of rights and related obligations set under the international human rights. The decisions of judicial organs or the books were written on the topics of international law following the rules defined under international customs or treaties. Therefore, these stand as subsidiary sources of international law. Although subsidiary sources are not binding, as international customs and treaties are, however, these sources may act as persuasive sources.[26] These sources include the works of the qualified publicist was in the context of undeveloped jurisprudence of international laws as well as human rights. Application of the subsidiary sources has always helped to clarify the rules elaborated under the treaties and international customs. Therefore, these subsidiary sources help to interpret and understand the primary sources of International Law.

2.3 Creation of 'Rights' in the international human rights law

This part of the study will focus on establishing the context of human rights in the international legal framework. Besides explaining the contextual construct of human rights, this part will also examine the classification of human rights under two categories: civil and political along with economic, social, and cultural rights. Explaining contextual developments of human rights will lead towards understanding access to medicine in the broader framework of the human rights interface.

2.3.1 Development of Contemporary Concept of Human Rights

[25] Ibid. 24

[26] Ibid.

The origins and foundations of human rights have always been a matter of debate among the writers on the subject.[27] Many approaches have tried to explain the origin of human rights. Stephen P. Marks has detailed various perspectives such as their relationship with philosophical and religious orientations and possible correlation with compassion, justice, charity, and individual worth.[28] Reference to respect to the right of life is available in teachings of various religions such as Judaism, Christianity, Islam, and Hinduism.[29] The Code of Hammurabi in Babylon, Charter of Cyrus in Persia, and edicts of Ashoka in India stand as precursors of modern human rights developments.[30]

Modern human rights stem from writings of 17th and 18th-century philosophical writings of the Enlightenment era and famous declarations of France and America. These writings inspired various movements to liberate women, labour, workers, and other exploited classes of society throughout the world.[31] Among these developments, Magna Carta 1215 bears a significant relevance to modern human rights codifications as the documents introduced systematic codification of various rights. [32] American Declaration of Independence adopted during 1776 defines the concept of human rights that, "all men are created equal, that they are endowed by their creator with certain unalienable rights, that among these are life, liberty and the pursuit of happiness".[33] Before the 20th century, human rights mainly revolved around various facets of liberty and freedom and reference to social and economic rights became relevant in the later days. World

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[27] Stephen P. Marks, Human *Rights: A Brief Introduction* (Harvard University 2016) 6; Lynn Hunt (ed.), *The French Revolution and Human Rights. A Brief Documentary History* (St. Martin's Press, 1996) 3; Amartya Sen, 'Elements of a Theory of Human Rights' (2004) 32 (4) *Philosophy & Public Affairs* 315-356, 320

[28] Stephen P. Marks, Human *Rights: A Brief Introduction* (Harvard University 2016) 6; Among fundamental human rights introduced by the Magna Carta were property rights, due process of law, and equality before law. Although Magna Carta do not include the spirit of rights mentioned in the International Bill of Rights, however, it can be taken as start of long journey of human rights.

[29] Ibid.

[30] Micheline Ishay, *The History of Human Rights: From Ancient Times to the Globalization Era, With a New Preface* (Norton and Co, 2008) 46

[31] Lynn Hunt (ed.), *The French Revolution and Human Rights. A Brief Documentary History* (St. Martin's Press, 1996) 3

[32] Michael Freeman, *Human Rights. An Interdisciplinary Approach* (Polity Press, 2002) 17,18

[33] Christian Tomuschat, *Human Rights Between Idealism and Realism* (Oxford University Press, 2003) 14

constitutions focused on securing physical and property-related rights such as life, property, and freedom of speech and religion.[34] Later, the 20th-century constitutionalism adopted rights related to health, education, and other social and economic rights.[35] The rights defined under the category of civil and political heading enjoy more enforcement standards in comparison with social and economic rights as later does not have consensus on their enforcing mechanism.[36] Human rights enforcement has remained the national subject and recently campaign of achieving their enforcement globally started.[37] Traditionally, international law confined itself to the Law of Nations. The treaties before the First World War did not directly refer to the rights of the individual immediately rather focus on relationships between states and individual human rights have no reference in them.[38] The rights of individuals remained prerogative of states and states were at liberty to define and regulate those rights with absolute liberty.[39] After World War 1, the treaties started referring to various rights such as the dignity of human life, security, and spiritual integrity. During 1919, the International Labour Organisation (ILO) started organised campaign for individual rights throughout the world. All these developments somehow paved the way for modern human rights and their universal charter but the most significant development was Nazi atrocities during World War II.[40] Widespread violence against life, property, and human dignity related rights turned international attention towards defining basic human rights.[41] Reflection on these inhumane violations of individual rights is reflected in the United Nations Charter that ensures the protection of human rights besides protecting international peace and security.[42]

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[34] Stephen P. Marks (n-28) 6

[35] Ibid.

[36] Ibid.

[37] Christian Tomuschat (n-33) 14.

[38] Holger Hestermeyer, *Human Rights and the WTO; The Case of Patents and Access to Medicines* (Oxford University Press 2008) 16.

[39] Ibid.; David Weissbrodt, Connie de la Vega, *International Human Rights Law; an Introduction* (University of Pennsylvania Press, 2007) 16.

[40] Holger (n-38) 80; Ibid.

[41] Ibid.

[42] United Nations, Charter of the United Nations, 24 October 1945, 1 UNTS XVI, Article 1 (3).

The contemporary concept of human rights mainly branches from the UN Charter. On the recommendation of various states, human rights were included in the draft of the charter.[43] Later, the UN worked on defining various categories of human rights in the shape of a uniform document. For this purpose, the Commission on Human Rights started its functioning to draft a unified list of human rights obligations. In 1948, the Commission's third session agreed to a draft. The same draft got to UN General Assembly. Resultantly, on 10th December 1948, the Universal Declaration of Human Rights (UDHR) was adopted.[44] The UDHR is the first consolidated document mentioning various human rights irrespective of sex, race, colour, language, and other kinds of discrimination.[45] The document stands as a major consensus on human rights for the reason that it is a declaration not a legally binding treaty in a sense.[46] Besides its non-binding nature, the declaration got the reference in the UN Charter and took a tangible status in interpreting human rights standards.

2.3.2 ICCPR and ICESCR; two different sources of human rights norms?

Core categorisation of human rights is available in the International Bill of Human Rights enumerating almost fifty normative foundations on which various human rights documents are constructed.[47] A good number of regional and international treaties have covered various aspects of human rights including rights in armed conflicts, labourers, refugees, persons with disabilities, and other areas.[48] International Bill of Rights includes five group rights, fourteen economic, social, and cultural rights (ESCRs), and twenty-four civil and political rights (CPRs).[49] Group rights

[43] Micheline Ishay, *The History of Human Rights; From Ancient Times to the Globalization Era* (University of California Press, 2008) 214–215

[44] Javaid Rehman (n-17) 76

[45] Ibid.

[46] Ibid. 78, 79

[47] Stephen P. Marks, Human *Rights: A Brief Introduction* (Harvard University 2016) 8

[48] Ibid.

[49] Ibid.

include self-determination, permanent sovereignty over land, ethnic, religious, and rights related to linguistic minorities.[50]

The present concept of human rights revolves around CPRs and ESCRs. Former are often named as first-generation rights while later are known as second-generation rights.[51] The CPRs enjoy precedence over ESCRs as realisation of the former is done more effectively.[52] Economic and social rights drew world attention during the 20th-century when ILO started focusing rights of labourers around the world and later the same trend was followed in UDHR. Economic and social rights got relevance through the speech of President Roosevelt (1941) that ideal of individual freedom cannot happen without the protection of social security and economic independence.[53] The same speech and campaign of including ECSRs led inclusion of them in UDHR in 1948, a document explaining both CPRs and ESCRs. Although, both categories of rights stem from the same source they remain different in their enforcement and international recognition. Both CPRs and ESCRs are treaty obligations and are enforceable through the international legal framework.[54]

The CPRs relate to life and related to its existence. Civil and political rights ensure life, personal liberties, and protection from arbitrary interference of states in these rights. Rights listed under the CPRs are also known as negative rights where states are under obligations not to interfere in these rights. For example, states must not interfere in the right to life, liberty, and freedoms without any due course of law. These rights, generally, do not require states to do but explain what states must not do or stop any other person doing so. While the ESCRs are rights, obliging states to take actions in the direction of protecting social, economic, and cultural rights of their populations. Therefore, these rights are positive rights and need the laws and policy of the state-directed towards fulfilment of ESCRs.[55] These rights include the right to health, education, and others and the nature of these rights calls states to intervene and ensure the provision of them. Usually, these

[50] Ibid.

[51] Philip Alston, Gerard Quinn, 'The Nature and Scope of States Parties' Obligations under the International Covenant on Economic, Social and Cultural Rights' (1987) 9 *Human Rights Quarterly* 156–229,159

[52] Ibid.

[53] J.K. Mapulanga-Hulston, 'Examining the Justiciability of Economic, Social and Cultural Rights' (2002) 6 (4) *The International Journal of Human Rights* 29–48, 34

[54] Ibid.

[55] Christian Tomuschat, *Human Rights Between Idealism and Realism* (Oxford University Press, 2003) 24

rights call for developing laws and policies along with resources towards their realisation. Critically examining, both the CPRs and ECSRs require state economic resources for their realisation. For example, protecting the right to life requires effective laws and policies along with an effective judicial system that requires the resources of the state for its realisation. Therefore, human rights are often close-knit and are indivisible.[56] The protection of human rights is interrelated and interdependent. Therefore, one cannot prioritise one human right over others, but their enforcement is achieved in a workable manner. Human rights share the ideal of establishing human dignity whether they fall under the CPRs or the ESCRs.[57]

The treatment of human rights has been different in political, enforcement, and interpretative levels. With context to the Cold War, the countries aligned themselves with a different set of rights. The same is reflected in the legal construct of the language used in the text. Article 2 of the ICCPR obliges the state parties to respect and ensure the rights without distinction of any kind.[58] However, thesimilar provision in ICESCR requires progressive compliance using appropriate means by taking the necessary steps. This affects the enforcement of both treaties. Furthermore, the enforcement of CPRs is effectively done by the HRCee while the ESCRs have been orphaned from the identical enforcement body for a long time. During the year 1985, the Committee on ESCRs established a body to conduct a periodic review of compliance. These periodic reviews are advisory. The disparity between CPRs and ESCRs can be analysed from the passing of Optional Protocols during 2008, almost 32 years after the treaty was adopted. Both CPRs and ESCRs stem from different treaties in international law and their enforcement mechanism is different but the objective remains the same.[59] The current categorisation of human rights in the CPRs and the ESCRs bases on the attitude of the states towards their enforcement where some prefer former while others stress later. The realisation of the ESCRs is often slow, as they require states to take positive actions that need more effort than the CPRs.[60] Moreover, the states often excuse because of the progressive nature of ESCRs.

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[56] Javaid Rehman (n-17) 140

[57] Ibid.

[58] International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171, Article 2 (1)

[59] Javaid Rehman (n-17) 140

[60] Javaid Rehman (n-17) 141.

2.3.3 Rights under ICCPR and ICESCR

Contemporary human rights are mainly realised under the UN platform. The UN Charter, in its preamble, clarifies its commitment towards human rights by mentioning its determination, "to reaffirm faith in fundamental human rights, in the dignity and worth of the human person, in the equal rights of men and women and nations large and small".[61] The statements mention that the protection of fundamental human rights without any discrimination is one of the commitments of the UN. Article 1.3 further explains various objectives as, "To achieve international cooperation in solving international problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respect for human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion".[62] The article calls for an international concentrated effort to solve various ESCRs issues along with CPRs. This provision is distinct in making a point of equality between various human rights. The textual interpretation sets that no distinction exists among various human rights. Article 55 of the UN Charter significantly highlights enforcement of human rights as international legal commitment in the following text[63]:

"With a view to the creation of conditions of stability and well-being which are necessary for peaceful and friendly relations among nations based on respect for the principle of equal rights and self-determination of peoples, the United Nations shall promote:

a. higher standards of living, full employment, and conditions of economic and social progress and development;

b. solutions of international economic, social, health, and related problems; and international cultural and educational cooperation; and

c. universal respect for, and observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion."

The provision takes the international community of states from the traditionalist framework of protecting peace and order towards new aspirations of ensuring stability, well-being, equal rights,

[61] Van Aggelen, Johannes, 'The Preamble of the United Nations Declaration of Human Rights' (1999) 28 *Denver Journal of International Law & Policy* 129-144, 130.

[62] United Nations, *Charter of the United Nations*, 24 October 1945, 1 UNTS XVI, Article 103

[63] Ibid. Article 55

self-determination, and overall progress of humanity.[64] This trend has obliged members of the UN with both co-existence at the international level and protecting the population against threats related to life, property, dignity, freedom, social status, economic progress, and other aspects of social progress.[65] Moreover, the provision mentions that states are obliged with both positive and negative duties towards their populations. Articles 56 of the UN charter obligates all state parties to take all necessary actions for fulfilling goals mentioned in Article 55 forwards commitment to the same objective. Interpretation of both Article 55 and 56, jointly hold the state parties responsible for their duties related to human dignity and welfare.[66] The principle of *travaux préparatoires* further substantiates the obligations of states towards realisation of human rights.

After the adoption of the UDHR in 1948, the Commission on Human Rights was established to prepare the draft of the International Bill of Rights. Although, the fundamental charter of international human rights remains the same their enforcement was sought more systematically through categorising them in two main headings; civil and political rights, social, economic, and cultural rights. Categorising the international human rights in these two sets remained a matter of debate between the member of the commission and it was several factors involving implementation, character, and definition of these rights that led to preparing two covenants during 1966 known as International Covenant on Civil and Political Rights and International Covenant on Economic, Social and Cultural Rights. Enforcement of the covenants commenced from 3 January 1976.[67] International Bill of Rights now includes the UDHR, the ICCPR, and the ICESCR. Later various human rights at regional and international levels drew inspiration from the International Bill of Rights. The international community of states has achieved several milestones towards the adoption and enforcement of human rights. Although human rights violations have been reported widely response in the current century against those violations has been highlighted and addressed effectively and systematically under the UN initiative in comparison with previous centuries.[68] The UN has led human rights evaluation programs through its agencies keeping an eye

[64] Dinah Shelton, *Remedies in International Human Rights law* (Oxford University Press, 2015) 33.

[65] Ibid.

[66] Javaid Rehman (n-17) 29.

[67] Micheline Ishay (n-43) 223

[68] Ibid.

on human welfare throughout the world. Human rights watch plans have been very vibrant in the 19th and 20th centuries.

The enforcement of human rights standards has always remained evolutionary. Over time, human rights have become effective at both substantive and procedural levels. The UN has been continuously observing the enforcement of human rights defined under the CPRs and the ESCRs. Bodies such as the Economic and Social Council (ECOSOC) and General Assembly (GA) itself have scrutinised enforcement of human rights standards in the world.[69] Furthermore, on the aspiration of the UN Charter, the council established two commissions and one of them is known as the Human Rights Commission (HRCion) during 1946.[70] The Human Rights Commission's functions, during the first 20 years, focused on defining standards of human rights enforcement. In this era, the commission confined its working to defining various human rights standards theatrically and did not intervene in the practical enforcement of human rights. It was later during the 1960s when the working of commission extended towards taking various human rights-related complaints and addressing them in cooperation with the member states.[71] The HRCion has been very effective at developing human rights on substantive and enforcement levels.[72] Moreover, the commission has observed the protection of human rights in various member states.[73] The commission continuously monitored adherence to human rights through Special Rapporteurs and working groups. Although working of human rights observers have been scrutinised based upon political bases but their role is significant towards pushing to make the states observe standards of human rights in their territories.[74]

The Human Rights Council (HRC) replaced HRCion during 2006. The council is responsible for, "promoting universal respect for the protection of all human rights and fundamental freedoms for

[69] United Nations, *Charter of the United Nations*, 24 October 1945, 1 UNTS XVI, Article 62 (2)

[70] Ibid. Article 68

[71] Javaid Rehman (n-17) 46.

[72] Ibid. 49.

[73] Ibid. 114.

[74] Ibid.

all, without distinction of any kind and in a fair and equal manner".[75] Apart from promoting and protecting universal respect for human rights indiscriminately, the council has also mandate to deal with human rights violations and recommend the UN rights to mainstream human rights in its framework.[76] The council takes the periodic review of human rights observance in the member states. Moreover, the HRC has its complaint system where individuals or groups from the member states may register confidentially complains of human rights violations.[77] The HRC has continued the working model of its predecessor the HRCion as it leads various independent experts on the field of human rights working as Special Rapporteurs and working groups to evaluate human rights violations in state parties.[78] The Special Rapporteurs are experts working independently, in a personal capacity, preparing a deep analysis of the on-ground situation of human rights violations. Findings made by these rapporteurs go to the council and later reach the UNGA. The term of appointment for the rapporteurs last for three years and is extendable. The appointment of Special Rapporteurs has been an effective way of observing human rights in various the member states. Although, reports and submissions of the UN Special Rapporteurs do not have direct enforcement mechanism, however their working can contribute towards human rights observance through the cooperation of the member states.[79] To establish the status of access to medicine in the international human rights framework, a brief discussion will focus on reports of UN Special Rapporteurs related to access to medicine as part of rights elaborated under the International Bill of Rights.[80]

The observation mechanism for the treaties is essential for the compliance of international human rights through appointing expert bodies. For instance, the Human Rights Committee (HRCee) is

[75] United Nations General Assembly, Resolution 60/251. Human Rights Council (UN Doc. A/ RES/60/251; 2006) 2

[76] Ibid. 3

[77] Javaid Rehman (n-17) 55.

[78] Ibid. 58

[79] Ibid. 65, 66.

[80] UN Commission on Human Rights, Resolution 2002/31. The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health (UN Doc. E/ CN.4/2002/31; 2002); UN Human Rights Council, Resolution 6/29. The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health (UN Doc. A/HRC/RES/6/29; 2009).

one of the forums of the same kind that monitors enforcement of the CPRs as contained in the ICCPR. The HRCee has been very effective in monitoring, interpreting, and guiding about the CPRs. The committee has observed protection of life and various freedoms related to its existence in the member states in an effective manner. Unlike the HRCee role on monitoring and advancing the CPRs, ESCRs do not enjoy the same level of monitoring and perusing committee. To perform functions like monitoring and pursuing enforcement of the ESCRs, the ECOSOC monitors enforcement of economic and social rights in the member states.[81] The composition of the ECOSOC is more political than administrative and it consists of UN members instead of independent experts. Before the 1980s, enforcement of the ESCRs has remained political rather international legal subject matter.[82] This was altered through the ECOSOC resolution 1985/17 that incepted Committee on Economic, Social, and Cultural Rights (CESCR). The CESCR includes 18 independent experts, working in an individual capacity to monitor enforcement of various rights under the ICESCR.[83] The committee monitors enforcement through various mechanisms such as complaint system, fact-findings, and reporting compliance of individual state parties. Moreover, the state parties to the ICESCR are obliged to submit an annual report of their compliance to rights mentioned under the document.[84] These reports then come under the observation of the CESCR and final observation is prepared by the committee to appreciate positive developments and recommend necessary measures in the future.[85] Enforcement of rights mentioned under the ESCRs is done in a gradual manner where the state parties try to realise these rights per their social and economic capacity. These rights need positive measures from states towards ensuring the ESCRs. The state parties to the ESCRs are often under capacity towards fulfilling these rights to their populations. The CESCR often prepares recommendations and suggestions for the state parties to fulfill their obligations towards the ESCRs. These suggestions and recommendations are not binding. However, it does not mean that these documents are of no

[81] International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, Article 16

[82] Christian Tomuschat (n-55)140, 141

[83] United Nations Economic and Social Council, Resolution 1985/17. Review of the Composition, Organisation and Administrative Arrangements of the Sessional Working Group of Governmental Experts on the Implementation of the International Covenant on Economic, Social and Cultural Rights (1985)

[84] International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, Article 16

[85] Birgit C.A. Toebes, *The Right to Health as a Human Right in International Law* (School of Human Rights Intersentia, 1999) 90.

worth as they form a tangible part of interpretative sources for various human rights-related issues at international forums.[86] Writers on enforcement of the ESCRs often suggest that these General Comment by the CESCR bear significant authority if accepted by states.[87] Moreover, the UN General Assembly has adopted Optional Protocols for ICESCR on 10 December 2008. The protocols have established individual complaint mechanisms similar to those for CPRs.

2.3.4 Normative status of rights under International Covenant on Civil and Political Rights (ICCPR)

The International Covenant on Civil and Political Rights commonly known as the ICCPR is a solid version of the UDHR.[88] Dominic McGoldrick explains the same in the following words, "The most signally important feature of the ICCPR is that it is a universal instrument which contains binding legal obligations for the States parties to it."[89] Currently, it reveals that 173 states are parties to the covenant and six others have signed it without not ratifying.[90] The ICCPR has been successful in its international legal effects. The covenant was also suspected as a document

[86] Christian Tomuschat (n-55) 190, 191

[87] Matthew C. R. Craven, *The International Covenant on Economic, Social and Cultural Rights: A Perspective on Its Development* (Oxford University Press, 1995) 91

[88] Christopher Harland, 'The Status of the International Covenant on Civil and Political Rights (ICCPR) in the Domestic Law of State Parties: An Initial Global Survey through UN Human Rights Committee Documents' (2000) 22 (1) Human Rights Quarterly 187-260, 187

[89] Dominic Mcgoldrick, The Human Rights Committee: Its Role In The Development Of The International Covenant On Civil And Political Rights (Oxford University Press, 1991) 20; Christopher Harland, 'The Status of the International Covenant on Civil and Political Rights (ICCPR) in the Domestic Law of State Parties: An Initial Global Survey through UN Human Rights Committee Documents' (2000) 22 (1) *Human Rights Quarterly* 187-260, 187.

[90] United Nations Treaty Collection < https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-4&chapter=4&clang=_en> accessed 9 March 2020.

stemming from Western philosophy to advance their hegemony over all other countries but over time, it got the assent of the international community of states.[91]

The HRCee has the mandate of monitoring enforcement of the ICCPR.[92] The committee works in close collaboration of the member states, receives reports of the CPRs compliance after every five years, and later prepares its recommendations for improving enforcement of the CPRs in the state parties. The committee also receives complaints about individuals of the state parties in case of violence related to the CPRs and prepares its view on these reports. These views are communicated to the states for necessary redressing actions. The international level of monitoring of the CPRs plays a pivotal role in their enforcement at domestic levels but direct steps towards protection of the CPRs remain prerogative of the state parties. National-level enforcement of the CPRs is more effective, speedy, and judicious.[93] ICCPR is an instrument that defines basic standards of protecting the CPRs in the state parties. Although, courts at national levels do not generally refer to the ICCPR, however, a good deal of constitutional guarantees inspire their role from standards set by the CPRs. The ICCPR includes a range of rights such as a free trial, voting rights, freedom of movement, and protection from arbitrary detention. A close analysis of these rights reveals that these rights are more focused and specific than those covered under the UDHR.

The ICCPR, like other international covenants, has the status of a law-making treaty that requires interpretation under international law. Interpretation of the ICCPR follows general rules of treaty interpretation defined in the VCLT as the ICCPR does not have provisions related to its interpretation. Interpretation of the ICCPR is often made by the state parties as per their circumstances. In case of conflict on interpretation, the ICCPR does not have a dispute resolution mechanism. The same issue persists with the ICESCR. In case of conflict, the issue may be resolved through inter-state negotiations. Although, the HRCee monitors enforcement of the ICCPR and it also claims interpreting the ICCPR. General Comment no. 24 states, "[t]he Committee's role under the Covenant, whether under Article 40 or the Optional Protocols, necessarily entails interpreting the provisions of the Covenant and the development of a

[91] Dominic Mcgoldrick (n-89) 20.

[91] UN Human Rights Indicator <http://indicators.ohchr.org/> accessed 14 February 2019

[92] Dominic Mcgoldrick (n-89) 20.

[93] Ibid.

jurisprudence".[94] Working with the HRCee has remained very effective towards enforcement of the CPR. The HRCee has a mandate towards evaluating reports from states periodically, inter-state communications related to enforcement of these rights, and addressing individual complaints and assisting their resolutions. In its process of addressing individual complaints and state reports, the HRCee works on three ways namely General Comment, examining reports submitted by the state parties, and redressing individual complaints. All of these documents play a pivotal role in the enforcement-related interpretation of the CPRs.

2.3.4.1 Evolved Concept of Right to Life as a wider norm

Recently, the trends of interpreting the scope of the right to life include various positive duties of the state parties.[95] The protection of life falls under the CPRs. The right to life is fundamental to all other human rights defined in both the UDHR and the ICCPR.[96] After its unanimous codification under Article 3 of UDHR, Article 6 of the ICCPR defines it in more detail. Unlike rights covered under the ESCRs, the right to life got effective protection as individual complaints may be launched under optional protocols adopted along with the ICCPR.[97] A majority of 115 states ratified these protocols.[98] Defining obligations of states towards rights covered under the ICCPR, Article 2 states:

"Each State Party to the present Covenant undertakes to respect and to ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the present Covenant, without distinction of any kind, such as

[94] United Nations Human Rights Committee, General Comment No. 24: General comment on issues relating to reservations made upon ratification or accession to the Covenant or the Optional Protocols thereto, or in relation to declarations under Article. 41 of the Covenant, para. 11, 1994.

[95] Human Rights Committee, General Comment No. 36 on Article 6 of the International Covenant on Civil and Political Rights – Right to life, para 26

[96] Bertrand Ramcharan (ed.), *The right to life in international law* (Martinus Nijhoff Publishers, 1985) 12

[97] Ibid.

[98] First Optional Protocol to the International Covenant on Civil and Political Rights (1976), <https://www.humanrights.ch/en/switzerland/un-conventions/non-ratified/optional-protocol-iccpr> accessed 14 February 2018

race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.'[99]

The provision sets the principle of indiscriminate observance of the CPRs in the state parties territories to every faction of society irrespective of colour, race, language, sex, religion, political affiliation, social origin, property, or any other status.[100] In this regard, the right to life is fundamental to all human rights, as the existence of life will lead to the need for other human rights. Protecting life is the root of protecting all other human rights.[101] Article 6 obligates the state parties in Article 6 to mention, "Every human being has the inherent right to life. Law shall protect this right. No one shall be arbitrarily deprived of his life."[102]

The protection of the right to life is widely observed around the world. As mentioned in the text of Article 6, the word 'inherent' stresses its significance. The enforcement of the right to life is connected to other rights. It has been argued that the right to life stands as fundamental *jus cogens*. Therefore, the right to life takes the status of globally accepted international norms. Moreover, the adoption of the right to life in the constitutions of members of the international community of states makes it continuous practice.[103] Protection of life, in most of civilised states, is fundamental commitment is the focus of constitution and domestic laws. The right to life puts a negative obligation on the state parties to abstain from interfering in the enjoyment of the right to life. This negative duty, a classical view of interpreting human rights, only extends to taking measures prejudicing the right to life. This interpretation does not include minimum standards of health and food. However, modern interpretations of the domain of right to life also take positive steps relevant to the protection of right and those are for minimum standards of sustenance of life. As quoted earlier, Article 2 of ICCPR states, "to take the necessary steps, under its constitutional processes and with the provisions of the present Covenant, to adopt such laws or other measures

[99] International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171, Article 2

[100] Jana Von Stein, 'Making promises, keeping promises: democracy, ratification and compliance in international human rights law' (2016) 46 (3) *British Journal of Political Science* 655-679.

[101] Ibid.

[102] International Covenant on Civil and Political Rights, Article 6

[103] Frans Viljoen, *International human rights Law in Africa* (Oxford University Press, 2007) 28.

as may be necessary to give effect to the rights recognized in the present Covenant."[104] The text of the provision generally talks about positive duty along with negative obligations. It mentions that the state parties need to take all necessary steps towards the protection of the CPRs in the constitutional process and codifications of domestic laws.

Moreover, the right to life, like other human rights, is indivisible, universal, and interrelated to various other rights. The protection of life cannot be achieved in isolation to economic and social rights.[105] The HRCee has recently asked for a wider interpretation of the right to life in its General Comment No. 36.[106] Based on these comment, one may construe that the right to life got two facets of obligations; the negative duty of abstaining from any measure against the right to life and positive obligations to take all necessary steps for the right to life. Therefore, the state parties' obligation towards the right to life may be interpreted flexibly, and apart from various steps abstaining from undue interference of states in right to life, the state parties owe their obligation towards various conditions for sustaining life in their jurisdictions. In response to the outbreak of the COVID-19 pandemic, the recent international and national developments towards access to medicines may elevate the status of access to medicines under the scope of the right to life.

2.3.5 Normative status of Economic, Social, and Cultural Rights (ESCR)

The ESCRs mainly stems from the UN Charter under Article 55 (a & b). The UDHR defines these ESCRs in its articles 22 to 27. Later, the ICESCR has codified these rights in an internationally enforceable format. One group of the international human rights writers and states argue that these rights are the continuation of civil and political rights while others consider strict enforcement of these rights contrasting to free market and thus do not give them status equal to the CPRs.[107] This debate is mainly composed of socialist and capitalist ideals of state roles in the

[104] International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171, Article 2

[105] Holger Hestermeyer (n-38) 116.

[106] United Nations Human Rights Committee, General Comment No. 36 on Article 6 of the International Covenant on Civil and Political Rights – Right to life, para 26

[107] Ilias Bantekas, Lutz Oette, *International human rights Law And Practice* (Cambridge University Press, 2011) 367

market. States as USSR called for strict and prompt enforcement of ESCRs while the USA and other western states objected to the inclusion of these rights in the Commission on Human Rights.[108] This divide is reflected in the enforcement of both the CPRs and the ESCRs as the monitoring of rights is not even.[109] The obligation of state parties towards the ESCRs is explained in Article 2 (1):

"Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures."[110]

The text of the provision mentions that the state parties will work individually and collectively for realisation of these rights in a progressive manner and these measures will be in accordance with the capacity of the state parties. For instance, the ICCPR while mentioning rights states that 'everyone shall have the rights'. Text of the ICESCR is not direct and calls the state parties to work individually and collectively for realisation of the ESCRs through the process not at once.[111] This creates a question that whether rights mentioned in the ICESR are enforceable at once or not. To explain this the CESCR General Comment 9 says that the ESCRs are binding on all state parties and are not advisory.[112] Moreover, these rights are enforceable after their adoption in respect of all rights mentioned in it.[113] The CESCR has defined obligations of the the state parties mentioning that the states are under obligation to ensure the ESCRs at a minimum level and these are known as minimum core obligations.[114] For example, in case of a serious shortage of food or an outbreak

[108] Ibid.

[109] Ibid.

[110] International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, Article 2 (1)

[111] Javaid Rehman (n-17)) 142.

[112] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 9: The domestic application of the Covenant*, 3 December 1998, E/C.12/1998/24, available at: <https://www.refworld.org/docid/47a7079d6.html> accessed 25 March 2020

[113] Ibid.

[114] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 3: The Nature of States Parties' Obligations (Art. 2, Para. 1, of the Covenant)*, 14 December 1990, E/1991/23, para 10.

of life-threatening epidemics, the state parties are under obligation to ensure food and medicines as a part of health care.[115] Obligations to the ESCRs are mainly categorised in three broad actions such as respect, protect, and fulfil. This will be explained in detail later in this chapter. In this case, we can discuss the right to health, and respect means refraining from any step impeding protection and realisation of health and health care. With the view of protecting, the state parties are under obligation to adopt those laws, which effectively protect the right to health in their jurisdictions.[116] Obligation to protect also includes access to health care and avoiding any threat to domestic health care. Obligation to fulfil include financial, administrative, judicial, and promotion measures.[117]

2.3.5.1 Justiciability of ESCR

The justiciability of the ESCRs relates to judicial enforcement of rights supported by mandatory rules rather than discriminatory.[118] Term justiciability is close to implementation of rights mentioned in the ICESCR and enforcement is independent of the capacity of state parties that means that enforcement of the ESCRs is achieved through legislative, administrative, and judicial working. The traditional concept of these rights related to the ESCRs is non-justifiable. In *Nigerian Education Case*, it was argued that the government is not legally responsible for the education of its citizens because of financial incapacity as a result of corruption and lack of funding towards educational budget but the ECOWAS court decided that right to education especially primary education is binding and justiciable even financial resources are not available.[119] On the other hand, the Swiss Federal Court found that the ESCRs are not justiciable as they are not directly

[115] Katharine G. Young, 'The Minimum Core of Economic and Social Rights: A Concept in Search of Content' (2008) 33 *The Yale Journal Of International Law* 113-174, 121-2

[116] Ibid.

[117] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, 11 August 2000, E/C.12/2000/4, paras 33-6

[118] M.J. Dennis, D.P. Stewart, 'Justiciability of economic, social and cultural rights (2004)98 *American Journal of International Law* 462, 474-5

[119] Ilias Bantekas, Lutz Oette (n-107) 380

enforceable in domestic laws.[120] For interpreting the ESCRs as justiciable, the judgment says that it can only be done by incorporating them in domestic constitutions. In the view of the Indian Supreme Court, interpretation of rights covered under the ESCRs includes rights of a healthy environment and adequate housing under the preview of the right to life.[121] Justiciability of the ESCRs has been direct and indirect in the interpretation of courts in the state parties. In the strict sense, interpretation does not include their wider scope if they are not covered under the national constitution, and in a flexible sense, their relevance is made while deciding cases of rights under social, economic, and cultural aspects.[122]

The realisation of ESCRs is the obligation of both state parties as well as the private sector working towards realisation of economic, social, and cultural rights. States must work for realisation of these rights progressively and cannot reverse measures taken towards the ESCRs.[123] Although non-state actors are not subject to the ESCRs and are not charged with their performance directly under the ICESCR if they are effectively discharging national obligations but some courts have accepted cases when they affect realisation of the ESCRs. For instance, *Etcheverry v. Omint* case, the claimant was HIV positive with a health-care plane from the employer, and later on his redundancy, he managed health care plans privately. The insurance company later refused his health care plan. The case came under the consideration of the Argentinian Supreme Court where it was decided that private health care providing companies have an obligation towards the right to health.[124] On the other hand, international forums interpreting obligations towards the ESCRs do not include private individuals under obligation towards social, economic, and cultural rights but this can be done by judicial review in national courts.[125] However, the states have obligations to protect the ESCRs from any adverse action of third parties. This includes companies and other actors who can affect the recognition and enforcement of ESCRs.

[120] Ibid.

[121]Ibid.

[122] Ibid.

[123] Ibid.

[124] Ibid.

[125]Ibid.

For enhancing enforceability, Optional Protocols for ICESCR were adopted by UNGA during 2008.[126] These protocols were specifically meant to deal with the issue of the justiciability of the ESCRs. Adoption of these protocols faced polarized views on enforcement of the ESCRs and state parties were skeptical as they thought that adoption of these protocols would provide the way of interference in managing internal resources and prioritising the protection of rights. These protocols set three ways of communication such as individual complaints, group complaints, and inter-state inquiry and communication procedures. Individual and group communication may be from minorities, indigenous persons, labour or trade unions, other classes. Moreover, the CESCR advice and recommendations are not binding on the state parties but act as guidelines to solve the ECSR related issues.[127]

2.3.6 Human Right to Health

Access to medicine is an integral part of the human right to health. To analyse the issue of access to medicine, it is important to explain the domain and scope of the human right to health in international law. The following part tries to analyse various international legal development with the view to establishing justiciability of the human rights to health in international law. To answer the question of the status of the right to health in international law, the main focus will be various treaties with special reference on ICESCR, its treaty interpretation by various international legal bodies, and customary practice.

2.3.6.1 Development of Right to Health

The right to health and obligation of states towards it are not very ancient. Although monarchs and rulers appreciated the development of new treatment and health care techniques but sovereign protection as we find today was not available to the public.[128] The modern concept of the human

[126]Ibid.

[127] Ibid.

[128] Ibid.

right to health can be traced to international legal developments after World War II. The UN Charter included the reference to protection to health.[129] Moreover, the World Health Organisation (WHO) recognised protection of the right to health in its charter stating, "enjoyment of the highest attainable standard of health" as "one of the fundamental rights of every human being".[130] The same approach was adopted in UDHR in a more refined manner in its Article 25 stating, "[e]veryone has the right to a standard of living adequate for the health and wellbeing of himself and of his family, including food, clothing, housing, and medical care and necessary social services".[131]

Later, the same commitment was included in the ICESCR in its Article 12. A diverse range of international treaties includes the right to health. Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) stresses the right to health of women in its articles 11.1, 12, 14.[132] Commitment to the right to health is included in the United Nations Convention on the Rights of the Child in its Article 24.[133] Protection of right to health is found in various regional treaties as well such as the European Social Charter 1961 calls for protection of health in its Article 11.[134] African Charter on Human and Peoples' Rights 1981 accommodate the same commitment in its Article 16, and Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights 1988 call for protecting the right to health in Article 10.[135]

2.3.6.2 Right to Health; Article 12 of ICESCR

[129] United Nations, *Charter of the United Nations*, 24 October 1945, 1 UNTS XVI, article 57.

[130] Constitution of the World Health Organization, Preamble.

[131] Universal Declaration of Human Rights (adopted 10 December 1948 UNGA Res 217 A(III) (UDHR) Article 25

[132] Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), Article 11, 12, 14.

[133] United Nations Convention on the Rights of the Child 1989, Article 24.

[134] European Social Charter 1966, Article 11.

[135] Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights 1988, article 10.

The right to health is defined in the text of Article 12 of ICESCR. It is a significant right that explains that everyone, living in the state parties, has the right to highest standards of both physical and mental health.[136] Defining the domain of right to health has always been challenging for the reason for the scope of word health.[137] The study argues to establish the status of access to medicines as a right under Article 12 of the ICESCR. It may be construed from the text that the right to highest standards of health does include minimum standards of sustaining life. Moreover, the same has been explained in the CESCR General Comment no. 14 that highlights that the meaning of highest standards of physical and mental health will also be analysed under the individual's biological conditions, socio-economic, and financial capacity of the state. Text of Article 12 explains the right to health in the following connotation:

"The steps to be taken by the State Parties to the present Covenant to achieve the full realisation of this right shall include those necessary for:

a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;

b) The improvement of all aspects of environmental and industrial hygiene;

c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness."

The provision focuses on various facets of protecting health concerning most elements such as reduction of stillbirth-rate, infant mortality, environmental and industrial hygiene, treatment and control of epidemic, endemic, and other diseases, and facilitating populations living in the state parties with all necessary medical services.[138] Here, the text includes all necessary health care facilities for the whole life-span. Article 12, in its part c, focuses on treatment for an epidemic, endemic, and other diseases demanding access to medicine. The provision obligates the state parties to take all necessary measures to create access to medicine and avoid obstacles if any.[139] As

[136] International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, article 12

[137] Brigit C.A. Toebes (n-85) 20.

[138] Alicia Ely Yamin, 'Not Just a tragedy access to medication as a right under international law' (2003) 25 *Boston University International Law Journal* 327, 325-369

[139] Holger Hestermeyer (n-38) 104

the list of health care is not extensive, part d of the same provision is relevant in defining the scope of access to medicine where it obligates the state parties to assure all medical services in the event of sickness.[140] The health care system in recent times tangibly relies on medicines for addressing diseases such as COVID-19, HIV/AIDS, cancer, malaria, TB, and other diseases.[141] That is why access to medicine forms a part of medical services provided by the state parties.

The rights included in the ICESCR do not enjoy the same enforcement status as those mentioned in the ICCPR. Article 4 of the ICCPR sets the principle of non-derogation from the CPRs while the ICESCR does not have a similar provision in its text. Moreover, Article 4 of the ICESCR provides state parties an authority to impose any kind of limitation on rights mentioned under the covenant.[142] These limitations must be legal limits and any arbitrary limits must not be imposed on the ESCRs.[143] The limitations on the ESCRs must be as per law, open for public access, and adopted transparently.[144] Moreover, the limitation on the ESCRs may not conflict with the fundamental nature of rights these rights and should not conflict with the core minimum standards of these rights.[145] Apart from all these conditions, any limitation on the ESCRs must be necessary for public interest and welfare. Authority of limiting the operation of the ESCRs is not absolute as standards for it are set. Moreover, these limitations are under the continuous scrutiny of the CESCRs that prepares a report on the observance of the ESCRs in the state parties. Since the ESCRs obligate the state parties to do positive steps towards realisation of economic, social, and cultural rights, that is why the state parties are given the flexibility to administer their resources by effectively planning realisation of these rights. These limitations, in no way, deviate member state obligations towards the ICESCR. Moreover, obligations to the ICESCR are substantially the same as those mentioned in the ICCPR and only differ in enforcement, as they are conditional to state resources.

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[140] Alicia Ely Yamin (n-138) 327

[141] Holger Hestermeyer (n-38) 104

[142] International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, article 4

[143] Philip Alston, Gerard Quinn, 'The Nature and Scope of States Parties' Obligations under the ICESCR' (1987) 9 (2) *Human Rights Quarterly* 156-229 192

[144] Ibid.

[145] Ibid.

2.3.6.3 Domain of Right to Health

As mentioned earlier, the right to health is not defined in a restricted manner. Article 12 of the ICESCR highlights various conditions for an individual to attain the highest standards of health. The CESCR includes the right to health care and underlying preconditions in defining the scope of the right to health.[146] The right to health care includes both preventive and remedial measures about an individual's health and underlying preconditions for health include the provision of clean drinking water, food and nutrition, best possible environment, sanitation, control of infectious diseases, and preventive measures such as vaccination.[147]

Article 12 (b) includes various health-related aspects for realisation of the highest standards of health. While interpreting the provision, the CESCR comment that the list in the provision is not exhaustive and acts as guidance for the state parties towards the full realisation of the right to health. The CESCR has time and again interpreted state obligations towards the right to health by including new facets such as Article 2 (c) has been interpreted to include emergencies such as accidents, epidemics, disaster relief, and humanitarian assistance in extreme situations under treatment and control of diseases.[148] The same way Article 12 (d) includes the provision of medicines to patients as part of the right to health.[149]

The CESCR has further explained realisation of the right to health at four stages. The first stage is the availability that connotes "[f]unctioning public health and health care facilities, goods and services, as well as programs, have to be available in sufficient quantity within the State Party".[150] The availability of health care includes meeting some standards relevant to protect health such as availability of clean drinking water, sanitation system, adequate medical professional staff,

[146] Brigit C.A. Toebes (n-85) 245, 246.

[147] Ibid.

[148] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, Para 31, 11 August 2000, E/C.12/2000/4 <https://www.refworld.org/docid/4538838d0.html> accessed 2 September 2019.

[149] Ibid.

[150] Ibid.

hospitals, and availability of medicine as per the description of the WHO.[151] Another standard defined by the CESCR is 'acceptability' that connotes respect to all health care ethics and standards by the health care infrastructure. This includes goods and services provided in these facilities should observe medical ethics related to health care.[152] Moreover, the criteria to fulfils already mentioned standards is the quality of a health care system. This condition obligates the state parties to ensure adequate quality of medical services such as medicine, services, and equipment at health care facilities should be adequate in quality and quantity. Accessibility is one of the prime conditions for establishing an effective health care system.[153] Explaining accessibility is also relevant to availability, affordability, quality of medicines. The CESCR explains accessibility in the following words, "Health facilities, goods, and services have to be accessible to everyone without discrimination, within the jurisdiction of the State Party".[154] The health care system that includes both goods and services should be accessible without any discrimination for the people living in the state parties. Moreover, these facilities should be available practically and mere promises are not enough to materialise protection of health.[155] A prominent aspect of accessibility is that the goods and services are in the financial strength of its population. This means the affordability of health care services, including medicines, for the populations.

2.3.6.4 State Parties Obligations to Right to Health

The state parties are under obligation to enforce the ESCRs included in ICESCR in their territories under their internal capacities. The state parties enjoy a certain level of discretion in prioritising

[151] Brigit C.A. Toebes (n-85) 38.

[152] Ibid.

[153] Ophelie Garnier et. al,. 'Right to Health and the Derivative Right to Access Medicines' (2012) 6 *Health, Law, and Policy Brief* 31-68, 35

[154] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, Para 12, 11 August 2000, E/C.12/2000/4 <https://www.refworld.org/docid/4538838d0.html> accessed 2 September 2019. (Hereinafter named General Comment No 14 of CESCR)

[155] Ophelie Garnier et. al, (n-153) 35

various ESCRs.[156] The obligations of state parties are defined in Article 2 (1) of the ICESCR. The provision obligates the state parties to recognise the rights mentioned under the covenant.[157] Moreover, the scope of recognising is not theoretical recognition of right but it is understood as acknowledging the existence, claim, and validity of rights mentioned under the covenant.[158] In this way, a state by recognising any social, cultural, or economic right guarantees its protection. Moreover, Article 2 explains the progressive realisation of the ESCRs and it means continuous efforts of the state parties towards achieving maximum standards of rights mentioned in the ESCRs. This in no way impacts the status of the obligations of the state towards the ESCRs. Furthermore, General Comment No 3 of the CESCR has further explained obligations toward the ESCRs by dividing them into two parts such as the obligation to conduct and obligation to result.[159] Although, the enforcement of the CPRs is more effective and direct in comparison with the ESCRs' principle of non-discrimination and obligation of taking steps towards the realisation of the ESCRs are direct. The state parties cannot excuse themselves from their core duties towards the right to health based on the text of Article 2 if they are not working towards the realisation of the ESCRs. Article 2 of the ICESCR obligates all state parties to take steps to their maximum possible efforts in terms of financial and legislative capacity for realisation of the ESCR. Thus, the state parties are under obligation to act towards the realisation of the ESCR after adopting the ICESCR.

The realisation of human rights is divided into following major parts; obligation to respect, protect, and fulfil. Duty to respect includes refraining from any step that interferes with the human right and avoiding any discrimination in enforcing the right.[160] In the case of the ESCRs, this duty extends to tolerating or sponsoring any policy or practice, the law that infringes right of an individual, or infringing any freedom related to realisation of the right. In this way, the duty to respect facilitates the indiscriminate provision of rights to every individual with equal treatment.[161] In case of the right to health with special reference to access to medicines, state parties are under

[156] Holger Hestermeyer (n-38)107.

[157] Brigit C.A. Toebes (n-85) 293.

[158] Holger Hestermeyer (n-38)108.

[159] Ibid.

[160] Alicia Ely Yamin (n-138) 325

[161] Ophelie Garnier et. al, (n-153) 35

obligation to refrain from any legislative, policy, or administrative steps that impede an individual's right to health care and access to medicines.[162] The state parties are under obligation to adopt policies and laws to realise the right to health and access to medicine. The duty to protect and promote includes preventing infringement of an individual's human rights from other individuals whether it is company or individual. It includes the adoption of laws that help individuals protect their valid rights. The duty to protect also include the promotion of right through awareness and facilitating its enforcement. The duty to fulfil is the most significant as it deals with overall recognition and enforcement of the right by using all necessary economic, social, and legal measures.

2.3.6.5 Right to Health; the Enforcement Status

The status of enforcement of human rights documents remained a source of debate among various international lawyers and scholars. Holger Hestermeyer calls for the establishment of human rights supremacy over all other rights while writers like Malcolm Shaw consider human rights having established supremacy over all other rights by establishing the binding status of the UDHR through state practices having the force of international custom and general principles of international law.[163] Likewise, Ian Brownlie considers the UDHR binding upon the states parties to it on the analogy of becoming principles of international law based upon humanity and tangibly significant to the international legal system.[164] The literature is available to describe the normativity and enforcement of the right to health recently.[165] The right to health has two main parts; health care and various prerequisites to protect health such as sanitation, clean water, and other relevant conditions of life.[166] Article 12.1 of the ICESCR describes the right to enjoy "the highest attainable

[162] Ibid.

[163] Malcolm N Shaw, *International Law* (Cambridge University Press, Cambridge 2003) 260, 261.

[164] Ian Brownlie, *Principles of Public International Law* (Oxford University Press 2008) 559-560.

[165] Virginia A Leary, 'The Right to Health in International Human Rights Law' (1994) *Health and Human Rights* 24.

[166] Brigit Toebes, 'The Right to Health' in Asbjorn Eide, Catarina Krause and Allan Rosas (eds), *Economic, Social and Cultural Rights* (Martinus Nijhoff Publishers 2001) 125.

standard of physical and mental health".[167] This includes access to medicine as the main part of the right to health and health care. The same has been illustrated in various international legal instruments explaining the right to health under the ICESCR.[168] The minimum protection of the right to health includes access to medicine in its definition.[169] Furthermore, access to medicine is further composed of availability, accessibility, acceptability, and quality of drugs.[170] If we just further explore the concept of accessibility, it may be understood that it includes affordability. The issue of affordability in developing and least developed countries is a significant question attached to the right to health.[171]

2.3.6.6 The Struggle for Right to Health

The COVID-19, HIV/AIDS, and other pandemics impact on the right to life and health. The issue of access to medicines has been a motivation for modern conceptualisation, enforcement, and human rights debate. The WHO and other international organisation started campaigning for universal protection of the right to health as closed knitted with the right to life.[172] During 1987, the WHO took the fight against HIV among its goals introducing effective strategies that included access to medicines.[173] To further support the right to health against all other rights, principle of

[167] International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, Article 12.1.

[168] General Comment No 14 of CESCR (n-154) para 9.

[169] Melissa McClellan, 'Tools for Success': The TRIPS Agreement and The Human Rights to Medicine' (2005) 12 *Washington and Lee Journal of Civil Rights and Social Justice* 153,160-161.

[170] General Comment No 14 of CESCR (n-154) para 9.

[171] Ibid.

[172] World Health Organisation, The Global Strategy for AIDS Prevention and Control, Document No. SPA/INF/87.1 (1987).

[173] Sofia Gruskin, Daniel Tarantola, 'Universal Access to HIV prevention, treatment and care: assessing the inclusion of human rights in international and national strategic plans' <http://www.who.int/hiv/events/artprevention/gruskin.pdf > accessed 2 March 2018

primacy of human rights was discussed by various writers of the international human rights law.[174] The campaign for the right to health was afterward expanded to other life-threatening diseases such as tuberculosis, malaria, and other infectious tropical diseases. During the1990s, the focus of the UN instruments expanded the enforcement of the right to health for child mortality and other life-threatening challenges.[175] The struggle for the protection of the right to health universally took a tangible turn after the adoption of Millennium Development Goals (MDGs). The rules were aimed at indiscriminate universal progress across the world making state parties effectively pursue them.[176] It is worth noting that the right to health is integral to almost all goals taken in the MDGs as it contains stress on the assurance of health care many times in the document. As a result of the MDGs, many human rights documents were adopted such as Convention on Disability and Convention on Migrants (Workers and Families) include health care as an element. The development of the establishment of the right to health rose to adoption and enforcement issues at both national and international fronts. On the national level, developing states felt under-capacity in terms of protection of the right to health on the level of standards mentioned in human rights instruments for the lack of economic, infrastructural, and technological progress. At the international level, the human right of health later became in conflict with commercial rights under global standards of pharmaceutical patent protection under the WTO regime. Countries like South Africa, Brazil, India, and other developing countries have justified their divergence from the TRIPS Agreement and global pharmaceutical patent protection based on universal protection of the right to health as a public interest.[177]

2.5 Conclusion

The chapter has systematically analysed the process of norm creation and enforcement in international human rights. This will help to construct arguments for establishing access to medicines as human right. Moreover, the analysis establishes that the status of human rights is

[174] Ibid.

[175]United Nations, General Assembly Declaration of Commitment on HIV/ AIDS <http://www.unaids.org/sites/default/files/sub_landing/files/aidsdeclaration_en_0.pdf > accessed 02 March 2018

[176] Ibid.

[177] Hans V Hogerzeil, Melanie Samson, Jaume Vidal Casanovas, Ladan Rahmani-Ocora, 'Is access to medicines as part of the fulfilment of the right to health enforceable through the courts? (2006) 368 *The Lancet 305*-311

more than of moral grounds as they are enforced under the international legal framework that is distinct from the enforcement of rights at national levels. By explaining the process of norm creation and the enforcement process, it contends that the international human rights call for both positive and negative duties. Starting from the non-binding charter of the UDHR and a later debate focused on the nature and enforcement of rights under both the CPRs and the ESCRs. The compliance of international human rights is not advisory for the state parties, as they owe obligations to respect, protect, and fulfil. The next chapter argues that access to medicine has been an integral part of both the right to life and the right to health under the ICCPR[178] and the ICESCR[179]. Therefore, the state parties to these covenants owe a duty for realisation of access to medicine under the CPRs and the ESCRs. Moreover, apart from treaties, customary international law is a significant source for human rights norms-creation and enforcement

[178] Prof Javaid Rehman mentions 'reduction in infant mortality' as inherent right under article 6 (1) of ICCPR. Further, it is observed that "The term 'inherent' as used in article 6 (1) connotes a positive and broad obligation including, for example prevention of wards and reduction in infant mortality." Reduction in infant mortality requires access to medicines and in this way access to medicine may be interpreted on analogical grounds for facilitating access to medicine in life threatening diseases under article 6 (1) of ICCPR; Javaid Rehman (n-17) 93.

[179] International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, Article 12

Chapter 3: Development of access to medicines as human right

3.1 Introduction

Stephen B. Marks states, "Perhaps the most obvious threat to human rights has come from the inability of people to achieve access to expensive medicine, particularly in the context of HIV and AIDS."[1] Recent academic research trends call for developing the space for access to medicines under the international human rights law.[2] The arguments in this chapter will examine the status of access to medicines under the international human rights law.

Access to Medicine Index Report 2018 finds almost 2 billion people around the globe face the issue of access to medicine.[3] Lack of access to medicine impacts the right to life and health in low-income countries, both developing and less developed.[4] Due to poverty and related factors, many of the populations living in developing and less-developed countries face difficulties in accessing medicines necessary for life and health. This issue becomes more relevant during the HIV/AIDS, and other pandemics where a big number of populations face a grim situation for the lack of medicines. Besides remarkable progress on the cure of HIV/AIDS, almost half of the affected population is still facing the issue of access to medicines. Alicia Yamin's considers the of access to medicines as a part of human rights, "forces us to face the momentous suffering and loss of life

[1] Stephen P. Marks, 'Access to medicines as a Component of the Right to Health' in Andrew Clapham, Mary Robinson (eds.) *Realizing the Right to Health* (Ruffer & Rub, 2009) 82; Benjamin Mason Meier, Alicia Ely Yamin, 'Right to Health Litigation and HIV/AIDS Policy' (2011) 39 (1) *Journal Of Law, Medicine & Ethics* 81-84

[2] Ruth L. Okediji, 'Does Intellectual Property Need Human Rights?' (2018) 15 (1) Journal of International Law And Politics 2-62; Holger Hestermeyer, *Human Rights and the WTO; The Case of Patents and Access to medicines* (Oxford University Press 2008) 116

[3] Access to Medicine Index (2018), Access To Medicine Foundation

[4] The World Medicine Situation 2011: Access to medicines as part of the Right to Health, (2011) World Health Organisation 1

that is occurring in developing countries due to HIV/AIDS, tuberculosis, malaria and other diseases as not just a tragedy; it forces us to recognise it as a horrific injustice".[5]

The issue of access to medicine is portentous in less-developed countries[6] where pandemics like the COVID-19, malaria, Tuberculosis (TB), HIV/AIDS, and other tropical diseases have affected their populations.[7] The term 'access to medicines' is evolving under the connotation of the right to health and life.[8] High prices of medicines, in low-income countries, affect the accessibility of these medicines concerning their affordability. These high prices got many causes such as poverty, lack of research and development, and patent monopolies. The issue of access to medicines is generally debated under the right to "enjoyment of the highest attainable standard of physical and mental health" of the ICESCR.[9] The provision obligates state parties to ensure the right to health care facilities with special consideration to marginalised groups and vulnerable factions of society.[10] Interpreting health care includes making medicines available, accessible, and affordable to their populations. Regarding diseases such as HIV/AIDS, the UN Human Rights Commission has focused more on states' obligations towards access to medicine extend to making medicines available for fulfilling their obligations towards the right to health.[11] This provides a reference to the significance of access to medicines towards the right to health.

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[5] Joo-Young Lee, *A Human Rights Framework for Intellectual Property* (Ashgate, 2015)121; Alicia Ely Yamin, 'Not Just a tragedy access to medication as a right under international law' (2003) 25 *Boston University International Law Journal* 327, 325-370

[6] Less developed countries include both developing and least-developed countries affected by issue of access to medicine.

[7] James Thuo Gathii, 'Rights, Patents, Markets and the Global AIDS Pandemic' (2002) 14 *Florida Journal of International Law* 261-352, 262

[8] Danwood Mzikenge Chirwa, 'The Right to Health in International Law: Its Implications for the Obligations of State and Non-State Actors in Ensuring Access to medicines' (2003) 19 *South African Journal of Human Rights* 541–566

[9] International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, Article 12; Brigit C.A. Toebes, *The Right to Health as a Human Right in International Law* (Oxford University Press, 1999) 18.

[10] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, 11 August 2000, E/C.12/2000/4, paras 33-6 (Hereinafter named General Comment No. 14 of the CESCR)

[11] Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria, C.H.R. Res. 2005/23, U.N. ESCOR, Common on Human Rights, 61st Sess., U.N. Doc. E/CN.4/RES/2005/23 (2005)

The bebate of access to medicine has relied on on moral grounds. This chapter will analyse of establishing access to medicines as an international legal norm under the right to life and health. The arguments explore if access to medicines is part of the international human rights law.

3.2 Concept of medicines

The World Health Assembly (WHA) requested the WHO for helping the member states in preparing a list of medicines along with the method of ensuring reasonable prices and good quality medicines.[12] In this regard, the first list included 205 products that was published in 1977.[13] During the Alma-Ata conference 1978, medicines were included in the main elements of primary health care.[14] Nairobi conference stands prominent in developing the WHO drug strategy. The Nairobi conference extended the scope of medicines from the selection and procurement of drugs to rational use, distribution, and quality assurance.[15] During the year 1991, the Committee on the Use of Medicines gave more representation to professionals from developing countries to balance the members.[16] The WHO defines medicines as something that satisfies the priority health-care needs of some populations.[17] The definition got the main focus on national context and further stresses the availability of medicines at all times, inadequate quantity, appropriate dosage, and affordable prices for community and individual.[18] The WHO keeps a close eye on the list and develops it

[12] The Lancet's Commission on Medicines Policies, ' medicines for universal health coverage' (2016) < https://www.thelancet.com/action/showPdf?pii=S0140-6736%2816%2931599-9> accessed 21 December 2018.

[13] Ibid.

[14] World Health Organisation/UNICEF, 'Primary health care: Report of the International Conference on Primary Health Care, Alma-Alta, USSR' (1978) < http://apps.who.int/iris/handle/10665/39228 > accessed 21 December 2018

[15] The Lancet's Commission on Medicines Policies (n-12)

[16] Richard Laing *et* al., '25 years of the WHO medicines lists: progress and challenges' (2003) *The Lancet* 1723-1729, 1723.

[17] Yoshiko Kojo, 'Global Issues and Business in International Relations: Intellectual Property Rights and Access to Medicines' (2018) 18 *International Relations of the Asia-Pacific* 5-23, 11.

[18] Ibid.

anticipating the needs of various people living in international communities. Therefore, it adopts various medicines as per national requirements. Recent cases of diseases such as AIDS, malaria, TB, and other ever-evolving infectious diseases require a vibrant adoptive list of medicines. Treating a robust increase in infectious disease has always remained a challenge for public health. Defining medicine is significant as no state is capable to fully equip itself with all necessary medicines. The list of medicine can help countries focus their resources on vital medicines effectively. Less developed countries, with limited financial resources, can tangibly use medicine list to spend their resources effectively. Therefore, the adoption of medicine as per national needs related to public health will improve managing medicine with the assurance of high quality and lower cost. The WHO has reflected upon the benefits of medicine lists in its various reports.[19]

Recently, the Lancet Commission on Medicines stressed the need for making medicines affordable to people living in low-income countries.[20] The commission records that access to medicines remains a challenge for the health-care system in less developed countries.[21] The WHO prepares medicine lists every two years and from 2007 onward it has specially mentioned medicines for children.[22] The list remains a guideline for all state parties to prepare their national or regional medicine lists.[23]

The state parties to WHO, while creating their medicine list, consider local diseases and medical challenges. For example, countries like India and Pakistan focus on malaria, TB, and other infectious diseases remedies. The medicines for local diseases are chosen from the WHO list that suggests affordable and effective medicines. For selecting the medicines, the fundamental consideration for the inclusion of the medicine in the WHO list to maintain the effectiveness of the medicines. Although, due consideration is given to the price and affordability of medicines.[24] The basic criteria for selecting medicine on the list include proof of concrete evidence of the safety

[19] World Health Organisation, 'The Selection of Medicines', (2002) *Policy Perspectives on Medicines* 4.

[20] The Lancet's Commission on Medicines Policies (n-12)

[21] Ibid.

[22] Ibid.

[23] World Health Organisation, 'The World Medicines Situation 2011 Medicines Prices, Availability And Affordability' (2011) < https://www.who.int/medicines/areas/policy/world_medicines_situation/WMS_ch6_wPricing_v6.pdf > accessed 21 December 2018.

[24] Ibid.

and effectiveness of the medicine. Moreover, the criteria call for cost-effectiveness, availability, and local considerations.[25] The WHO and national governments maintain and update the medicine list. To keep the list updated, the WHO needs revisiting the list regularly keeping in mind multiple requirements of various populations around the world. The WHO records that almost half of the volumes of medicines globally are used inappropriately.[26] The inappropriate use of medicine may be fatal in cases of diseases such as malaria, TB, cancer, AIDS, and others.

3.2.1 Issue of Access to Medicine

The issue of access to medicine has always been a challenge at both national and international levels. Challenges of access to medicine include under-developed national health care systems and modern standards of pharmaceutical patent protection.[27] The matter of access to medicine is serious in less-developing countries of Asia and Africa where the COVID-19, AIDS, cancer, malaria, and TB are challenging the right to life and health. General Comment No. 14 by Committee on Social, Economic, and Cultural Rights have included access to medicine in the scope of the right to health.[28] The provision of medicine is among national obligations towards their populations. To fulfill the obligations related to access to medicine, it includes availability, accessibility, affordability, and quality of medicines. The availability of medicine is interpreted as the supply of adequate volume of medicine to the market. Furthermore, accessibility of medicine is interpreted as the provision of medicine without any discrimination of class, colour, or race. Assurance of quality of medicine is made by states through their regulatory frameworks where medicine is examined and its standards are checked. The affordability of medicine is directly relevant to our discussion where medicines under patent monopoly are not in reach of population. The WHO helps defining the scope of access to medicines. This framework, as elaborated earlier,

[25] Yoshiko Kojo (n-17) 11

[26] Richard Laing *et* al., '25 years of the WHO medicines lists: progress and challenges' (2003) *The Lancet* 1723-1729, 1723.

[27] Access to Medicine Foundation, 'Access to Medicine Report 2018' (2018) < https://accesstomedicinefoundation.org/media/uploads/downloads/5c1a82b34aa87_Access-to-Medicine-Index-2018.pdf> accessed 21 December 2018.

[28] General Comment No. 14 of the CESCR (n-10) para 43(d).

explains various medicines for public health. This includes selecting and using medicines rationally, insuring affordable prices of medicines, sustainable and fair financing of medicine by government, reliable supplies, and effective health care system.[29]

The Issue of access to medicine is vital for less developed countries where financial capacity is limited. Therefore, states are bound to prepare their list of medicine rationally that may ensure access to medicines. National drug policies need special attention regarding the maximum utilisation of limited resources. Although, states try their level best to optimise their list of medicine, however, the challenges of diseases, pandemics, and other health emergencies put the issue of access out of the capacity of governments. A major challenge for access is the protection of pharmaceutical patents.[30]

Access to medicine is a challenge that requires both national and international attention. In less developed countries, a limited quantity of medicine is supported by states, and rest is purchased by individuals privately. Pharmaceutical patent protection provides companies an edge over prices of medicines which later creates the question of affordability. States have various tools for controlling prices of medicines such as competition laws, facilitating generic market, issuing compulsory licenses, and effective regulation of market entry of medicines. However, it is worthy to note that less developed countries often do not have the legal and technical expertise to deal with complex patent issues.[31]

3.2.2 Public health and access to medicine

Access to medicine is an integral part of protecting public health. The prevalent situation of infectious diseases in developing countries is impacting average life expectancy, especially in less-developed countries. The invention of penicillin and other medicines revolutionised public health around the globe. The absence of monopolies helped the global use of these medicines and improvements in both national and international health-care standards. Although low-income

[29] World Health Organisation (The World Medicines Situation), 'Equitable Access to medicines: A Framework for Collective Action' (2004) 64–65.

[30] World Health Organisation (n-23)

[31] Frederick M. Abbott, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health' (2005) 99 *American Journal of International Law* 317-358.

countries tried their level best to benefit from modern scientific and medical inventions it remained limited for lack of financial resources, and during the 1950s and onwards developing countries started managing critical medicines with scarce resources.[32] The developing countries spend almost 40 percent of their health expenditure on medicines. Therefore, these countries often advocate for low-cost medicines for their populations. As elaborated earlier, the WHO has embarked upon helping developing countries by making a list of medicines to manage finances effectively. After the rise of the modern pharmaceutical industry, governments started exploring low-cost medicines for their populations. By preparing the medicine list, the WHO has helped less-developed countries for their pursuit of low-cost medicines. The HIV/AIDS pandemic has given the impetus of efforts of access to medicine especially concerning the crisis in Africa, Thailand, and other badly hit areas. In response to movement by various international groups, the WHO collaborated with UNICEF and the United Nations to form the UNAIDS program to facilitate access to HIV/AIDS-related medicines. While the issue of access to medicine was under discussion, the TRIPS Agreement was introduced. The TRIPS Agreement has always criticised by NGOs like Oxfam, Me´dicines Sans Frontie`res (MSF), and HAI. In 1999, an organised Access Campaign to facilitate access and development of medicines. The campaign revolved around a high cost of life-saving medicines treating HIV/AIDS. International campaigns for access to medicines fundamentally considered the pharmaceutical industry for the high cost of medicines resulting in the availability and affordability of medicines.

3.3.3 Access to Medicines in WHO legal framework

The WHO remains a significant inter-governmental forum to set the standards for the protection of health. Through its constitution, the WHO has served the purpose of protecting the right to health through the adoption of conventions[33], defining regulations[34], and providing recommendations.[35] However, the process and working of the WHO has been confined itself to

[32] World Health Organisation, 'The Selection of Drugs, Report of a WHO Expert Committee' (1977) <http://apps.who.int/iris/handle/10665/41272> accessed 21 December 2018

[33] Constitution of The World Health Organization, Article 19

[34] Ibid. Article 21

[35] Ibid. Article 23

standards-setting for the protection of health. The WHO has a limited focus on defining international legal aspects of the right to health.[36] In the last two decades, the WHO has started the efforts for effective enforcement of the right to health.

The WHO can adopt conventions under the umbrella of the World Health Assembly (WHA) using Article 19 of its constitution. In response to tobacco epidemics, the response of the WHA was effective by adopting the Framework Convention on Tobacco Control (FCTC) during 2003 that entered in force during 2005.[37] The tobacco industry tried to resist the convention arguing open market principles for the business. However, the covenant introduced the powers of states to regulate taxes, prices, and other regulatory measures for reducing tobacco consumption. The convention also introduced various regulations to educate people against the harmful effects of tobacco use on its labeling and packaging. This shows the start of the era of effective intervention by the WHO towards effective protection of the right to health. Article 21 of the Constitution of WHO mandates the organisation to form legally binding regulations for the quality of pharmaceutical and biological products. It is pertinent to note that for adopting the regulations, the WHO does not need the consent of the member states.[38] The regulations define the role of the member states to address public health issues of the international level. Apart from regulations, the WHO authorises the WHA to recommend the member states on a specific issue. One of the examples of such recommendations is the International Code of Marketing of Breast-Milk Substitutes. The recommendation stands as the non-binding but authoritative guidelines for the member states. Several other recommendations from the WHA guide the member states on the issue of physical activity, infant feeding, and nutrition.[39]

The role of the WHO has become very effective in not only setting standards of health but also the organisation has started helping the member states in protecting the right to health and access to medicines by defining its benchmarks. About access to medicines, the WHO has always helped member states in defining medicines lists that help them ineffective management of health-related

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[36] Obijiofor Aginam, 'Mission (Im)possible, The WHO as a 'Norm Entrepreneur' in Global Health Governance', in Michael Freeman, Sarah Hawkes & Belinda Bennett (eds.) *Law and Global Health: Current Legal Issues Volume 16* (OUP, Oxford, 2014) 560–573, 562

[37] Ruth Roemer, Allyn Taylor & Jean Lariviere, 'Origins of the Framework Convention on Tobacco Control' (2005) 95(6) *American Journal of Public Health* 936–938

[38] Brigit Toebes (n-4) 299-328

[39] Ibid.

issues and setting priorities. In 1987, the WHO adopted the Alma-Ata Declaration on Primary Health Care setting the targets to be achieved by 2000.[40] The commitments were not met effectively and the WHO suggested the same targets during 2008. It is significant to note that General Comment No. 14 of the CESCR has reflected upon the objectives of the Alma-Ata declarations that will be discussed in later parts of the arguments in the chapter. This shows that the objectives of WHO complements the efforts of the human rights framework for the right to health and access to medicines.

3.3 Towards the evolution of access to medicine as Human Right

The issue of access to medicine has been interpreted as a part of the right to health and life. It takes space in major international and regional treaties, and the WHO constitution mentioning the right to health as one of the fundamental rights granted to every human being irrespective of race, religion, economic or social status.[41] Moreover, the right to health has been part of the UDHR as Article 25 mentions "[e]veryone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing, and medical care and necessary social services."[42] The same commitment repeats in the ICESCR, an enforceable treaty, stating that the right to health includes the enjoyment of the highest health standard related to both physical and mental health.[43] Both texts, if interpreted in a textual and contextual manner, include access to medicine as an integral part of the right to health. The UN Secretary-General Panel on Intellectual Property (IP) and access to medicine recognised the significance of access to medicine with the patent on medicines stating:

"Policies and agreements related to human rights, trade, [IP] rights and public health were developed with different objectives at different times. State obligations include duties not only to respect, but to protect and fulfil the right to health. This requires taking proactive measures to promote public health . . . . [E]nsuring access to medicines, and

[40] World Health Organisation, Declaration of Alma-Ata, Primary Health Care, Report of the International Conference on Primary Health Care, Alma-Ata, USSR, 6–12 September 1978, 'Health for All' Series No 1, WHO, Geneva/New York, 1978.

[41] Constitution of the World Health Organization (n-33)

[42] Universal Declaration of Human Rights (adopted 10 December 1948 UNGA Res 217 A(III) (UDHR) Article 25

[43] Ibid. Article 12

particularly to medicines, is a fundamental element of these obligations. Trade rules and [IP] laws were developed to promote economic growth and incentive innovation. On the one hand, governments seek the economic benefits of increased trade. On the other, the imperative to respect patents on health technologies could, in certain instances, create obstacles to the public health objectives of [WTO] members."[44]

The panel calls for measures to promote public health with special reference to access to medicines. The UN Sub-Commission for Promotion and Protection of Human Rights included access to medicines as an integral part of human rights to health.[45] Moreover, the same forum calls for primacy of access to medicines over patents on medicine in case of conflict.[46]

The issue of access to medicines emerges from two main reasons, unavailability and unaffordability. Access to medicine campaign largely remained successful on social and legal levels in developing and least developed countries. However, the cost of medicines in these countries is rising with every passing day. The world faces the challenge of access to medicine. The UN High-Level Panel explained the same:

"Market-driven R&D has been credited by some for producing a number of important health technologies that have improved health outcomes significantly worldwide. However, significant gaps in health technology innovation and access persist . . . . Rare diseases that affect comparatively small proportions of the population have not traditionally attracted investments although this is changing. Various efforts are being undertaken by governments, philanthropic organizations, international entities, civil society groups and the private sector to resolve the incoherence between market-driven approaches and public health needs. However, such efforts tend to be fragmented, disparate and insufficient to deal with priority health needs on a sustainable, long-term basis. A much greater effort must be directed to supplementing the existing market-driven system by investing in new mechanisms that delink the costs of R&D from the end prices of health technologies."[47]

The issue of access to medicine has been highlighted on both human rights as well as at the WTO forums including international organisations such as the United Nations, WHO, Human Rights

[44] Report of the United Nations Secretary-General's High-Level Panel On Access To medicines (2016), Promoting Innovation And Access To Health Technologies 8; Kelly Morris, 'Global Initiatives To Promote Wider Access To medicines' (2008) 8 (9) *The Lancet Infectious Diseases* 535

[45] Laurence R. Helfer, 'Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order on Access to medicines', in Terence C. Halliday, Gregory Shaffer (eds.) *Transnational Legal Orders* (Cambridge University Press, 2015) 311, 312

[46] Ruth L. Okediji (n-2) 43, 2-66

[47] Report of the United Nations Secretary-General's High-Level Panel On Access To medicines (n-44) 8

Council, Ministerial Committee of WTO members, and INGOs. Moreover, juristic writings on the topic do not oppose the idea of access to medicine as part of human rights. In this regard, controlling high prices of medicine is one of the important issues to make medicines affordable for populations living in developing and least-developed countries. The issue of access to medicine stands as a derivative right under both rights to life and the right to health.[48] Access to medicine has gained both normative and legal recognition from international legal bodies.

3.3.1 Access to Medicine under Right to Life

The UN Human Rights Committee and other human rights bodies interpret access to medicine as minimum conditions of survival. Furthermore, F. Menghistu argues that 'survival requirements (for the right to life) are minimum requirements which are related to the concept of basic needs'.[49]As per the argument, access to medicine in life-threatening diseases such as HIV/AIDS, Cancer, and tropical diseases sufficiently constitute the right of access to medicine in the domain of the right to life. The scope of general access to medicine is different from medicines treating life-threatening diseases. The same approach was confirmed in *Smity v. State of West Bengal* where the Indian Supreme Court confirmed that failure of government related to health care where a person's life is under threat violates Article 21 of the constitution mentioning protection of life, a fundamental right.[50] The interpretation from Indian apex court is significant in establishing the indivisibility of human rights. Moreover, the case law highlights the wider interpretation of the right to life. To courts in several countries have started interpreting the scope of the right to life in wider sense in case of absence of constitutional rights to protect health, environment and other essential aspects fo human life. In this regard, the Columbian Constitutional Court made the same interpretation where it was settled that denial of antiretroviral drugs a violation of the right to life.

The recent explanation of the right to life calls for its wider interpretation. The committee mentions that the inherent charter of the right to life call for positive steps from the state parties towards the protection of the right for reducing infant mortality, malnutrition, and epidemics. All

[48] Stephen P. Marks (n-1) 96

[49] F. Menghistu, 'Satisfaction for the Survival Requirement' in Bertrand G. Ramcharan (ed.), *The Right to Life in International* Law (Martinus Nijhoff 1985) 68, 63-83; Joo-Young Lee (n-5) 134

[50] Smity v State of West Bengal [1996] AIR 2426 SC

these positive steps require access to medicines for fulfilling the obligation. The call for positive steps towards realisation of the right to life comes from both international and regional human rights instruments. For instance, the ECHR includes the positive duty of states to take all appropriate steps for its realisation.[51] The commission includes appropriate and adequate health care in the domain of protecting the right to life.[52] The same approach comes from the interpretation of the African Commission on Human and Peoples' Right where it includes environment pollution and degradation in the scope of the right to life if the conditions are humanely inacceptable.[53] Indian Constitution includes the right to livelihood or the right to live with all human dignity. The protection of health and access to medicines falls under minimum requirements to sustain life.[54] In *Morals v. Guatemala*, adopts the same approach including positive duties towards the protection of the right to life among negative duties of the state parties.[55] While interpreting the right to life and the notion of 'arbitrary deprivation' of life, it includes the right to live with all dignity.

The traditional view of the right to life includes only negative duties where the state parties are under an obligation not to interfere in human life by arbitrarily depriving anyone. Moreover, this approach claims that the right to life does not include housing, food, health care, or other necessary living conditions. The traditional view advocates that there is a distinction between the right to life and the sustenance of life.[56] Critically examining, the right to life cannot be alienated from life. It is not possible to keep on living without food and health care that includes medicines. In the case of life-threatening disease, how it is possible to separate access to medicines from the right to life. The HRC rejected the strict interpretation of the right to life and included infant mortality, life expectancy, fighting diseases in the scope of the right to life.

Given these arguments, Article 6(1) of the ICCPR demands protection of the right to life by all state parties. Moreover, enforcement of obligations under the ICCPR is not progressive in

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[51] Association X v. United Kingdom, Application No. 7154/7514 (1987) *European Commission of Human Rights* 32

[52] Joo-Young Lee (n-5) 134

[53] Ibid.

[54] Holger Hestermeyer, *Human Rights and the WTO; The Case of Patents and Access to medicines* (Oxford University Press 2008) 117

[55] Ibid.

[56] James E. S. Fawcett, *The Application of the European Convention on Human Rights* (Oxford University Press 1987) 37

comparison with the ICESCR. Under the right to life, all state parties are under obligation to perform negative duties of refraining from violating any aspect of the right to life as well as positive duties towards fulfilling their obligations towards its sustenance from any individual or private parties.[57] The state parties to the ICCPR are under obligation to establish a legal, administrative, and judicial system that ensures access to lifesaving medicines. This obligation includes protecting the individuals against any action of a third party that leads to a violation of the right to life. In this way, the right to life will cover a part of obligation related to access to medicines and the rest may fall under the right to health.

3.3.2 Domain of access to medicine in Right to Health of ICESCR

Access to medicine is an obligation for the state parties by the virtue of Article 2 (1) of the ICESCR. The covenant sets the obligations in the following words:

"Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures."[58]

The issue of access to medicine is an integral part of health care services, an obligation on state towards their populations. This obligation extends to all events of prevention and sickness, treatment, and control of diseases. To fulfil this obligation, access to medicine stands part of it.[59] Moreover, the obligation of state parties towards access to medicine under the ICESCR is further elaborated in General Comment no. 14 of the CESCR mentioning drugs as part of necessary steps towards realisation of conditions to assure medical services in case of sickness.[60] The Human Rights Council of the UN has emphasised the same in various resolutions stating that access to

[57] Holger Hestermeyer (n-54)118

[58] International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, Article 2.1

[59] Ibid. Article 12

[60] General Comment No. 14 of the CESCR (n-10) para 39

medicine is one of the integral parts for achieving the right of highest attainable standards of mental and physical health.[61]

To understand the domain of access to medicine, the CESCR in its General Comment No. 3 highlights obligations of the state parties towards access to medicine and the same issue is highlighted concerning the right to health in General Comment No. 14. The obligations of state parties towards realisation of access to medicine and health work in a progressive manner. The term 'progressive realisation' means evolution in the protection of economic and social rights including the right to health and access to medicines. The concept of progressive duty obligates the member state to work all possible measures for realisation of economic and social rights. If we analyse the text of Article 2 (1) of the ICESCR, it calls for immediate state action supported by maximum state resources available for realisation of the right to health and access to medicine.[62] Although, low-income countries suffer from economic and financial constraints towards realisation of the right to health overall and access to medicine. Still, this hindrance does not provide the excuse to state parties rather calls for the maximum allocation of resources progressively to solve the issue of health care and access to medicine. The progressive realisation of the right to health and access to medicines has been part of national judicial interpretation. The Venezuelan Supreme Court considered adequate budget relevant for deciding progressive realisation of the right to health. The case involved the issue of access to antiretroviral medicines to the HIV/AIDS suffering population where the Ministry of Health contested a lack of budget to address the issue of access to medicines. The court decided that the government did not perform its duty towards the protection of health and ensuring access to medicines.[63] The case decided that the mere argument of lack of resources does not suffice but the government needs to contend that it has taken all possible steps towards ensuring access to medicine. In another case of South Africa, the question of the domain of access to medicine was discussed. In *Soombramoney Case*, the question was whether everyone among the population has the right to health care? The findings of the court stressed for maximum utility of available resources of the state to help health care. Understanding this interpretation of the domain of access to medicine, we find that the interpretation accepts access to medicines as a part of the right to health but also looks at a possible solution that is

[61] Joo-Young Lee (n-5) 124

[62] Patrick L. Wojahn, 'A Conflict of Rights: Intellectual Property under Trips, the Right to Health, and Aids' (2001) 6 *UCL Journal of International Law and Foreign Affairs* 465-497

[63] Joo-Young Lee (n-5) 127

available by state. Moreover, it stresses that the state must use its available resources in optimum ways.

3.3.3 The standards of access to medicines

General Comment No 14 of the CESCR has defined four main elements for enforcing the right to health. These elements include availability, accessibility, acceptability, and quality of right to health-related facilities. The comment includes medicines as a part of the right to health along with health facilities, services, and goods. The comment requires the state parties to ensure sufficient availability of health-related facilities, their indiscriminate accessibility to all classes, their cultural acceptability, and maintaining their standard quality.[64] To further elaborate the obligations of the state related to access to medicines, the states are under obligation to make all known medicines available for the public but they need to pursue the development of new medicines.[65] The issue of access to medicines is grim in developing countries where the populations are facing the issue of neglected diseases. Apart from the availability of the medicines, the states are under obligation to make them affordable without any discrimination of economic capacity. Along with the obligation of availability, the states are under obligation to make medicines culturally acceptable and ensure the quality of the medicines. The following part will explain various standards for access to medicines.

3.3.3.1 Availability of medicines

General Comment No. 14 of the CESCR explains the parameters for ensuring the right to health.[66] These parameters include ensuring the availability of medicines. The availability of public health facilities needed to be adequate for the population. This includes the obligation of the states to ensure a sufficient quantity of medicines to the public. However, the states may be different in their economic capacity to meet with the obligations. The comment further suggest that the states

[64] Joo-Young Lee (n-5) 130

[65] Joo-Young Lee (n-5) 130

[66] General Comment No. 14 of the CESCR (n-10) para 12

are under obligation to do maximum possible efforts for meeting their obligations towards creating the availability of medicines. Moreover, it also depends on the overall development levels of the states. The comment has mentioned that the states are under obligation to ensure the availability of medicines included in the WHO medicines list.[67]

The issue of access to medicine has many facets. Most prominent of all include availability and affordability in the result of patent protection of pharmaceuticals. Availability of medicine may be an issue of fewer concerns but affordability remains a bigger challenge in low-income countries where population, mostly, relies on private procurement of medicines. High prices of medicines restrict access to medicine for people living in less developed countries. Although, the issue of access to medicine does not have consistent severity as it changes in different countries. The WHO, in collaboration with Health Action International (HAI), has started collecting data on access to medicine regarding availability, affordability, and prices of medicines.[68] The Availability of medicine is one of the elements of measuring the potentials of health care facilities. On the matter of availability of medicine, statistics of the WHO show it below 30 percent, and standard may remain between 50-80 percent as normal.[69] The HAI reports that the availability of generic medicine is also lower than 60 percent in developing countries.[70]

Pharmaceutical companies are well equipped with all legal and technical expertise to set the prices of medicines in less developed countries. Some studies show that the price of the same medicine is lower in developed countries as their regulatory systems are effective, and the same medicine is offered at high prices in low-income countries.[71] Public hospitals in less-developed countries do not have an adequate supply of medicines and people are left to buy medicines privately at high

[67] Ibid.

[68] Susanne Gelders et al., 'Price, Availability and Affordability; an International Comparison of Chronic Disease Medicines. Background Report Prepared for the WHO Planning Meeting on the Global Initiative for Treatment of Chronic Diseases Held in Cairo in December 2005' (2005) < http://haiweb.org/wp-content/uploads/2015/08/Price-Availability-Affordability-An-International-Comparison-of-Chronic-Disease-Medicines.pdf> accessed 21 December 2018.

[69] World Health Organisation (n-23)

[70] Ibid.

[71] Keren Bright, Lois Muraguri, 'Access to Medicines: Intellectual Property Rights, Human Rights and Justice', in Aurora Voiculescu and Helen Yanacopulos (eds.), *The Business of Human Rights* (Zed Books, 2011) 109.

prices. Moreover, medicines offered privately are high prices as compare to state procurement.[72] Studies suggest that high prices of medicine are the main obstacle in the way of access to medicines.[73]

3.3.3.2 Accessibility of Medicines

Accessibility of medicines is another element for ensuring obligations related to the right to health. In the case of the *Minister of Health v. Treatment Action Plan,* the South African case discusses the elements of accessibility of medicines. Nevirapine, an effective anti-retroviral remedy was available only on two sites, and the affected people in remote places could not access the medicines. The court of South Africa found that the policy fails to meet the standards of accessibility.[74] Breach of accessibility of medicines in violation of obligations under the right to health according to General Comment No. 14 of the ICESCR as well as later interpretations of the obligations to ensure access to medicines.[75]

To qualify the standards of accessibility, the states are further obligated to ensure indiscriminate, physical, economic, and information accessibility. The standard of indiscriminate accessibility of medicines to all factions of the society including the vulnerable classes, marginalised groups, and minorities. The meaning of physical accessibility includes medicines that are accessible to ethnic minorities, children, women, older people, disables, and people infected with diseases like COVID-19, AIDS, Cancer, etc. The condition of economic accessibility mainly encompasses the issue of affordability. The general comment obliges the state parties to establish equitable support for making medicines affordable. The last but not least standard of accessibility is access to information on the health and the medicines issues. However, access to information does not include access to confidential data related to any aspect of health.

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[72] Ibid.

[73] Laurens M. Niëns *et* al., 'Quantifying the Impoverishing Effects of Purchasing Medicines: A Cross-Country Comparison of the Affordability of Medicines in the Developing World', (2010)7 (8) *PLoS Medicine* 1-8.

[74] General Comment No. 14 of the CESCR (n-10) para 12

[75] Ibid.

3.3.3.3 Acceptability and Quality of Medicines

The right to health of ICESCR obligates state parties to respect the cultural and medical ethics related to products and services. The general comment requires state parties to ensure that medical services and goods including medicines pass the standards of the culture of individuals and minorities.

Moreover, the obligations related to the right to health include ensuring the quality of products and services related to health. The quality includes medicines following agreed medical standards, availability of qualified staff to prescribe them, unexpired and scientifically approved drugs, equipment to save them, and equipped hospitals.

3.3.4 Are the obligations under ICESCR binding?

The ICESCR, in both text and later interpretations, explains access to medicine as an enforceable human right. The CESCR has highlighted the duties of state parties towards access to medicine and the right to health mentioning them as minimum core obligations. The fulfillment of these core obligations is obligatory on state parties.[76] The committee, while interpreting the right to health and access to medicine under the ICESCR has highlighted that without enforcement of minimum core cultural, social, and economic obligations, the document loses its purpose and objective. The comment notes, "a state party in which any significant number of individuals is deprived of foodstuffs, of primary health care, of basic shelter and housing, or the most basic form of education is, prima facie, failing to discharge its obligations under the covenant".[77] It is pertinent to mention here that the construction of text in General Comment No. 3 does not only focus on progressive realisation but call for all possible steps to solve the issue of access to medicines and the right to health. Moreover, the comment have explained the situation in which a member state cannot deal with the issue of access to medicine stating that the state parties need contenting that it has provided all necessary support to satisfy and fulfil the minimum core obligations under the

[76] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 3: The Nature of States Parties' Obligations (Art. 2, Para. 1, of the Covenant)*, 14 December 1990, E/1991/23, available at: https://www.refworld.org/docid/4538838e10.html [accessed 17 May 2020

[77] Ibid.

ICESCR.[78] Additionally, the state parties are free to set their priorities towards fulfilling their obligations towards access to medicines and the right to health. The right to access to medicines is an integral part of minimum core obligations and the same as described under General Comment No. 14.[79] The fulfillment of core obligations is immediate and the state parties are under obligation to content that they are doing their best to perform these obligations under the maximum available resources. Regarding access to medicine, the concept of medicines under the WHO aspiration plays a very pivotal role. The WHO defines medicines as those that satisfy the priority health care for the populations. The selection of medicines is made based upon the prevalence of the disease, evidence of safety and efficacy, and cost. Moreover, the state parties must keep their medicines lists updated as per the guidance of the WHO. This helps state setting priority related to spending on health care. It is the state obligation to create access to essential medicines while the rest of the medicines are worked progressively.[80]

3.3.5 Human Right to the Benefit of Science and Access to Medicine

The Right of access to medicines can be interpreted under the right to enjoy a benefit scientific progress, its application. Article 27 of the UDHR explains that humanity will share scientific progress. The same commitment is included in the ICESCR through article 15 (1) (b) as under:

> *"The States Parties to the present Covenant recognize the right of everyone:*
>
> *a. To take part in cultural life;*
>
> *b. To enjoy the benefits of scientific progress and its applications;*
>
> *c. To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.*
>
> *d. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.*

[78] Ibid.

[79] Joo-Young Lee (n-5) 129

[80] Joo-Young Lee (n-5) 129

e. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.

The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields."81

The text of the article explains both the access and protection of scientific research. The state parties are under obligation to ensure that everyone living in their territories is enjoying the benefit of scientific progress. Additionally, the state parties are under the obligation to take all necessary steps to protect research and creative activity to keep the innovation in sciences flourish in their territories.

The right of access to medicines, as part of the right to health, is the significant part of recent development. The right to health and access to medicines is explained in various universal and regional treaties. Moreover, the right to health, including access to medicines, has started becoming part of national legal systems. The same has been mentioned in earlier arguments. The invention of new medicines rightly connects with the protection of pandemics such as the COVID-19, AIDS, Cancer, Malaria, and Tuberculosis. In the case of protecting the right to life and health concerning these diseases, access to medicines becomes an essential part. It is the obligation of states under Article 15 of ICESCR that they take all necessary steps for creating access to medicines as part of their obligations to make their populations enjoy scientific progress and its application in medicines.

The state parties to the ICESCR are under obligation to fulfil their duties towards the right of access to medicines under the right to enjoy the benefits of scientific progress. The extent of obligations towards rights mentioned under the ICESCR are of progressive realisation.[82] The developing and least-developed countries do not have enough capacity to fulfil their duties towards facilitating their populations to enjoy all the benefits of scientific progress. However, the progressive realisation of rights under the ICESCR cannot stand justification for avoiding obligations under the covenant. Article(1) of the ICESCR calls each member state, "…undertakes to take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, to achieve progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including

[81] Holger Hestermeyer (n-2) 130

[82] Ibid.

particularly the adoption of legislative measures."[83] To add further, Article 2(2) of the ICESCR obligates state parties to ban any discrimination in the way of enjoyment of rights under the covenant.[84] In this way, state parties are required to take all positive and negative steps to help their population enjoy benefits of scientific progress including scientific progress in the field of medicines as a matter of human rights. Moreover, the state parties are under obligation to take the necessary steps in a reasonable time.[85]

For arguing the right of everyone to enjoy scientific progress, the state parties have often relied on their limited economic and financial resources. As quoted earlier, judgments from developing countries have applied the principle of maximum efforts made by the states towards realisation of the right to health and access to medicines. The same reasoning may stand relevant in this case.[86] The state parties to the ICESCR are under obligation to use their maximum available economic and financial resources for the progressive realisation of the right of everyone to benefit and enjoy scientific progress. In the case of access to medicines, the parity between availability and accessibility of medicines is very clear. In the case of diseases affecting child mortality in developing and least-developed counties, and tropical diseases, millions of people cannot enjoy the benefits of advanced medical innovations for the reason of affordability.[87]

The obligation under Article 15 of the ICESCR towards facilitating everyone to enjoy and benefit from scientific progress has two national and two international obligations. On national levels, state parties are under obligation to facilitate scientific research to grow through protecting innovation, research, and development. Additionally, the states need to protect the right of everyone to enjoy the benefit of scientific progress. The same two layers of obligations collectively oblige state parties to the ICESCR to work for balancing between protecting scientific progress in terms of innovation, at the same time create a mechanism that allows everyone globally to access and enjoy the benefit of scientific progress.

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[83] Ibid.

[84] Yvonne Donders, 'The right to enjoy the benefits of scientific progress: in search of state obligations in relation to health' (2011) 14 *Medical Health Care and Philosophy* 375, 371-281

[85] Ibid.

[86] Ibid.

[87] Ibid.

3.3.6 Right of Access to medicines under Customary International Law

With special reference to the recent outbreak of the COVID-19 pandemic, the state practice on providing access to health care and medicines is uniform. Moreover, the statements form regional and international bodies are recognising the need for enforcing the right to life and health with reference to the COVID-19. The states' practice and recognition of access to healthcare and medicines may develop it to the level of customary international law. For instance, the Constitution of the Islamic Republic of Pakistan does not include the right to health or access to medicines among fundamental rights. However, after the outbreak of the recent COVID-19 in Pakistan, the state has found it under obligation to protect the right to health of the infected masses. The Supreme Court of Pakistan, by taking an action under its constitutional power, has directed the government doing all possible for protecting the right to health and access to medicines to the people affected by the COVID-19 pandemic.[88] The Supreme Court of Pakistan relied on the right to life with its wider approach of interpreting protecting life and security of person. Moreover, the government has tried to allocate maximum economic sources to protect the health in its territory and the citizens abroad. A similar situation prevails in most of the countries around the world.

The same can be observed from the case of the HIV/AIDS pandemic, a good number of the UNGA Resolutions have called for making the pharmaceutical products and technology available and affordable as soon as possible.[89] The resolutions have asked member states of the UN to work in cooperation to solve the issues related to availability, accessibility, affordability, and quality of AIDS, a life-threatening disease. During 2001, a resolution mentions commitment from member states for addressing factors affecting the availability and provision of antiretroviral AIDS medicines, their affordability, and capacity building of health care facilities to assist the affected populations in their territories.[90] The scope of access to medicines got a new definition by GA Resolution 58/179 asking members states to adopt policies for promoting affordability,

[88] (Suo Moto Action Regarding Combating the Pandemic of Corona Virus (COVID -19) S.M.C. 01/ 2020 <https://www.supremecourt.gov.pk/downloads_judgements/s.m.c._1_2020_20042020.pdf> accessed 21 April 2020.

[89] Eckart Klein, 'The Duty To Protect And To Ensure Human Rights Under The International Covenant On Civil And Political Rights' in Eckart Klein (ed.) *The Duty To Protect And To Ensure Human Rights* (BWV Berliner-Wissenschaft 2000) 296-297

[90] Holger Hestermeyer (n-2)130

availability, and accessibility of life-saving medicines related to diseases like malaria and tuberculosis along with HIV/AIDS.[91] The commitment to promoting access to medicines was reaffirmed during the year 2006 by the member states.

It is pertinent to mention that the right to health has secured its place in more than 63 constitutions in the world.[92] One may argue that only listing the right to health does not ensure its enforcement as the enforcement of the right to health is a matter of debate for its wider interpretations. On the other side, the right to life widely protected in majority of states. Moreover, it is termed as an inherent right of everyone without any discrimination. Both national and international law are unanimous on its binding nature and enforcement through international treaties and national constitutions.[93]

In the view of the states' practice towards the human rights of access to medicines, the commitment to respect, protect, and fulfil obligations related to ensuring access to medicine is found in various forms of international documents. To conclude it may be right to say that the right of access to medicines, concerning pandemics and endemics, is developing as part of rules of customary international law.[94] The commitment to protect the right of access to medicines is found in numerous international human rights documents and the same has been included in national legal systems of the member states as an obligation to protect. This highlights the status of access to medicines as state practice and international customary norm.

3.3.8 Human Rights Obligations of Non-State Actors towards Access to medicines

Traditionally, states have been the subjects of international law and human rights obligations. The states must ensure the enforcement of the international human rights law in their jurisdictions. To become a state, an entity requires a permanent population, defined territory, stable government, and capacity to conduct international relations. The rest of the international and national

[91] Ibid.

[92] Virginia A. Leary, 'The Right to Health in International human rights Law' (1994) 1 (1) *Health and Human Rights* 37, 24-56

[93] Holger Hestermeyer (n-2) 128

[94] International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, Article 15

organisation may be understood as non-state actors in the case of defining human rights-related responsibilities relevant to access to medicine. These entities include transnational companies (TNCs), international and national NGOs, international organisations, donor agencies, and charitable organisations. Moreover, non-state armed or rebel groups may have some role in the issue of access to medicines. General Comment No. 14 recognise the role of non-state actors towards their role in the enforcement of economic and social rights by commenting:

"While only States are parties to the Covenant and thus ultimately accountable for compliance with it, all members of society — individuals, including health professionals, families, local communities, intergovernmental and non-governmental organizations, civil society organizations, as well as the private business sector — have responsibilities regarding the realization of the right to health. State parties should therefore provide an environment which facilitates the discharge of these responsibilities."[95]

The comment calls for obligations of the state parties towards realisation of the right to health. Moreover, the comment includes individuals, professionals, the governmental and non-governmental organisation as an overall part of states' responsibilities towards the right to right to health and access to medicines. Non-state actors particularly fall under the duty to protect that requires all state parties to prevent any third party from infringing the right to health and access to medicines of individuals. In this regard, the state parties are under obligation to fulfil their duty by establishing a domestic legal framework that stops any corporation, organisation, or any other third party from interfering in access to medicine as a part of the right to health and life. With specific reference to human rights for access to medicines, the state parties got limitations towards establishing the legal framework protecting the human rights of individuals. These limitations may include lucrative foreign direct investment from Trans-national Companies (TNCs) with huge budgets. Additionally, there is the conflict between various international obligations under international agreements imposing two different sets of obligations, as is the case of access to medicines where the TRIPS Agreement calls for compliance of patents standards of medicines and the ICESCR calls for protecting individual's right to health and access to medicines.

The states are the main subjects of international law and human rights but the responsibilities of non-state actors are somewhat relevant for realisation of human rights obligations. For instance, the International Convention on Civil Liability for Oil Pollution Damage put direct liabilities on legal persons. Corporations working in the the member states of the World Bank may fall within

[95] Anand Grover et, al. 'Pharmaceutical Companies and Global Lack of Access to medicines: Strengthening Accountability under the Right to Health' (2012*) Journal Of Law, Medicine & Ethics* 237, 234-250

the jurisdiction of the convention.[96] In the European Union, several cases have fixed liability of non-state actors concerning human rights under the ECHR.[97] This may substantiate the argument that non-state actors such as companies are subjects for violation of international human rights.[98]

The UDHR, in its preamble, sets duties of non-state actors towards human rights stating, "every individual and every organ of society… shall strive… to promote respect for these rights and freedoms and by…"[99] By mentioning 'every organ' in a state, it may be construed that the TNCs and other organisation working or supporting for realisation of human rights fall under obligations. Additionally, Article 30 of the UDHR states, "Nothing in this Declaration may be interpreted as implying for any State, group or person any right to engage in any activity or to perform any act aimed at the destruction of any of the rights and freedoms set forth herein."[100] The article mentions that any individual or group may not act contrary to realisation of rights mentioned in the UDHR. In this way, third parties become relevant to the enforcement of human rights to the extent of respecting human rights. One may argue that the declaration does not enjoy enforcement standards of a treaty but still, the declaration has attained the status of customary international law that elevates it somewhat binding in interpreting the right to health and access to medicines along with other human rights.

Another argument is the limited scope of non-state actors at the time of the adoption of vital human rights instruments. Since the role of corporations and other national and international organisations is widening towards realisation of human rights every passing day, the responsibility of these non-state actors also needs reinterpretation. The fundamental questions related to the human rights obligation of non-state actors may be the potential of these third parties in violating human rights. The corporations and other national and international organisations can violate human rights or hinder their realisation in one way or another. Therefore, if these non-state actors can violate human rights, they are under obligation to perform positively towards their realisation. Moreover, these non-state actors are not only responsible for state laws to help enforcement of international human rights but they are also responsible for the international human rights

[96] Ibid.

[97] Andrew Clapham, *Human Rights Obligations of Non-State Actors* (Oxford University Press 2006) 349.

[98] Anand Grover et, al. (n-112) 237, 234-250

[99] Ibid.

[100] Universal Declaration of Human Rights (adopted 10 December 1948 UNGA Res 217 A(III) (UDHR), Article 30

standards settled by the international human rights laws. In case of access to medicines, pharmaceutical companies especially, own a major part of patent monopolies on medicines particular, and lifesaving medicines and they may help to solve the issue of access to medicines by rationalising the profitability.[101]

3.5 Conclusion

The chapter has argued that the right of access to medicines is an evolving right under multiple sources of international law and the international human rights instruments. Moreover, the arguments highlight a coherent study of international legal instruments setting normativity for access to medicines. However, the enforcement standards of the right of access to medicines may vary under various rights such as the right to life of the ICCPR and the right to health of the ICESCR. The right of access to medicines broadly calls state parties to the International Bill of Rights to facilitate their population against issues of availability, accessibility, and affordability of medicines. The accessibility of medicines mainly relies on the affordability of medicines. Normative construction of access to medicines may be supported through multiple sources of international law. Access to medicines forms part of fundamental human rights included in international agreements emerging from the forums of the WHO and the international human rights frameworks. Benefiting from the indivisibility of human rights, the recognition, and enforcement of access to medicines can mainly be done under the right to life and health.

[101] Keith Syrett, 'Essential but expensive? The World Health Organization, access to medicines and human rights' (2019) 37 (2) Netherlands Quarterly of Human Rights 139-156, 145

Chapter 4: State obligations towards access to medicines

4.1 Introduction

The international community of states has been creating space for access to medicines under domestic and international legal frameworks. This commitment is witnessed in human rights developments as well as Sustainable Development Goals (SDGs) adopted during 2015.[1] The goals include a commitment to ensure healthy lives and well-being for the people across the world. Goal 3 aims at ending epidemics such as HIV/AIDS, malaria, TB, and other neglected diseases by the year 2030.[2] The commitment to contain pandemics and epidemics requires access to medicines as is the case of the recent COVID-19 pandemic. Moreover, the arguments in previous chapters presented the case of access to medicines as part of human rights.

The human right to health and access to medicines has been remotely interpreted that has affected the status of human rights obligations. Moreover, the domain of access to medicines is often contested under the right to life. The state parties to human rights instruments and non-state parties take concession for under-defined obligations of subjects towards access to medicines related human rights obligations.[3] To build the case of access to medicines as a human right, this chapter will argue that the obligations related to access to medicines can be deduced from the framework of the international human rights law. Moreover, these obligations are not fictional rather can be enforced through practical and determined measures. By examining the obligations of the state parties towards access to medicines, these arguments will contend that the states are not only under moral obligations to ensure access to medicines rather they owe obligations under the international human rights law. These obligations include the duty to respect access to medicines as part of human rights that means avoiding any measures conflicting with the rights in their territories. The state parties are under obligation to their part for protecting human rights

[1] Paul Hunt, 'Interpreting the International Right to Health in a Human Rights-Based Approach to Health' 18 (2) *Health and Human Rights Journal* 109-130

[2] Ibid.

[3] UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 9: The domestic application of the Covenant, 3 December 1998, E/C.12/1998/24 <https://www.refworld.org/docid/47a7079d6.html> accessed 27 March 2020

including access to medicines.[4] Finally, the state parties have the legal obligation to fulfil their commitment towards access to medicines by effectively legislating and enforcing the right of access to medicines in their territories.

Human rights obligations related to access to medicines require the state parties to create indiscriminate access to medicines to all their population. To achieve the goal, the state parties need to take all necessary positive steps such as adopting medicines and health-related policies, giving priority to health in national spending, regulating pricing and licensing, and other related legislative and administrative measures. The access to medicines-related human rights obligations is often objected based on limited financial resources available in developing and least-developed states. However, the study will examine the extent of obligations under the human rights framework and the criteria for assessing the performance of the state parties.

For thoroughly analysing the issue, the discussion will include the nature of obligations in relation to access to medicines under the CPRs and the ESCRs. The chapter aims at examining the obligations related to access to medicines within human rights to guide legislation and policy-making on the topic. Moreover, the study not only focuses on the obligations of the state parties but also analyses the obligations of pharmaceutical companies and other stakeholders to human rights.

4.2 Nature of Obligations related to access to medicines

4.2.1 The nature of access to medicines-related obligations?

The nature of access to medicines under the right to health of Article 12 of the ICESCR calls for solving the issue of access to medicines progressively with an aim of full realisation of the right. From the term 'progressive', it is generally understood that the states have the intention along with commitment towards the recognised right.[5] The obligations related to access to medicines under ESCRs differ from the obligation under the right to life of ICCPR as the former is progressive

[4] Brigit Toebes, 'International health law: an emerging field of public international law' (2015) 55 (3) *Indian Journal of International Law* 299-328

[5] Ibid.

while the later are immediate in their realisation. The obligations of states towards the right to life are immediate. As it is argued earlier, the nature of access to medicines related human rights obligations falls under both the right to health as well as the right to life. This is why the obligations of the state parties towards access to medicines are both progressive as well as immediate.

To elaborate the concept of progressive realisation of access to medicines as a part of the right to health, General Comment No. 14 explains that the term progressive realisation will include both immediate as well as progressive obligations. The comment acknowledges that the states have limited capacity to protect the right to health as well as access to medicines. The immediate obligations of states include indiscriminate access to health and access to medicines as core obligations. The states should take positive, deliberate, and targeted steps for the protection of the right to health.[6] The comment also identifies that the term progressive realisation does not mean defeating the obligations under the covenant as the progressive nature of rights demands states to take all necessary positive steps for the relevant enforcement. Moreover, the states must avoid any sort of retrogressive steps against access to medicines or any other right included in the covenant. The states are under obligation to justify retrogressive steps by them under certain circumstances. Moreover, as part of progressive duty towards rights under the ICESCR, the state parties are under the positive obligation to use all possible resources to realise the rights.

General Comment No. 3 recognise that enforcing ESCRs is not a prompt process rather the realisation of the right to health and other rights will require gradual enforcement. The comment suggests, "full realisation of all economic, social, and cultural rights will generally not be able to be achieved in a short period".[7] The obligations under the progressive nature demand all state parties work as effectively as possible for the full enforcement of ESCRs without any possible reverting manners.[8] The states may take some measures that limit the enforcement of the rights to prioritise their scarce resources. However, they need to justify the need for actions. In case of access to medicines as a part of the right to health, the states often justify their inability based upon weaker economic conditions. The existence of the right to health does not provide every individual in a

[6] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, 11 August 2000, E/C.12/2000/4, paras 30. Herein after called 'General Comment No.14 of the CESCR'

[7] The Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 3, 'The Nature of States Parties' Obligations' < https://www.refworld.org/pdfid/4538838e10.pdf> accessed 23 October 2019

[8] Ibid.

state to access all sorts of health facilities. The situation in the member states may vary as per the economic and technological progress. This is why developing and least-developing states define their priorities based upon available resources. The states, in case of access to medicines, define the medicines list with the guidance of the WHO and later priorities the medicines procurement as per national policies.[9] The right to health and access to medicines is knitted to health, life, human dignity, equality, access to information, equality, and prohibition of torture.[10] Therefore, the state parties are under obligation to allocate their financial resources in a way that the rights are interrelated. For the nature of progressive realisation, the states have certain flexibility to set their priorities related to the right to health and access to medicines.

Learning from domestic jurisprudence for interpreting the concept of progressive realisation concerning access to medicines, the Venezuelan apex court interpreted the notion of progressive realisation in the context of budget allocation.[11] The issue involved the failure of the state to provide access to HIV/AID treatment. The court required the government to satisfy that it has taken all necessary steps to perform its obligations related to access to medicines. The decision highlighted the criteria for the performance of the state towards performing human rights obligation that if the state has allocated the financed reasonably to fulfil its obligations towards the right to health. The court accepted the argument of scarce financial resources by the Venezuelan government. The court found that the Ministry of Health does not have adequate funding to support access to medicines and found that the government has tried its best to make possible the available sources. Therefore, the issue, in some instances, goes beyond the financial capacity of the government.[12] The same issue came under scrutiny during the *Soobramoney Case* of South African constitutional court. The issue before the court was deciding the right of everyone to the health

[9] Norman Daniel, Just Health: Meeting health needs fairly (2008) 86 (6) *Bulletin of the World Health Organisation* 653

[10] General Comment No.14 of the CESCR (n-6) paras 3

[11] Cruz del Valle Bermúdez, et al. v. Ministerio de Sanidad y Asistencia Social (MSAS), < https://www.globalhealthrights.org/health-topics/health-care-and-health-services/cruz-del-valle-bermudez-ors-v-ministerio-de-sanidad-y-asistencia-social-msas/ > accessed 28 October 2019

[12] Mary Ann Torres, 'The Human Right to Health, National Courts, and Access to HIV/AIDS Treatment: A case study from Venezuela', in Sofia Gruskin, Miceal A. Grodin (eds), *Perspectives on Health and Human Rights* (Routledge 2005) 507-18

care where the state has very limited financial resources. The court found that the states must utilize their available resources optimally to protect the rights of health care, water, and food.[13]

In the view of discussion, one may draw an inference that progressive realisation of the right to health or other rights under ICESCR does not allow states to leave these rights ineffective. The state parties to ICESCR are under legal obligations to perform their duties optimally with available financial resources. To comply with the obligations of the state parties towards the right to health and access to medicines, the states need to demonstrate that they are doing their level best for respecting, promoting, and fulfilling their obligations towards access to medicines. Furthermore, the state parties must demonstrate that they have utilised their financial resources adequately and equitably to protect the right of health of those who require it most as per the human rights framework.

4.2.2 Enforcing the right without discrimination

There is an emergent trend in jurisprudence and academic writings that access to medicines forms an indispensable part of the right to health as well as the right to life.[14] Both rights demand state parties to ensure access to medicines for the populations living in their countries without discrimination. Achieving indiscriminate access to medicines remains a challenge to the day. Pandemics such as the COVID-19, AIDS, TB, and malaria remain a test case for the societies where people cannot equally excess lifesaving medicines for various economic, social, and cultural reasons. The discrimination on the bases of gender, sex, race, and poverty remains a big challenge for the ideals of access to medicines as part of human rights.

Paul Hunt, the former UN Special Rapporteur, highlighted the issue of discrimination. In his report, he stressed that the member states to the UN human rights framework need working on removing the discrimination and stigma in relation to people suffering from certain health

[13] Octavio Luiz Motta Ferraz, 'The Right to Health in the Courts of Brazil: Worsening Health Inequities?' (2009) 11 (2) *Health and Human Rights* 33-45

[14] Alicia Ely Yamin, 'Not Just A Tragedy: Access to Medications as A Right under International Law' (2003) 21 *Boston University International Law Journal* 325-369.

conditions.[15] The same issue came under scrutiny during General Comment of the Committee on the Rights of Child stating, "[d]discrimination is responsible for heightening the vulnerability of children to HIV and AIDS, as well as seriously impacting the lives of children who are affected by HIV/AIDS, or are themselves HIV infected. Girls and boys of parents living with HIV/AIDS are often victims of stigma and discrimination as they too are often assumed to be infected."[16] Moreover, the fear of stigma significantly impacts the issue of access to medicines for the affected people. It is the case for women as the status of women often relates to honour of the family or society that is why the affected women are often not taken to health care facilities or to use effective medicines. The sex-workers, especially women, often face discrimination to access the necessary lifesaving medicines. On some occasions, the sex-workers are discriminated based on their migrant status and citizenship, however, the human rights framework demands the member states to protect the rights of the people based on their status as human beings.[17]

The international human rights framework obligates member states to enforce all human rights including access to medicines as part of the right to health or life without any discrimination of colour, sexual orientation, gender, race, and other marginalised groups.[18] Non-discrimination and equality remain the fundamental principles of international human rights.[19] Human rights standards related to access to medicines under ICESCR demand state parties to protect the right of every individual without any sort of discrimination or status in the societies.[20] The same

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[15] Paul Hunt, 'Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' < https://www.ohchr.org/en/issues/health/pages/srrighthealthindex.aspx> accessed 1 May 2020.

[16] UN Committee on the Rights of the Child, General Comment No. 3, 'HIV/AIDS and the Rights of the Child, Committee on the Rights of the Child' (2003) U.N. Doc. CRC/GC/2003/1

[17] Alicia Ely Yamin (n-14) 325-369.

[18] The Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 3, 'The Nature of States Parties' Obligations' < https://www.refworld.org/pdfid/4538838e10.pdf> accessed 23 October 2019

[19] Office of the United Nations High Commissioner for Human Rights and World Health Organization, 'The Right to Health' Fact Sheet No.31 <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf> accessed 23 October 2019

[20] Office of the United Nations High Commissioner for Human Rights and World Health Organization, 'The Right to Health' Fact Sheet No.31 <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf> accessed 23 October 2019

obligations under the International Convention on the Elimination of All Forms of Racial Discrimination demand the state parties to eliminate all sorts of racial discrimination towards public health and medical facilities.[21] In case of any sort of discrimination towards realising the right to health or access to medicines will be a violation of access to medicines. The states are under positive obligations to lift all types of discrimination in the way of access to medicines as part of human rights obligation. The following part will elaborate on various facets of discrimination in the way of access to medicines.

4.2.2.1 Access to medicines related human rights obligations for HIV/AIDS infected people

Obligations of access to medicines for protecting people infected with the COVID-19, HIV/AIDS, and other diseases have not effectively been included in both national and international legal frameworks. Almost 30 million people died for the disease and a similar number of people are infected with the virus needing necessary medicines to protect their lives.[22] The issue is serious in low-income countries where states cannot provide medicines to all infected people. Moreover, the number of AIDS-affected people is rising with every passing year.[23] The populations living in developing and least developed countries are more vulnerable to gender inequality, and socio-economic conditions of the infected people.

The treatment for HIV/AIDS was invented during the 1990s. However, adequate access to treatment remains a challenge for the world. The treatment for HIV/AIDS is antiretroviral (AVR) therapy. The therapy is the composition of three antiretroviral drugs that help in controlling and developing the HIV/AIDS virus. During 2011, 54 percent of the infected people had access to

[21] Office of the United Nations High Commissioner for Human Rights and World Health Organization, 'The Right to Health' Fact Sheet No.31 <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf> accessed 23 October 2019

[22] UN General Assembly, 'Political Declaration on HIV/AIDS: Intensifying our Efforts to Eliminate HIV/AIDS', A/RES/65/277 (June 10, 2011)

[23] S. Krista Oehlke, et. al., 'Access to Medicines and Human Rights' < https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/> accessed 23 October 2019

medicines and in the case of children, the number was as low as 28 percent.[24] The issue of access to medicines has multiple factors such as affordability, accessibility, and availability. During the last 20 years, access to antiretroviral has improved through price reduction after legal and civil society struggles around the world. However, the issue of access to antiretroviral still exists as the number of infected people is on the rise.

The member states, around the world, are under the human rights obligations to create access to medicines to the infected populations as the virus, if not treated, violates right to life and health of infected patients. The states are under obligation to respect, protect, and fulfil the right of their populations for access to medicines. For instance, Namibia is struggling with its access to medicines programs related to HIV/AIDS infected people. It is an international legal obligation of Namibia to ensure that no obstruction to access to medicines exists in its territories. This may be affordability, accessibility, availability, or quality of medicines. Further, the state is under obligation to create awareness about the right of people to access the medicines among pharmaceutical companies and other stakeholders. Finally, yet importantly, the state must adopt laws and policies to create access to medicines. Apart from the national obligations of Namibia towards creating access to medicines, it is the international obligation under ICESCR for the state parties to help Namibia deal with the issue of threat to the right to health and right to life.[25]

4.2.2.2 The obligation of access to medicines for children

Almost 8 million children around the world die for curable diseases like diarrhea, pneumonia, TB, and HIV/AIDS before reaching the age of five.[26] The issue of HIV/AIDS is significant as the virus is transmitted to newly born children. The virus develops slowly and that is why it is hard to diagnose and start early treatment. Other diseases such as malaria, TB, and infectious diseases, for

[24] S. Krista Oehlke, et. al., 'Access to Medicines and Human Rights' < https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/> accessed 23 October 2019

[25] World Health Organisation, 'HIV/AIDS: Antiretroviral Therapy' < www.who.int/hiv/topics/treatment/en/> accessed 23 October 2019

[26] S. Krista Oehlke, et. al., 'Access to Medicines and Human Rights' < https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/> accessed 23 October 2019

poor health conditions and malnourishment issues, affect the children in low-income countries. For this reason, a large number of children cannot reach the age of 5 years.[27]

The populations living in developing and least-developed countries often cannot access medicines for treating infant disease that is a violation of the right to health as well as the right to life. The issue of drugs required by children is more serious as it requires certain conditions of age, weight, and physical conditions. It is a part of human rights obligations that not only treatment is available but also suitable to treat children. The WHO addressed the same issue by defining and medicines list for the children.

4.2.2.3 Access to medicines for Women

Creating the right to health facilities for women has been a challenge in developing and least-developed countries for socio-economic and cultural reasons. The women often face the issue of maternal mortality, shortage of medicines for females, less access to health care facilities for limited mobilisation opportunities, substantial blood loss, and unavailability of female medical experts.[28] Moreover, access to medicines related to reproductive and sexual health is one of the duties of the states under General Comment No. 22 explains the right to reproductive and sexual health.[29] For enforcing CEDAW, the committee for implementation of the treaty stressed the issue of sexually transmitted diseases as part of women the right to health. The recommendations included obligations of the states to provide information and services related to sex-related health issues.[30] The recommendations mention that "States parties should ensure, without prejudice or

[27] S. Krista Oehlke, et. al., 'Access to Medicines and Human Rights' < https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/> accessed 23 October 2019

[28] World Health Organization, 'WHO Recommendations for the Prevention and Treatment of Postpartum Haemorrhage' (Geneva: WHO, 2012)

[29] Committee on Economic, Social and Cultural Rights, 'General comment No. 22 (2016) on the right to sexual and reproductive health'

[30] S. Krista Oehlke, et. al., 'Access to Medicines and Human Rights' < https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/> accessed 23 October 2019

discrimination, the right to sexual health information, education, and services for all women and girls."[31] The issue of access to medicines is seriously related to women's health.

The women living in low-income countries face discrimination in accessing medicines and other health facilities. The aforementioned arguments have highlighted the concerns of UN Special Rapporteur the issue of discrimination and stigma related to treating women related disease. Recently, viruses such as Ebola, Zika, and other diseases have affected women more than other factions of society. The states are under obligation to remove all barriers to sexual, reproductive, and medicines treating prevalent diseases in low-income countries.

To deal with the recent outbreak of the COVID-19 outbreak, the committee for CEDAW called all state parties to protect the human rights concerns concerning women. The committee has stressed on mitigating the impact of socio-economic change on the women to create a gender balance. The committee calls all state parties to keep a gender-balanced approach in protecting health, and other socio-economic aspects of human life.[32] The statement from the committee notes, "The Committee also fears that restrictions imposed due to the health threats could fuel nationalism, populism, xenophobia as well as compounded and multiple discrimination against women belonging to minority groups of all kinds in particular women at the bottom of the economic ladder."[33] The issue of COVID-19 and other pandemics needs global solidarity and non-discrimination in protecting everyone as the disease does not discriminate against anyone or any class.

4.2.2.4 Issue of access to medicines for Prisoners

With special reference to the COVID-19, the prisoners are more vulnerable to contract contagious diseases. Several states have started releasing a large number of inmates to save their right to life and health. The right to health for prisoners and detained often comes under domestic and

[31] S. Krista Oehlke, et. al., 'Access to Medicines and Human Rights' < https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/> accessed 23 October 2019

[32] Committee on The Elimination of Discrimination Against Women, 'Call for joint action in the times of the COVID-19 pandemic' < https://www.ohchr.org/en/hrbodies/cedaw/pages/cedawindex.aspx> accessed 1 May 2020.

[33] Committee on The Elimination of Discrimination Against Women, 'Call for joint action in the times of the COVID-19 pandemic' < https://www.ohchr.org/en/hrbodies/cedaw/pages/cedawindex.aspx> accessed 1 May 2020.

international discussions. The right to health grants protection of rights for every individual without the discrimination of prisoners or free persons. The states are under obligation to protect the right to health as well as the life of a person under detention or prison. Being in detention does not deprive a human being of his or her basic human rights. However, the conditions in the jails are not as they are in normal life. The prisoners are more prone to human rights violations including access to medicines.[34]

Prisoners are more vulnerable to diseases because of poor health conditions, malnutrition, inadequate health care system, and the spread of infectious diseases because of continuous contact with other prison mates. Diseases such as the COVID-19, TB, malaria, and other infectious diseases spread at a fast pace among the prisoners. Moreover, the prisoners are open to unsafe sexual contacts that may cause them to suffer from the HIV/AIDS virus. In countries like the USA, Russia, and prisons of other states have been alleged for violations of human rights especially access to health care facilities.[35]

It is worth understanding that prisoners have less privileged to access medicines in comparison with free persons, as they are very dependent on jail authorities. There are other issues related to access to medicines for example affordability and prescription system. This leads to a violation of rights related to access to medicines. The prisoners are one of the vulnerable factions that may suffer worse from the issue of access to medicines. Therefore, the state parties must create indiscriminate access to medicines of the prisoners in their territories.

4.2.2.5 Prevention of Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment

The prevention of torture and inhuman treatment becomes relevant to access to medicines in the case of pandemics such as the COVID-19. Not only the prisoners are under threat of inhuman and degrading treatment but also it affects the life of families of the prisoners and the staff working to control the pandemics. The right is non-derogable and the states are under obligation to protect its populations from any aspect of inhuman and degrading treatment. On the 7th of April 2020, the

[34] S. Krista Oehlke, et. al., 'Access to Medicines and Human Rights' < https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/> accessed 23 October 2019

[35] S. Krista Oehlke, et. al., 'Access to Medicines and Human Rights' < https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/> accessed 23 October 2019

sub-Committee on the prevention of torture has issued guidance for the state parties to protect the vulnerable citizens in prisons, liberty-deprived, refugee camps, hospitals, quarantine facilities, psychiatric medical facilities, and other government-controlled places.[36] The committee has prepared a detailed guideline for the states to make sure that the prisoners or other people affected by the pandemics do not face any facet of torture, inhuman or degrading treatment.[37] The committee has also elaborated various standards of protecting the human liberty of those who are placed in the quarantine facilities. The suggestions include taking all emergency measures to protect the right to health and the right to life of citizens.

The recent outbreak of the COVID-19 has highlighted the issue of access to medicines and health-care for prisoners and others who are possibly affected by the diseases. The guidelines of the committee under the optional protocols find its obligations of the state parties to prioritise the protection of the health of all those who are affected by the disease. Treating the issue of access to medicines under the right of the prohibition of torture and other cruel or inhuman treatment can elevate the standards of protecting access to medicines as a human right.

4.3 States obligations under Right to Life

The obligations related to the right to life has been evolving from negative obligations to positive measures for protecting life and its related facets.[38] The HRC, in its recent General Comment No. 36 on right to life of ICCPR, requires the wider interpretation of the right to life mentioning: "The right to life is a right which should not be interpreted narrowly. It concerns the entitlement of individuals to be free from acts and omissions that are intended or may be expected to cause their

[36] UN Subcommittee on Prevention of Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment 'Advice of the Subcommittee to States parties and national preventive mechanisms relating to the coronavirus disease' < https://undocs.org/CAT/OP/10> accessed 1 May 2020.

[37] UN Subcommittee on Prevention of Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment 'Advice of the Subcommittee to States parties and national preventive mechanisms relating to the coronavirus disease' < https://undocs.org/CAT/OP/10> accessed 1 May 2020.

[38] United Nations Human Rights Committee, General Comment No. 36 on Article 6 of the International Covenant on Civil and Political Rights – Right to life, para 26; UN Human Rights Committee (HRC), *CCPR General Comment No. 6: Article 6 (Right to Life)*, 30 April 1982 <https://www.refworld.org/docid/45388400a.html> accessed 16 September 2019

unnatural or premature death, as well as to enjoy a life with dignity."[39] The comment include positive measures in the scope of the right to life stating that the states are under obligation to protect the right to life of its citizens against unnatural and premature death. The interpretation agrees with the academic arguments demanding the positive obligations of the state parties under the scope of the right to life.

The status of the right to life is the most significant among all other human rights.[40] In the case of access to medicine, the domain of rights often overlaps between the protection of health and life. The issue of access to medicines becomes acute in the case of life-threatening diseases such as HIV/AIDS, cancer, and others. On the same notion, diseases such as the COVID-19, TB, Malaria, and infections, if not treated with proper medicines, often lead to the death of the patients. In this situation, the state parties' inaction towards creating availability, accessibility, and affordability can deprive the populations of their right to life. The text of Article 6 of the ICCPR mentions that "no one shall be arbitrarily deprived of his life".[41] As mentioned in the earlier paragraph, the scope of the right to life is widening and it is not only death resulting from the direct action of the sates but also it applies to the obligations of the state parties to create necessary conditions for the existence of life that include access to medicines to treat life-threatening diseases.[42] In 1982, the HRC called for the wider interpretation of the right to life stating that the restrictive interpretation of the right does not effectively protect the individuals in the state parties.[43] The committee called state parties to take all necessary positive steps towards their obligations under the right to life. These positive obligations reducing infant mortality, eliminating epidemics, and increasing life expectancy in their territories.[44]

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[39] United Nations Human Rights Committee, General Comment No. 36 on Article 6 of the International Covenant on Civil and Political Rights – Right to life, para 26; UN Human Rights Committee (HRC), *CCPR General Comment No. 6: Article 6 (Right to Life)*, 30 April 1982 <https://www.refworld.org/docid/45388400a.html> accessed 16 September 2019

[40] Alicia Ely Yamin (n-14) 325-369.

[41] International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171, Article 6 (1)

[42] Alicia Ely Yamin (n-14) 325-369.

[43] Ibid.

[44] Alicia Ely Yamin (n-14) 325-369.

The European Convention on Human Rights adopts the wider interpretation approach towards the right to life. Article 2(1) of the convention includes the right of everyone towards the protection of life under the law.[45] The interpretation of right includes the obligations of states to prevent itself from arbitrary killing along with taking all necessary steps for the unintentional deprivation of life.[46] Learning from European jurisprudence, the Indian Supreme Court, in *Frances Mullen v. Union Territory of Delhi*, found that the right to life includes the standards of living with the dignity that includes necessities of life such as shelter, clothing, nutrition. The court found that the acts that obstruct or impair human dignity might violate the right to life itself.[47] In case of access to medicines, the India Supreme court has found that living with dignity is closely knitted with the right to health.[48] The scope of the right to life, concerning access to medicine, is found in the findings of the Columbian Constitutional Court that finds that the treatment of HIV/AIDS falls under the right to life and human dignity. The court affirmed that the right to life is not a mere biological existence. Rather, states must facilitate the population to live with dignity.[49]

General Comment No. 36 of the HRC interpreted obligations under the right to life including positive steps by the state parties towards protecting the populations from both direct and indirect threats to the enjoyment of life with dignity. The comment note:

"The duty to protect life also implies that states parties should take appropriate measures to address the general conditions in society that may give rise to direct threat to life or prevent individuals form enjoying their right to life with dignity. The general conditions may include high levels of criminal and gun violence…, the prevalence of life threatening diseases, such as AIDs, tuberculosis or malaria, and for improving access to medical examinations and treatments designed to reduce maternal and infant mortality."[50]

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[45] The European Convention on Human Rights (ECHR), Article 2

[46] Alicia Ely Yamin (n-14) 325-369.

[47] Francis Coralie Mullin v. The Administrator, Union Territory of Delhi (1981) 2 SCR 516; *Sheetal Shah, 'Illuminating the Possible in the Developing World: Guaranteeing the Human Right to Health in India' (1999) 32 Vanderbilt Journal of Transitional Law 435, 467*

[48] Francis Coralie Mullin v. The Administrator, Union Territory of Delhi (1981) 2 SCR 516; Ibid.

[49] Alicia Ely Yamin (n-14) 325-369.

[50] United Nations Human Rights Committee, General Comment No. 36 on Article 6 of the International Covenant on Civil and Political Rights – Right to life, para 26; UN Human Rights Committee (HRC), *CCPR General Comment*

The right to life is a supreme and non-derogable right.[51] Moreover, the right to life overlaps in its obligations with the right to health in case of life-threatening diseases. In case of access to medicines in life-threatening diseases such as the COVID-19, HIV/AID, malaria, TB, and other infectious diseases, it is not only domain and scope of the right to health rather the state parties are under an international legal obligation to protect the right to life of the patients. The comment calls all state parties to give a wider interpretation of obligations under the right to life. The restraint of the state parties from depriving the individuals of arbitrary death does not suffice the purpose of the provision. The state parties to ICCPR are under obligation to take positive steps for realisation of the right to life. These positive steps include access to medicines in pandemics and epidemics where a part of the population is suffering from life-threatening diseases. Thus, Article 6 of the ICCPR not only guarantees life but also obligates the state parties to help their populations lead their lives with dignity.

4.4 Obligations of Access to Medicines under the right to health

The demand for access to medicines forms part of the obligations of states under the right to health of ICESCR. Along with the ICESCR, several treaties include provisions of protecting the health of children, women, prisoners, and other vulnerable factions of the society.[52] Defining the domain of health has always been debated. However, the recent interpretation by the CESCR, the WHO, and other international forums have marked the fundamental elements of the obligations related to the right to health.[53] The fundamental provision of international legal framework setting the right to health remains Article 12 of the ICESR that recognizes the right of everyone, without

No. 6: Article 6 (Right to Life), 30 April 1982 <https://www.refworld.org/docid/45388400a.html> accessed 16 September 2019

[51] United Nations Human Rights Committee, General Comment No. 36 on Article 6 of the International Covenant on Civil and Political Rights – Right to life, para 26; UN Human Rights Committee (HRC), *CCPR General Comment No. 6: Article 6 (Right to Life)*, 30 April 1982 <https://www.refworld.org/docid/45388400a.html> accessed 16 September 2019

[52] General Comment No.14 of the CESCR (n-6)

[53] Sheetal Shah, Illuminating the Possible in the Developing World: Guaranteeing the Human Right to Health in India, 32 *Vanderbilt Journal of Transnational Law* 435, 467 (1999) 442-50

discrimination, to enjoy the highest attainable standards of health, both physical and mental. Therefore, parties to the ICESCR are under the international legal obligation to take all necessary steps to protect the right to health of their populations.

To elaborate the scope of the issue of access to medicines, Article 12 states that the states parties to the covenant are under obligation to take steps for the "the prevention, treatment and control of epidemics, endemics, occupation and other diseases".[54] Concerning the control of the diseases as part of human rights obligations, the state parties are under obligation to create necessary conditions to ensure medical services for the patients. The part of the provision witnesses that access to medicines is part of obligations related to the right to health. Treating people suffering from epidemics, pandemics, and other widespread diseases are not possible without access to required medicines. The elements of access to medicines have already been discussed those include availability, affordability, accessibility, and quality of the medicines. Moreover, the role of WHO is elementary in defining the list of medicines that helps the state parties in performing their obligations towards the right to health of the ICESCR.

The authoritative interpretation of the right to health is available in the shape of General Comment. The comment is not binding but they are authoritative in terms of defining the contents of the covenant. The CESCR, in its General Comment No. 14, has thoroughly interpreted the obligations of state parties to ICESCR regarding the right to health. The committee has explained the obligations under main titles such as availability, accessibility, affordability, and quality. The state parties to the ICESCR are under obligation to provide health-related goods, services, facilities making them adequately available, indiscriminately accessible, culturally acceptable, and with appropriate quality. In the case of access to medicines, the element of accessibility is very significant as it encompasses the physical accessibility of medicines without any discrimination, economically affordable, and knowledge about the use of the medicines.[55] General Comment No. 14 includes access to drugs among various obligations of the state parties towards protecting the right to health. For defining the domain of access to medicines, the comment adopts the WHO medicines list to refine the scope of the obligations of the state parties.

General Comment No. 14 interprets the role of medicines as the core obligations of the state parties towards protecting the right to health. The core obligations, in contrast with the concept of progressive realization, are prompt and the states are under obligations to their obligations

[54] International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, Article 12.2 (C,D)

[55] General Comment No.14 of the CESCR (n-6) paras 3

without derogation. Moreover, the concept of core obligations under the right to health is not dependent on the development levels of the state parties. In the case of HIV/AIDS, the CESCR has identified the failures of the state parties in performing their obligations towards medicines to deal with epidemic diseases.

As mentioned earlier, the right to health has been included in various international and regional treaties. The obligations under international and regional treaties are mainly connected to the right to health of ICESCR. For instance, Children Convention under Article 24 sets the rule of the right to health for the children.[56] The CEDAW calls all state parties to ensure indiscriminate protection of health for the women as vulnerable factions of the societies.[57] On regional levels, the obligations related to the right to health have been included to set states' obligations for the sick and diseased towards access to public health for protection against endemics and epidemics. The European Social Charter calls all state parties to prevent all endemics, epidemics, and other diseases threatening health and life.[58] Article XI of the American Declaration of Man requires all state parties to protect the right of everyone for the preservation of health with the help of ensuring housing, food, and medical care.[59] The petitioners in Brazil have benefited from the same provision where the courts found that the Brazilian government is under obligation to take necessary curative and preventive steps for protection of the health of part of its population prone to contagious and infectious disease.[60] The fundamental nature of human rights is indivisible as they are interconnected. The rights under international and regional treaties are interrelated and protection of one right is related to the other rights.

Apart from the inclusion of the right to health and access to medicines in international and regional treaties, more than sixty constitutions include provisions for the protection of health in one way

[56] Article 24(1) of the Children's Convention mentions, 'States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services'.

[57] International Convention on the Elimination of all Forms of Racial Discrimination, adopted by UNGA 21 Dec. 1965, U.N. GAOR Res. 2106 A(XX) (entered into force Jan. 4, 1969)

[58] European Social Charter, Art. 11(3) <http://www. conventions.coe.int/Treaty/en/treaties/html/035.htm> accessed 28 October 20

[59] American Declaration of the Rights and Duties of Man, art. 11, OEA/Ser.L.V/ II.82 doc. 6 rev.1, at 17 (1948).

[60] Alicia Ely Yamin (n-14) 325-369.

or another.[61] The domestic courts have started interpreting access to medicines under the right to health, life, dignity, and other related rights. Among these domestic courts from various countries, Argentina, Brazil, Costa Rica, Columbia, India, South Africa, and Venezuela are significant in interpreting the obligations of the state to protect their population from serious issues of access to medicines.[62] The judicial interpretation from these countries include references to the international human rights law. The human rights approach for protecting access to medicines is taking grounds in legal and interpretative frameworks of international human rights as well as at national levels. This approach has become prominent after the issue of HIV/AIDS and access to medicines. The domain of the right to health and life overlap in cases of access to medicines. The courts in Costa Rica explain the obligations for the right to life and health are interconnected.[63]

The state parties to ICESCR are under obligation to protect the right to health and access to medicines under Article 12. The provision obligates state parties to create availability, acceptability, accessibility, and quality of medicines defined by the WHO. The arguments that the right to health and access to medicines is not tenable after the authoritative interpretations by the CESCR. General Comment No. 14 read with WHO guidelines mark the obligations of the state parties towards the right to health especially access to medicines. Therefore, the state parties cannot avoid their core obligations under article 12 of the ICESCR and these core obligations include access to medicines.

4.4.1 Elements of Right of Access to Medicine

Access to medicine has various elements related to the fulfillment of the obligations by the state parties. These elements are interpreted by the CESCR under the right to health. Fundamentally, the right to health calls all state parties to ensure the availability of the health care system including

[61] The Right of Everyone to the Highest Attainable Standard of Physical and Mental Health: Report of the Special Rapporteur, Paul Hunt, submitted in accordance with Commission Resolution 2002/31, U.N. ESCOR, 59th Sess., Agenda Item 23, 20, U.N. Doc. E/CN.4/2003/58 (2003)

[62] Minister of Health v. Treatment Action Campaign, CCT 8/02 (Constitutional Court of South Africa, July 2002); Ceballos v. Instituto de Seguros Sociales, T-484 (Corte Constitucional de Colombia 1992); Alvarez v. Caja Costarricense de Seguro Social, Exp. 5778-V-97, No. 5934-97

[63] Alicia Ely Yamin, (n-14) 325-369

services and medicines. The availability of the medicines further includes a sufficient supply of required quantity, accessibility for everyone without any discrimination in both physical and economic manner, medicines passing the test of cultural needs and medical ethics, and acceptable quality standards.[64] Paul Hunt, the former UN Special rapporteur on the right to health also highlighted the same issue by further explaining these four elements stating that the medicines should not only be available in required quantity but also the state parties must take all necessary measures for developing new medicines to address the issue of diseases in their territory. This guidance was significant towards solving the diseases of various national territories especially neglected diseases where research and development are negligible and the diseases are strengthening every passing day. These diseases include various tropical diseases and other prevailing in less-developed countries because of unhygienic living conditions. The rapporteur further notes that accessibility of medicines includes indiscriminate access to medicines in economic aspects that means affordable to everyone. Another element for access to medicine, in view of the rapporteur, was cultural and medical ethics standards of medicines. The rapporteur explained a condition that the medicines available should comply with the cultural and medical ethics of the beneficiary society. Finally, yet importantly, the condition for access to medicine standards is the quality of available medicine as per effectiveness, efficacy, and quality standards. To add further, Christian Courtis notes, "to ensure indiscriminate access to medicine for all, that they are affordable, effective, safe, and of good quality".[65]

Elements of access to medicine come under judicial examination in various domestic jurisdictions. For instance, the *Minister of Health v. Treatment Action Campaign* discussed the issue of accessibility of Nevirapine, an antiretroviral medicine, that was in stopping HIV/AIDS virus from infected mothers to newly born children.[66] The drug was available at very limited health points and it was not accessible to a major part of the population. In this case, it is important to know that the drug was available free of cost but it was not made accessible for a large number of population. In this case, the Constitutional Court of South Africa interpreted that providing Nevirapine at two centers

[64] General Comment No.14 of the CESCR (n-6)

[65] Christian Courtis, 'Socio-economic Rights before the courts in Argentina' in Fons Coomans (ed.) *Justifiability of Economic and Social Rights: Experiences from Domestic System* (Intersentia 2006) 330

[66] *Minister of Health v. Treatment Action Campaign and Others*, CCT 8/02, SA 721

per province is a failure to address the requirement of affected mothers and children who cannot access the drug for lack of access to these centers.[67]

Almost all human rights form duties to respect, promote, and protect them in member state territories. These steps are taken towards fulfilment of human rights. The following part of the discussion will discuss the right of access to medicine related to respecting, promoting, promoting, and fulfilment.

4.4.2 Duty to Respect Access to medicines

The duty to respect the access to medicine obligates the state parties to refrain from taking any action that interferes with the right of access to medicines. This obligation further extends to abstaining, preventing, or hindering access to medicine in any other possible manner.[68] It was argued that the impairing or preventing access to medicine is in itself broad enough that it includes policies and administration that may result in denial or poor access to medicine rather than interfering in existing right to access health care and medicines.[69] By respecting access to medicines, it includes respecting right holders in their autonomy, freedom, liberty, resources, and action.[70] From this interpretation, it may be understood that the state parties, under the duty to respect, should promote equal access to both access to medicine and other facets of health care.[71] Any denial of access to medicine or other related product may be termed as a violation of the obligation under the right to health of the ICESCR. Under this part of the obligation, the state parties are responsible for avoiding any form of discrimination related to access to medicines. Moreover, states must control any supply of unsafe medicines. The state parties have a positive

[67] *Minister of Health v. Treatment Action Campaign and Others*, CCT 8/02, SA 721

[68] *Government of the Republic of South Africa v. Grootboom* 2001 (1) SA 46 (CC) (Grootboom); *Minister of Health v. Treatment Action Campaign* No 2 2002 (5) SA 721 (CC) (TAC)

[69] Danwood Mzikenge Chirwa, 'The Right to Health in International Law: Its Implications for the Obligations of State and Non-State Actors in Ensuring Access To Medicine' (2003) 19 (4) *South African Journal on Human Rights* 558, 541-566

[70] Ibid.

[71] General Comment No.14 of the CESCR (n-6) para 34

duty to provide all necessary information important for the use of medicines to treat diseases.[72] It will be a violation of the obligation to respect if any policy, legislation, or administrative action of state hinders right to access to medicine in any way possible.[73] Additionally, the state parties are under obligation to keep in mind their duties towards the right of access to medicine when they are entering in any international or regional treaty that may impact the right of access to medicine.[74]

The duty to respect access to medicine is very broad in its interpretation when it covers both domestic and international interaction of the state parties. Access to medicine is not only a national subject but it obligates under the international obligation of the state parties to the ICESCR to respect access to medicines. By the virtue of duty to respect access to medicines, both states and the international community are under obligation to address any national or international law affecting access to medicines.

4.4.3 Duty to Protect Access to medicines

The element of the duty to protect obligates the state parties to take all positive actions necessary saving its populations from any steps that may harm their right of access to medicines. These steps may be of regulating private sector companies and other legal entities who produce or deal with medicines. General Comment No 14 explain the duty to protect:

"inter alia, the duties of state to adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties; to ensure that privatisation of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services; to control the marketing of medical equipment and medicines by third parties…"[75]

Moreover, the duty to protect include assuring equal and indiscriminate access to medicines as well as health care.[76] Under the duty to protect, the state has an obligation to ensure that companies or any other person dealing with medicines makes relevant information available for general

[72] Ibid.

[73] Ibid.

[74] Ibid. para 50

[75] Holger Hestermeyer, *Human Rights and the WTO; The Case of Patents and Access to medicines* (Oxford University Press 2008) 109

[76] General Comment No.14 of the CESCR (n-6)

populations. In the case of market control or private health care facilities, it is the obligation of the state that it meets the criteria of accessibility, availability, and quality of facilities related to health care.[77] Additionally, the member state will ensure that medical practitioners and other professionals have standard skills, education, and follow codes of conduct in health care.[78] The duty to protect extends to vulnerable groups and disables more effectively as the CESCR notes:

"In a context in which arrangements for the provision of public services are increasingly being privatised and in which the free market is being relied upon to an ever greater extent, it is that private employers, private suppliers of goods and services, and other non-public entities be subject to both non-discrimination and equality norms in relationto persons with disabilities."[79]

Discharge of duty to protect access to the medicines of populations can be done by creating systems through laws and policies for the exercise of individuals' rights. The system may include positive duties to act and negative duties to stop certain action those may impede access to medicine. It is not sufficient that the states adopt the laws including access to medicine as human rights. The states need to effectively use all possible administrative and enforcement institutions to achieve realisation of access to medicine effectively. For instance, in corporate governance shareholders get a certain level of protection against company directors and others controlling the finances. The same approach may be applied in access to medicines; it is the duty of the state to ensure that populations exercise their right of access to medicine against all possible impeding practices of companies or any third party.

4.4.4 Duty to Fulfil Right of Access to Medicine

The Duty to fulfil includes taking all necessary steps towards the full realisation of access to medicine for all through legislative, policy, budgetary, and other necessary governmental actions.[80]

[77] Ibid.

[78] Ibid.

[79] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 5: Persons with Disabilities*, 9 December 1994, E/1995/22, available at: https://www.refworld.org/docid/4538838f0.html [accessed 17 May 2020]

[80] Holger Hestermeyer (n-75) 109

The duty also envisages the obligation to promote access to medicines.[81] The state parties are under obligation to ensure that all members of populations are enabled to exercise their right of access to medicine with all freedom by creating awareness of the right.[82] All these steps demonstrate the full realisation of the right. Moreover, as part of the obligation, the states need to give sufficient recognition to the right of access to medicine in their domestic legal system. General Comment No. 14 describes duty to fulfil that the states have,

"to ensure the appropriate training of doctors and other medical personnel, the provision of a sufficient number of hospitals, clinics and other health-related facilities, and the promotion and support of the establishment of institutions providing counselling and mental health services with due regard to equitable distribution throughout the country".[83]

The comment explains that duty to fulfil is the final step towards ensuring access to medicine for the populations living in the member states. The obligation is wider in its scope as it finally includes all steps described in duty to respect and protect. The obligation to fulfil looks a summary of what is described earlier. In this way, the duty to fulfil provides an overall view of elements of the right of access to medicine. Moreover, the comment of the CESCR call the state parties to provide health insurance to their populations as it can play a pivotal role in protecting people against sudden diseases and lack of necessary medicines.[84] Moreover, the state must provide affordable insurance systems in public and private health care systems.

In summary, the right to fulfil requires the state parties to work towards all necessary steps necessary for assuring access to medicine to individuals or communities without any discrimination. Additionally, the state must protect individuals or groups who cannot access the medicines because of financial or other factors.[85]

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[81] Danwood Mzikenge Chirwa, 'The Right to Health in International Law: Its Implications for the Obligations of State and Non-State Actors in Ensuring Access to Medicine' (2003) 19 (4) *South African Journal on Human Rights* 560, 541-566

[82] Ibid.

[83] General Comment No.14 of the CESCR (n-6) para 36

[84] Ibid.

[85] Danwood Mzikenge Chirwa (n-81) 561, 541-566

4.5 Access to medicines Obligations of Pharmaceutical Companies

Human rights campaign for setting liabilities of pharmaceutical companies towards the right to health became prominent after extraordinary prices of first-line anti-retroviral medicines treating HIV/AIDS. Access to medicine related concerns were raised by affected populations living in low-income countries, civil societies, INGOs, and other international organisations. This resulted in creating awareness and certain steps taken by the pharmaceutical companies towards rationalising their approach for access to medicines. Although, the campaign for human rights consideration was not successful to a greater extent it brought awareness, development of voluntary guidelines by corporations to avoid possible human rights violations, and mechanism to ease access to medicines in low-income countries.[86] These efforts remained to the level of establishing a conceptual framework towards the right of access to medicines and now it is time to create legally binding obligations of pharmaceutical companies towards human rights in general and access to medicine particularly.

On obligations of pharmaceutical companies towards the right of access to medicines, UN Special Rapporteurs and the General Comment by the CESCR have tried to provide a normative framework for binging obligations related to access to medicines. The issue of access to medicine is trans-national and it takes global cooperation and coordination to serve the concerns of access to medicines. This framework may follow principles settled by Article 12 of the ICESCR, the WHO constitution, the UDHR, the Convention on the Elimination of All Forms of Discriminations, General Comment No. 4, and the convention on the Rights of Child. To create legally binding rules on the protection of health and access to medicines, a framework convention will help clarifying obligations of non-state actors towards the right to health and access to medicines. The UN Special Rapporteur has called for the same in the report named 'Human Rights Guidelines for Pharmaceutical Companies' related to access to medicines.

To highlight the obligations of pharmaceutical companies, Holger Hestermeyer has argued that the text of human rights instruments is reflected in deciding obligations for the pharmaceutical companies. He argues that where obligations apply to states and non-state actors, text generally defines obligation such as 'no one shall be held in slavery' and when it is the obligation of states it

[86] Anand Grover et, al. 'Pharmaceutical Companies and Global Lack of Access to medicines: Strengthening Accountability under the Right to Health' (2012) *Journal Of Law, Medicine & Ethics* 237, 234-250

mentions the words like 'The states parties to the present Convention…'[87] The Portuguese Constitution adopts the same approach where it obligates public and private organisations towards freedoms and rights guaranteed in it.[88] In a way, pharmaceutical companies become responsible for their duties of respecting the right of access to medicines.

The ICESCR and the ICCPR on subjects of human rights mention that "The individuals, having duties to other individuals and to the community to which he belongs, is under a responsibility to strive for the promotion and observance of the rights recognised in the present Covenant".[89] The same approach has been observed by Holger in interpreting Article 29(1) of UDHR mentioning that everyone got duties related to the community were free and full development of his personality. Although preambles do not have the binding force they can guide for framing future legal obligations of pharmaceutical companies towards the right to health and access to medicines. Arguments of the other side focus on the text of Article 2 of the ICESCR where it makes states the only subject of the covenant. Holger quotes that the arguments may be rebutted by the text of Article 5(1) of the ICCPR that states: "nothing in the present Covenant may be interpreted as implying for the State, group or person any right to engage in any activity or perform any act aimed at the destruction of any of the rights and freedoms recognised herein…"[90] Interpreting the duties of corporations towards the international human rights treaties, the US Supreme Court has held corporations liable towards international agreements.[91] In this regard, the operation of pharmaceutical companies often interferes with the issue of access to medicines.

Moreover, pharmaceutical companies play an important role in both research and development and access to medicines worldwide. Their role is significant towards the protection of the right to health and access to medicines. Although pharmaceutical companies have developed their voluntary mechanism to support access to medicines, however, it needs development at

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[87] Holger Hestermeyer (n-75) 95

[88] Danwood Mzikenge Chirwa (n-81) Rights 564, 541-566

[89] Holger Hestermeyer (n-75) 95

[90] International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171, article 5.1; Holger Hestermeyer, *Human Rights and the WTO; The Case of Patents and Access to medicines* (Oxford University Press 2008) 96

[91] Paul Hunt, 'Human Rights Guidelines for Pharmaceutical companies In Relation to Access To Medicines' < http://repository.essex.ac.uk/4425/1/human-rights-guidelines-pharmaceutical-companies-access-medicines.pdf > accessed 1 May 2020.

international legal standards under guidelines of the ICCPR and the ICCESR. The UN Special Rapporteurs have stressed on the need for establishing obligations of pharmaceutical companies towards access to medicines in their reports. Therefore, it is need of the time that a framework convention on obligations of the corporation and other third parties, who can potentially affect access to medicines, is done to solve the issue.

4.6 The UN Special Rapporteur on the Obligations of Pharmaceutical Companies

Paul Hunt, the former UN Special Rapporteur, presented his findings in a report titled "Human Rights Guidelines for Pharmaceutical Companies concerning Access to medicines".[92] The report helped to establish the normative framework for the human rights obligations of pharmaceutical companies. The guidelines focused on the right to health and access to medicines as a part of the obligations of pharmaceutical companies. The fundamental purpose of these guidelines is to include pharmaceutical companies in efforts for creating access to health and medicines globally. Although these guidelines stand as one of the significant steps towards highlighting the importance of the right to health and access to medicines they suffer enforcement challenges, as they do not take the status of the direct and legal obligation of pharmaceutical companies.[93] The preamble mentions the work of Special Representative, John Ruggie, and explains that private corporations and organisations owe duties towards human rights. The same notion is explained that pharmaceutical companies, individual patent holders, generic companies need to perform their duties towards the human right of access to medicines.[94]

Human rights guidelines for pharmaceutical companies include the adoption of human rights policy recognising the significance of human rights with special focus on right to highest attainable standards of health towards their programs, policies, projects, and strategies.[95] Another guideline focuses on integrating the human right of health in all research and development activities of

[92] Anand Grover et, al. (n-86) 237, 234-250

[93] Ibid.

[94] Ibid.

[95] Ibid.

pharmaceutical companies.[96] These guidelines focus on human rights generally and access to medicine in particular under human the right to health. There is no binding or legal effect of these guidelines rather they are recommendations for the pharmaceutical companies. Even if the pharmaceutical companies adopt these guidelines; there is no enforcement mechanism for them. However, these guidelines stand as the start of developing an international legal framework to control the conduct of pharmaceutical companies towards access to medicines. The guidelines may act as accountability standards for future international human rights regulations for pharmaceutical companies. Part eight of the guidelines mention that company alone or in collaboration with other companies should establish an independent forum for considering that may arise in relation to access to medicines. The body will act as an accountability and monitoring mechanism. This will form an internal accountability mechanism for pharmaceutical companies concerning human the right to health and access to medicines. However, the state parties to the international human rights law can bind the pharmaceutical companies to access to medicines related human rights.

4.7 Conclusion

The examination of the arguments finds that the state parties to the International Bill of Rights and other international are under obligation to protect, promote, and fulfill the access to medicines related human rights obligations. The access to medicines related human rights obligations is evolving in their domain and scope at both national and international levels. The chapter has focused on the nature of access to medicines related human rights obligations stemming from the right to life and health. In the virtue of the right to health, the research finds that the scope of access to medicines under the right to health is well explained by the General Comment of the CESCR. Moreover, the definition of medicines is well-established in the WHO documents. The research thoroughly examined the nature of rights to health as progressive. The arguments contend that access to medicines falls under the core obligations of the state parties under the right to health and progressive charter of realizing the right to health cannot be used as an excuse. The states are allowed to priorities their national requirements in terms of access to medicines. However, they cannot use limited finances or other justifications from satisfying their maximum efforts to deal with the issue of access to medicines. Moreover, the states are under obligation to create indiscriminate access to medicines in case of pandemics, and epidemics to all of their population especially most vulnerable such as women, children, prisoners, and other vulnerable factions. The chapter finds that the scope of access to medicines is widening as recent General Comment by the HRC include access to medicines under the preview of the right to life. The

[96] Ibid.

Comment call all state parties to take all necessary steps protecting their populations from life-threatening diseases. Moreover, the comment call the state parties not to interpret the right to life in a narrower sense. This will help the state parties to adopt a new approach towards the right to life in their domestic laws. Moreover, the wider interpretive approach towards the right to life will help courts in the state parties to interpret access to medicines under both the right of health and life.

Chapter 05: The Limitations related to States obligations of Access to Medicines

5.1 Introduction

This chapter maps the limitations in the way of recognising and enforcing access to medicines related human rights obligations. The state parties to the international human rights instruments face several limitations in enforcing access to medicines related human rights obligations. Along with the lack of adequate financial resources, the state parties to human rights instruments try to find refuge in the progressive nature of access to medicines, weaker remedial system, and lack of international enforcement framework. Protecting patents on medicines under the TRIPS Agreement is also one of the significant limitations affecting access to medicines as a human right. Protection of patents, in isolation to human rights ideals, adversely affects the availability, accessibility, and most important affordability of medicines. These limitations affect the ability of developing and least-developed states to perform their access to medicines related human rights obligations.

The chapter will critically examine the limitations to map various challenges in the way of establishing access to medicines as a part of international human rights. The examination of the limitations in the way of access to medicines can help in developing an effective human rights framework. The arguments will help to suggest a workable human rights framework for access to medicines in the coming chapter.

5.1 General Limitations

5.1.1 Poverty and access to medicines

The recent outbreak of the COVID-19 pandemic shows that how the diseases and health-care issues impact the personal and national economic systems. On the national level, the countries are trying to balance the impact of lockdown and unemployment on national economies. Similarly, the individuals are facing the financial issues and fear of being evicted from their properties by the landlords and financial institutions. The issue of adequate health-care and access to medicines impacts compound on almost all aspects of individual and national life.

The correlation between poverty and access to medicines is multi-dimensional. Depriving the masses of medicines may lead to poor health that may lead to a threat to life as well. The issue of

poverty and access to medicines is directly proportional to each other as poverty leads to poor health conditions and otherwise. Poverty may lead to various factors such as sanitation issues, lack of hygienic living conditions, lower quality food, and water that may lead to disease. Whenever health-related facilities, including access to medicines, are not available or delayed, the conditions of the health standards deteriorate with the issue of poverty.[1] The populations living in low-income countries do not enjoy the equal levels of access to medicines in comparison with the developed countries. Economic empowerment helps the populations choose their healthy lifestyles. Economic empowerment and health go hand in hand, as the relative finances help building capabilities and these capabilities can turn in accessing basic health care facilities including access to medicines. The issue of inequitable access to medicines is not an alone challenge for the economic front as it also falls under human the right to health and life.

Although it is challenging to define the term poverty, however, there is the agreement that poverty is a state where the population faces unjust differences in potentials and limitations in making choices related to health-related facilities including access to medicines.[2] A low-income that may put a person on the status where one cannot access health care facilities may be understood as poverty. The issue of accessing medicines often require multi-facet accessibility challenges that depend on adequate finances. The patients, in low-income countries, often need traveling a long distance to access health care services including access to medicines. The other part is affordability where the prices of the medicines are within the economic capabilities of the patients.

The issue of poverty affects access to medicines at both individual and state levels. The developing and least-developed countries often have less health care establishments in comparison with developed countries for inadequate financing of health-related issues. The low-income countries, where diseases burden is almost 90 percent, spend only 12 percent of the total global spending.[3] For instance, the USA spends almost USD 3039 per capita on its population as compared to an average of USD 30 per capita in low-income countries.[4] For the reason of parity in total health spending, the health-related facilities in low-income countries are scarce in comparison with developed countries. The populations living in developed countries often rely on national health

[1] Deepa Narayan, et al., *Voices of the Poor: Can Anyone Hear Us?* (Oxford University Press 2000) 44

[2] Ibid.

[3] P.G.Schieber Gottret, 'Health FinancingRevisited: A Practitioner's Guide' (2008) The World Bank.Washington.

[4] Pablo Gottret and George Schieber, *Health Financing Revisited: A Practitioner's Guide* (The World Bank 2006) 38

care while it is very hard for low-income countries to provide similar health care for all its populations. This is why diseases further worsen the conditions of poverty where almost 60 percent of the total populations privately finance their health care facilitates including access to medicines. In case of access to medicines, the investment in research and development of new medicines is very large in comparison with low-income countries.

Despite uplifting efforts to create access to medicines in developing and least-developed countries, the gap in accessing health care facilities is widening. The poor populations in low-income countries do not have equitable access to medicines and suffer from high disease burden with very scare access to health facilities. The fundamental issue related to accessing medicines is affordability. The issue needs a human rights framework for creating access to medicines for the poor populations living in developing and lease-developing countries.

5.1.2 Health Systems and Access to Medicines

The issue of access to medicines does not stand aloof from the overall health care system and the regulation by the states. A poorly regulated and less-organized health care system may adversely contribute to the issue of access to medicines.[5] The availability, accessibility, and affordability of medicines form a part of the overall health care system. The role of medicines is integral for smoothly running primary health care systems. However, the regulation of medicines and pharmaceutical producers include various factors such as licensing, registration, procurement, selection, procurement, and clinical trials. The states have the authority to regulate medicines related issues. The states are under obligation to deal with the issue of availability, affordability, and accessibility of medicines. The weak regulation of medicines related issues may affect access to medicines and health care systems in developing and least developing countries.

Ineffective public or state accountability, corruption, and lower priority to health systems may contribute to the issue of access to medicines. Moreover, the states have conflicting obligations towards protecting the economic and trade interest of pharmaceutical companies and on the other hand, they need to protect the standards of access to medicines under human rights commitments in both international and national laws. The issue of protecting intellectual property rights under

[5] Ibid.

the WTO aspirations and performing duties towards access to medicines under the human rights framework often come under debate. Conflicting regulations adversely affect access to medicines. Protecting intellectual property ideals related to patents on medicines may lead to the issue of affordability of access to medicines.

The factors behind access to medicines are challenging as it includes health regulation, human resource, health information, and regulating pricing, procurement, licensing, and registration of medicines. An effective system of regulating health-related aspects of medicines can play a role in solving the issue of access to medicines. The states need to effectively deal with the issue of access to medicines by adopting policies, regulations, adequate distribution, and a supportive health care system.

5.1.3 Neglected Diseases and Access to Medicine

Almost one billion people suffer from one of the neglected diseases all around the world.[6] Almost 149 states battle with neglected diseases where 70 percent of affected patients are facing two or more diseases.[7] Neglected diseases are those tropical or other diseases prevailing in poor communities where earning volume, on average, is less than one dollar while the cost of curing these neglected diseases is 0.02-1 USD. James Love, a famous health activist, calls for public funding towards inventing medicines related to neglected medicines and state:

"[G]overnments could expand direct funding for drug development, either through the exi[s]ting structures such as the NIH collaborations with industry and academia, or through non-profit development projects, such as those currently resourced to address treatments for neglected diseases like malaria and TB"[8]

[6] Amal K. Mitra, Anthony R. Mawson, 'Neglected tropical diseases: epidemiology and global burden' (2017) 2 (3) Tropical medicine and infectious disease 36-51; Bryan Christopher Mercurio, 'Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to medicines' (2007) 5 *Northwestern University Journal of international human rights* 1-40

[7] Ibid.

[8] Tim Hubbard, James Love, 'A New Trade Framework for Global Healthcare R&D' (2004) 2 (2) *PLOS Biology* 147-150

If we compare this price with developing countries, it is very negligible and can be afforded by everyone but the poverty-line is not the same all across the world. For example, the people living in San Francisco earning less than USD 11700 were declared low income during 2018 and if the figure is compared to developing countries, the same figure may define the elite class.[9] As quoted earlier, a famous study conducted by Thomas Pogge has highlighted the issue of neglected diseases with his famous 90/10 gaps. His study reveals that 90 percent of research and development focus on diseases prevalent in developed countries where a portion of total world disease is a mere 10 percent.[10] On the other hand, developing countries are badly fighting 90 percent of the total volume of disease with a mere 10 percent of research and development for innovating medicines.[11] This is all for the reason of the margin of profitability. Pharmaceutical companies retain the biggest portion of patents on medicines and for the reason of high income and purchasing power in the developed world, they focus on 10 percent of diseases and ignore the rest of 90 percent in developing and least developed countries because of low profitability.[12]

Although neglected diseases such as tropical infections do not lead towards death in the majority of the cases but leave the affected person impaired.[13] Lymphatic filariasis leprosy and leishmaniasis cause deformation in the body leaving it disabled. Schistosomiasis and Guinea-worm are the main factors impacting education and mobility in children. Dengue African trypanosomiasis (sleeping sickness), dengue hemorrhagic fever, Buruli ulcer, and leishmaniasis are those kinds of infectious diseases that may be fatal, in case not treated with a proper medicine.[14] For instance, there are apprehensions for the accessibility of anticipated vaccine to treat COVID-19. The WHO and the UN treaty bodies have expressed their concerns on the accessibility and availability of the vaccine in developing and least developed countries. Moreover, the WHO has asked the state parties to show solidarity in tackling the disease.

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9 <https://sanfrancisco.cbslocal.com/2018/06/26/hud-117000-low-income-san-mateo-san-francisco-marin/> accessed 18th August 2018

10 Matt Peterson, Aidan Hollis, Thomas Pogge, 'A Critique in Need of Critique' (2010) 3(2) *Public Health Ethics* 178, 183

11 Ibid.

12 Ibid.

13 (n-9)

14 Matt Peterson, Aidan Hollis, Thomas Pogge (n-10) 178, 183.

To solve the issue of research and development for neglected diseases, private models are available medicines and acute diseases such as AIDS while diseases like malaria, pneumonia, and other tropical diseases are continuously ignored.[15] Among them is the establishment of the Health Impact Fund (HIF). The fund has not yet turned into a practical venture. Although the HIF model looks attractive in solving the issue of neglected diseases the model has not turned in practice yet. Another issue that we will focus later is companies will join this model as a working model explains the voluntary framework for companies to join HIF or not. Moreover, HIF remains open to the traditional patent practice of medicine, and a patent holder may register its invention to HIF and at the same time enjoy its incentives through the exercise of a patent license. The issue of 'orphan drugs' is also a concern for HIF that cannot be effectively dealt with HIF model.[16] One may contend that the HIF model is still not working and may solve the issue of neglected medicines effectively. Another model is the Medicines Patent Pool (MPP). The pool has started working and has done a good deal of efforts to solve the issue of lifesaving AVRs for AIDS in African countries and other effected developing and least developed countries. MPP is utilising all its possible energies to solve the issue of access to medicine but a critical analysis of the model reveals that it is mainly focused on already existing medicines under patent licenses. The issue of access is resolved through patent-holder consent for registering its product under MPP and later on the production of the same product will be sub-licensed to create market competition. The fundamental model does not have much for the invention of new medicines in developing and least developed countries with the lower scientific and technological capacity to fight neglected diseases.[17] In this way, MPP's operation is very limited in solving the issue of neglected diseases.

Neglected diseases such as TB, malaria, pneumonia, and others quoted above are products of pollution from the evolution of the industrial revolution.[18] Global industries are contributing to the global environment. In this way, it also attracts global responsibility to protect health and access to medicine. However, the debates on protecting health and access to medicine often lose from

[15] Ibid.

[16] Ibid.

[17] Ellen 't Hoen, 'TRIPS, Pharmaceutical Patents, and Access to medicines: A Long Way From Seattle to Doha' (2002) 3 (1) *Chicago Journal of International Law* 27-46, 40

[18] Ibid.

strict pharmaceutical patent protection under the aggressive WTO regime.[19] Moreover, alternate models, discussed in the last chapter, rely on voluntary licensing where pharmaceutical companies are at advantage to facilitate access to medicine at their convenience.[20]

5.1.4 The Issue of Research and Development

The basic reason for protecting patents as intellectual property rights is an incentive. In the case of non-protection of patents, inventors will not have any inspiration for investing their tangible and intangible assists in developing solutions to existing diseases. The conventional patent system offers it for 20 years that is criticised based on high-profit margins, especially in pharmaceutical patents. As quoted earlier, developing a pharmaceutical remedy for existing disease required almost USD 800 million on average which is a huge sum of money. Although there is no proper study to quantify these investments and pharmaceutical companies do not reveal their investment but studies criticise the length of patent protection along with profitability margins. Alternate models have embarked on the journey for compensating patent holders with other than market funding and in return providing medicines on very marginal prices. Funding pharmaceutical incentives remains an issue of concern.

During 2007 WHA stressed on the significance of international public funding for solving the issue of access to medicine in asked Director-General to:

"encourage the development of proposals for health-needs driven research and development for discussion at the Intergovernmental Working Group that includes a range of incentive mechanisms including also addressing the linkage of the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products and a method for tailoring the optimal mix of incentives to a particular condition or product, with the objective of addressing diseases that disproportionately affect developing countries."[21]

[19] Ellen 't Hoen, Bernard Pecoul and Hans Hogerzeil, 'Developing Missing Medicines' in Veronika J Wirtz, Hans V Hogerzeil, Andrew L Gray, et al., *Medicines For Universal Health Coverage* (The Lancet, 2017) < https://www.thelancet.com/commissions/-medicines> accessed 25 December 2018

[20] Ibid.

[21] Ellen F.M. 't Hoen, *The Global Politics Of Pharmaceutical Monopoly Power* (AMB 2009) 12

Various efforts have been made to alienate the cost of research and development of drugs from the price of medicine through the system of incentive.[22] These incentive systems are private and still needs to turn towards public cooperation on collaborating financially in research and development of drugs. A mechanism to boost this cooperation can be achieved as:

"Encourage further exploratory discussions on the utility of possible instruments or mechanisms for health and biomedical R&D, including inter alia, an health and biomedical R&D treaty."[23]

Various international organisations, working for access to medicines, have presented the idea of non-profit research and development and a very few of them have turned in effective production towards access to medicine. Famous Novartis proposal also focused on the issue of neglected diseases.[24] The model did not work for the lack of funding. Another thought of developing prize as an incentive for the inventor of the pharmaceutical drug failed even it was materialised in the shape of legislation.[25]

5.2 Limitations within the Human Rights Framework

5.2.1 Divisibility of human rights treatment

The international human rights theoretically remain indivisible, as they are interconnected. However, practically their enforcement got two different tiers. Indivisibility of human rights is clear from UDHR as a prime document of human rights but the declaration remains non-binding. The binding structure of human rights is bifurcated in two covenants dividing them into CPRs and ESCR.[26] As mentioned earlier, the UDHR, ICESCR, and ICCPR form the International Bill of Rights. It is pertinent to mention that these documents include various human rights with the

[22] Ellen 't Hoen, Bernard Pecoul and Hans Hogerzeil (n-18)

[23] Ellen F.M. 't Hoen (n-21) 12

[24] Ibid.

[25] M.L Barer, et.al., 'Breakthrough drugs and growth in expenditure on prescription drugs in Canada' (2005) *British Medical Journal* 331, 815-16.

[26] Javaid Rehman, *International Human Rights Law* (Pearson, 2012) 141; Mathew Craven, *The International Covenant on Economic, Social, and Cultural Rights, A Perspective on its Development* (Clarendon Press, 1995) 9

principle of indivisibility.[27] Later on, international agreements and regional human rights agreements confirmed the binding and indivisible status of international human rights.[28]

Principles of indivisibility of human rights are for realisation of the international human rights framework under the international bill of rights.[29] The realisation of one aspect of human rights connects with other human rights. For instance, access to medicines mainly falls under the right to health of ICESCR. The implantation of health and life is often interconnected. In the case of COVID-19, HIV/AIDs, and other like life-threatening diseases, it does not only matter or the right to health but also falls under the right to life. Moreover, the right to health and access to medicines share the same normative aspects with the right to human dignity. In this way, enforcing civil and political rights depend on the fulfilment of economic, social, and cultural rights. Dividing rights between two different treaties with distinct enforcement status has been counterproductive towards the universal status of human rights.[30] This is why, the status of enforcement of economic, social, and cultural rights has been inferior to civil and political rights.[31] The same divisibility of rights has been reflected in regional agreements and national treatment of rights under ICESCR. The states have focused on compliance of obligations towards ICCPR and neglected other rights.

For the reason of the divisible treatment of human rights, the justiciability of ESCRs has been under debate. The CPRs have been widely incorporated in domestic constitutions making hem justifiable where domestic courts can interpret any action of legislature or executive against the spirits of civil and political rights.[32] Contrary to this, the ESCRs did not enjoy the same level, as a

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[27] Ibid.; Ida Elisabeth Koch, 'Dichotomies, Trichotomies or Waves of Duties' (2005) 5 *Human Rights Law Review* 81-103; Ibid.

[28] UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 9: The domestic application of the Covenant, 3 December 1998, E/C.12/1998/24 <https://www.refworld.org/docid/47a7079d6.html> accessed 27 March 2020; Mónica Feria Tinta, 'Justiciability of Economic, Social, and Cultural Rights in the Inter-American System of Protection of Human Rights: Beyond Traditional Paradigms and Notions' (2007) 29 *Human Rights Quarterly* 431-459

[29] Daniel Whelan, *The Indivisibility of Human Rights, A History* (University of Pennsylvania Press, 2010) 55

[30] Varun Gauri and Daniel Brinks, *Courting Social Justice: Judicial Enforcement of Social and Economic Rights in the Developing World* (Cambridge University Press, 2010) 16

[31] Katie Boyle, Edel Hughes, 'Identifying routes to remedy for violations of economic, social and cultural rights' (2018) 22 (1) *The International Journal of Human Rights* 43-69

[32] Ibid.

violation of these rights did not allow courts to interpret the level of states' obligations.[33] The CESCR has always worked to elevate the status of rights under ICESCR to the same level as civil and political rights enjoy.[34] The realisation of ESCRs is progressive and this includes various steps such as respect, protect, and fulfil duties. States parties to the ICESCR cannot deny any right under the covenant rather they need to content that the states have taken all possible measures for the enforcement of these rights.

The body of human rights is evolving. Civil, political, economic, social, and cultural rights are open for change by enforcing states except the non-derogable rights. The states may put limitations or define the method of enforcing various human rights in their territories. However, they need to ensure that the measures taken are indiscriminate and with maximum efforts to realise the spirit of human rights. Therefore, the enforcement of ESCRs is always assessed subject to the capacity of states towards these rights. For instance, the right to health and its enforcement will be assessed with different standards among developed, developing, and least-developed countries.[35]

5.2.2 Weaker Remedial System

The international human rights framework provides a remedial system in case of violation of human rights around the world. The concept of remedies is described in Article 8 of UDHR that states, "everyone has the right to an effective remedy by the competent national tribunals for acts violating the fundamental rights granted him by the constitution or by law".[36] UDHR, although a declaration, stands as a mother document for all other human rights documents. Moreover, UDHR does not discriminate among various human rights included in it. This is why Article 8 enshrines the principle of effective remedy from national forums in case of violation of human rights guaranteed by national laws or constitutions.

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[33] Ibid.

[34] Christian Courtis, 'Standards to Make ESC Rights Justiciable: A Summary Explanation' (2009) 2 *Erasmus Law Review* 379-394

[35] Anashri Pillay, 'Economic and Social Rights Adjudication: Developing Principles of Judicial Restraint in South Africa and the United Kingdom' (2013) 3 *Public Law* 599-617

[36] Universal Declaration of Human Rights (adopted 10 December 1948 UNGA Res 217 A(III) (UDHR) Article 8

Differential treatment to the enforcement of human rights happened after the adoption of the ICESCR and ICCPR. The remedial system for human rights may form in two parts. In the first part, national courts recognise human rights and the next stage is their enforcement. The remedies under ICCPR demand state obligations without financial liabilities and ESCR obligations need positive action of state those may include financial liabilities. Overall, remedies against human rights violations may be remedial justice, compensation, condemnation of the retribution, deterrence, or any other form prescribed by the states.[37] Legal remedies for violation of human rights may form two steps such as:

"In the first sense, remedies are the processes by which arguable claims of human rights violations are heard and decided, whether by courts, administrative agencies, or other competent bodies. The second notion of remedies refers to the outcome of the proceedings, the relief afforded the successful claimant."[38]

The opinion defines both theoretical and applied concepts of remedies in the international human rights law. The international human rights, in the first instance, need recognition through state organs such as courts and other bodies dealing with recognition of human rights. The next step is their enforcement and outcomes against human rights-related grievances.

During 2005, the GA resolution 60/147 sets basic guidelines on the remedies against the gross violation of international human rights. The resolution sets basic principles of remedying a violation of human rights and these remedies include cessation of the violence, restitution, compensation for mental and physical loss, moral damage, losing opportunities, rehabilitation by medical facilities, socio-legal services, disclosure of truth, administrative and judicial sanctions, and reforming legislative measures.[39] The resolution is not binding, however, it may help in defining remedies under the international human rights framework.

5.2.3 Are 'access to medicines' related human rights obligations justiciable?

[37] Dinah Shelton, *Remedies in International human rights Law* (Oxford University Press, 2005) 10-15

[38] Ibid. 7

[39] General Assembly resolution 60/147 of 16 December 2005, Basic Principles and Guidelines on the Right to a Remedy and Reparation for Victims of Gross Violations of International Human Rights Law and Serious Violations of International Humanitarian Law

State obligations related to access to medicines fall under both the right to life and health. Human rights are indivisible and there should not exist any discrimination in their enforcement standards. However, the following discussion will examine various limitations in the way of justiciability of access to medicines.

Traditional approaches towards interpreting the right to life do not include access to medicines under the scope of the right. The remedies available under the right to life encompass only negative obligations of the state parties where an individual or group is under threat of losing their lives arbitrarily. However, in recent academic and legal discussions, it is suggested that the scope of the right to life may be open for wider interpretations from just obliging state parties to kill the people or protect them from arbitrary murder. This must also include access to medicines as part of saving a life.[40] The HRC adopts a similar approach by recommending the wider interpretation of the right to life where it may include positive measures towards the protection of the right to life along with negative measures. This includes access to medicines as part of the right to life. Article 2 of the ECHR also endorses the same interpretation where it obligates state parties to adopt positive measures protecting the right to life.[41] However, the issue of access to medicines has not been covered under the right to life or the CPRs enforcement framework in practice. International forums interpreting the right to life limit their interpretations to the extent of states' actions of depriving lives without due process of law. Any arbitrary action by the state against the right to life, or not protecting lives from private parties, may fall under the scope of the right to life. In this case, obligations of state parties remain negative where the state parties are supposed to refrain from any action depriving people of arbitrary loss of life. All other positive steps for saving a life, such as creating access to medicines in case of serious diseases, do not fall under interpretations of obligations related to the right to life. The enforcement of civil and political rights has been more effective than other rights but the issue of access to medicines has not been successful in entering the domain of the right to life yet.

The human rights obligations related to access to medicines also fall under the right to health of ICESCR. Arguments for the non-justiciability of ESCRs base on the undecided domain of these rights as well as their progressive charter. Moreover, the argument focus that the state parties do

[40] Bertand F. Ramacharan, 'The concept and Dimensions of Right to life' in Bertand F. Ramacharan (ed.) *The Right to Life in International Law* (Martinus Nijhoff, 1985) 2, 1-32

[41] Association X v. United Kingdom, Application No. 7154/75 14 Decision and Report 31 (1987) European Commission of Human Rights 32

not have equal capacity to enforce these rights in their states. Another argument uses the concept of separation of power where it reasons that economic, social, and cultural rights will provide more power to judicial organs interfering in the domain of legislatures and states' enforcement agencies. These arguments, if accepted, raise serious concerns about the international legal status of ICESCR. It is general principles of interpretation of statutes that statutes should have a beneficial interpretation that keeps a legal document alive.[42] Judicial organs in the state parties may interpret these rights proportionate to the capacity of the states. The ESCRs, including the issue of access to medicines, are justiciable where the judiciary may play a very vital role by reviewing the governments' endeavors towards enforcing human rights. Judicial organs, in the state parties, mainly balance between the rights of disadvantaged and those who are controlling power. In case of access to medicine, the people who are facing the issue may fall under the definition of marginalised group and the judiciary may stand as custodian of their human rights in case of states' non-compliance with their obligations.[43] Therefore, it may be argued that ESCRs are justiciable and the concept of these rights is not fiction rather of legal obligations.[44] The realisation of ESCRs is progressive but it does not mean that the state parties have unlimited time for their actual enforcement in their territories. These rights, if included in national laws, may provide judicial organs an opportunity to assess the states' measures for their enforcement. The ESCRs are justiciable as CPRs are. The arguments on non-justiciability do not gather mass as ESCRs are for universal human progress.[45]

Human rights obligations related to access to medicines have not succeeded in achieving full enforcement status in the international human rights framework. Although the right to life includes the normativity of access to medicines, however, the interpretation of the right does not include the positive obligations of providing medicines to needy. Academic and legal fraternity have started propagating the inclusion of positive duties under the right to life but it is not successful yet. The limitation of enforcing access to medicines under the right to health are ranging from progressive

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[42] Akirti A. Shashni, 'Beneficial Interpretation in Welfare Legislation: Study of Judicial Decisions in India' (2013) Available at SSRN 2298771 (2013) <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2298771> accessed 26 August 2019

[43] Katie Boyle, Edel Hughes (n-31) 43-69

[44] Mónica Feria Tinta, 'Justiciability of Economic, Social, and Cultural Rights in the Inter-American System of Protection of Human Rights: Beyond Traditional Paradigms and Notions' (2007) 29 *Human Rights Quarterly* 431-459

[45] Ibid.

realisation to the question of justiciability.[46] Avoiding enforcement of the ESCRs because of its broad scope and domain will not benefit the spirit of the declaration and it will influence the credibility of the international human rights framework. Ensuring access to medicines relates to both the right to health and life. The right to health, in many instances, links with the right to life. Mere lesser enforcement standards for the ESCRs that do not lower down the status of these rights. Access to medicines related human rights obligations needs effective enforcement. There are challenges in the way of enforcing access to medicines as a matter of human rights; however, substantive human rights law is clear on the content of access to medicines as part of the right to life and health. Moreover, it would be true to say that, the issue of access to medicines is justiciable under both the CPRs and ESCRs.

5.2.4 Non-binding nature of States obligations

General Comment No. 14 of ICESCR demonstrates explains state responsibility to protect the right to health and access to medicine in the following words:

Ensuring that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilitates, goods and services; controlling the marketing of medical equipment and medicines by third parties; and states ensuring that third parties do not limit people's access to health-related information and services."[47]

The aforementioned paragraph demonstrates the state's duties towards protecting the right to health. This duty is extended towards protecting standards of health and access to medicine from other factors such as trade, corporate hegemony, and other mal-practices having an impact on the right to health as public interest under aspirations of ICESCR.[48] In this way, a state got enough prerogatives to intervene in the case of fake drugs and other practices having an impact on the right to health. It is the obligation of state as is the obligation to protect life and all ancillary threats to life.

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[46] Ibid.

[47] Alicia Ely Yamin, 'Not Just A Tragedy: Access To Medications As A Right Under International Law' (2003) 21 *Boston University International Law Journal* 325-369, 325.

[48] Patrick Wojahn, 'A Conflict of Rights; Intellectual Property under TRIPS, the Right to Health and AIDS Drugs', (2001) 6 UCLA *Journal of International Law and Foreign Affairs* 463-497,96.

In the case of patent monopolies, the state is under obligation to protect monopolies for incentive-based research and development. At the same time, the state must check anti-competitive practices and equitable distribution of medicine ensuring accessibility, affordability, and availability of medicines. Establishment of an efficient regulatory system for access to medicine is the obligation of state not only under national laws but also international laws stress the same. Doha Declarations are specific on the point stating, "each member has the right to grant compulsory licenses and the freedom to determine the ground upon which these licenses are granted".[49] It is worth noting that the use of compulsory licensing to break the cover of the patent monopoly of some lifesaving drug ensuring availability and accessibility has been defined as a sole prerogative of the state, although, the issue of various international and national hindrances remains otherwise. The state must break all abusive practices of patent-holding companies multiplying their profit margins. Various studies have demonstrated these practices by studying barriers affecting access to medicine.[50]

The ICESCR demonstrates that protecting the right to health is a constitutional and international obligation of the state. The state parties are under obligation to develop their laws in consonance with the right to health. Any legislation that impacts the right to health or access to medicines is a clear violation of international law. The states owe obligations towards this covenant to utilise their resources to guarantee indiscriminate access to health and health-care infrastructure. A good deal of other international instruments binds states to perform the same. TheMDGs contain a promise to fight diseases such as AIDS, cancer, tuberculosis, and malaria as universal plans.[51] The CESCR summarises the state obligation towards health in the following words:

"The failure to adopt or implement a national health policy designed to ensure the right to health for anyone; insufficient expenditure or misallocation of public resources which results in the non-enjoyment of the right to health by individuals or groups, particularly the vulnerable marginalised; … and the failure to take measures to reduce the inequitable distribution of health facilities, goods and services."[52]

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[49] Sean Flynn, 'Legal Strategies for Expanding Access to medicines' (2003) *17 Emory International Law Review* 535.

[50] Ibid.

[51] United Nations Millennium Development Goals <http://www.un.org/millenniumgoals/> accessed 9 February 2018.

[52] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, 11 August 2000, E/C.12/2000/4 <https://www.refworld.org/docid/4538838d0.html> accessed 2 September 2019. Herein after named 'General Comment No. 14 of the CESCR'

The courts, in South Africa, have defined the state's responsibility with an objective test of 'reasonable measures' ensuring access to medicine. One of the court's findings noted, "it is courts role 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 have budgetary implications, but are not in themselves directed at rearranging budget".[53] Moreover, this reasonableness may also be seen from the tax and tariff system of the state in the field of pharmaceutical products.

Both national and international instruments make their duty of the state to protect health with all its dedication. An objective test may help in measuring states' efforts towards enforcing human rights. It may be reasonableness in some states while others may be analysed on the bases of their tax and tariff system. Among all this, one standard is common; access to drugs is one of the fundamental pillars to protect the right to health of the population. Now, in the modern globalised patent protection regime, it is uncontested that prices of drugs surge when monopolised. It is not the obligation of states and international organisation to find a balance between pharmaceutical patent protection and the right to health.

5.2.5 The issue of enforcing rights under ICESCR

The scope of the ESCRs is evolving.[54] Although the ESCRs have started gaining strength, however, their status has been marginalised by various factors.[55] The fundamental framework of ESCRs obligates the state parties with human rights obligations included in the covenant. The adoption of Optional Protocols during the year 2008 and the reference of ESCRs in domestic and regional case laws make ESCRs justiciable.[56] However, the ESCRs have not yet gained equal status to CPRs for internal and external reasons. Internally, the textual construction of the ESCRs is not effective

[53] Minister of Health v. Treatment Action Campaign [2002] < https://www.escr-net.org/caselaw/2006/minister-health-v-treatment-action-campaign-tac-2002-5-sa-721-cc> accessed 9 February 201.8

[54] Mashood A. Baderin, Manisuli Ssenyonjo, 'Development of international human rights law before and after the UDHR', in Mashood A. Baderin, Manisuli Ssenyonjo, *International Human Rights Law: Six Decades After the UDHR and Beyond* (Ashgate Publishing 2010) 3 – 27.

[55] Ibid.

[56] Ibid.

for enforcement in comparison with the CPRs. Externally, the state parties, especially developing and least developed states, find it difficult to perform their positive obligations concerning the ESCRs especially the right to health and access to medicines.

The term right to health has been defined as health care, health protection, and health rights.[57] Various national and international legal instruments have taken the right as a basic guarantee for human life. The right to health has developed a significant status in the recent conceptualisation of the welfare state as an integral duty to state towards masses.[58] On international levels, the right forms a part of UDHR and ICESCE, root instruments describing states' duties towards human rights.[59] The status of enforcement of human rights documents has remained a source of debate among various international lawyers and scholars. Holger Hestermeyer calls for the establishment of human rights supremacy over all other rights while writers like Malcolm Shaw consider human rights having established supremacy over all other rights by establishing the binding status of UDHR through state practices having the force of international custom and general principles of international law.[60] Likewise, Ian Brownlie considers UDHR binding upon state parties to it on the analogy of becoming principles of international law based upon humanity and tangibly significant to the international legal system.[61] The literature is available to describe the normativity and enforcement of the right to health recently.[62] The right to health has two main parts; health care and various prerequisites to protect health such as sanitation, clean water, and other relevant conditions of life.[63] Article 12.1 of ICESCR describes the right to enjoy "the highest attainable standard of physical and mental health".[64] This includes access to medicine as the main pillar of

[57] Brigit Toebes, 'The Right to Health' in Asbjorn Eide, Catarina Krause and Allan Rosas (eds), *Economic, Social and Cultural Rights* (Martinus Nijhoff Publishers 2001) 169, 170.

[58] Anthony D'Amato, *The concept of Custom in International Law* (Cornell University Press 1971) 90.

[59] Lisa Forman, 'Ensuring Reasonable Health: Health Rights, The Judiciary, and South African HIV/AIDS Policy' (2005) 33 *Journal of Law Medicine & Ethics* 711-724.

[60] Malcolm N Shaw, *International Law* (Cambridge University Press, Cambridge 2003) 260, 261.

[61] Ian Brownlie, *Principles of Public International Law* (Oxford University Press 2008) 559-560.

[62] Virginia A Leary, 'The Right to Health in International Human Rights Law' (1994) *Health and Human Rights* 24.

[63] Brigit Toebes, (n-57) 125.

[64] International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, Article 12.1.

the right to health and health care. The same connotation of right is included in regional and international treaties.[65] The minimum protection of the right to health includes access to medicine in its definition.[66] Furthermore, access to medicine is further composed of availability, accessibility, acceptability, and quality of drugs.[67] The issue of affordability in developing and least developed countries is a significant question attached to the right to health.[68]

5.3 Does Conflict Exist within the Human Rights Framework?

Article 27 of UDHR and article 15 in the ICESCR set principle of participation of everyone in science and culture under human rights. These provisions provide everyone with the right to participate in cultural life and benefiting from scientific progress as well as the right of inventors or contributors in the development of culture and science. Critical analysis of rights available for users and inventors may further help to find resolution mechanisms for patents and access to medicines.

Article 15 of the ICESCR is significant towards finding a way for access to medicines, as international forums such as CESCR has deliberated on the issue of a possible relation between intellectual property rights and right of everyone under ICESCR to participate and benefit from cultural and scientific progress. In this part of the chapter, the focus will remain on human rights provisions dealing with the right of inventor or contributor towards science and culture. Moreover, this part will focus on how to ensure participation and access to scientific and cultural progress.

5.3.1 Analysis of Article 27 of UDHR

The UDHR is one of the significant documents of modern the international human rights framework demonstrating the intention behind various rights. While addressing modern cultural

[65] General Comment No. 14 of the CESCR (n-52) para 9, 11

[66] Melissa McClellan, 'Tools for Success': The TRIPS Agreement and The Human Rights to Medicine' (2005) 12 *Washington and Lee Journal of Civil Rights and Social Justice* 153,160-161.

[67] General Comment No. 14 of the CESCR (n-52) para 9, 11

[68] Ibid.

and scientific progress, it includes the rights of inventors and users in the same provision.[69] It is also worth mentioning that the provisions were adopted with minor disputes over their contents.[70] The text of article 27 includes:

"(1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.

(2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."

The provision sets a principle that everyone has the right to participate in culture, enjoyment of art, and benefiting from scientific progress. This enshrines that everyone will enjoy equal opportunity to enjoy all these benefits of progress in the world. Moreover, other parts of the provision sets the principle of intellectual property rights for creators. It mentions that everyone will have the right to moral and material interest from his or her scientific, literary, or artistic work. This includes various intellectual property rights such as patents, copyrights, trademarks, design, and others.

The provision tries to balance between monopolies and human rights. Monopolies over rights resulting from creation are not absolute rather they have been created in a way to benefit society. One may interpret that the provision bears internal conflict. However, cannons of legal interpretation call for harmonising operation of various provisions of law. In this way, interpretation of provision may present that everyone has the right to protect moral or material interests from his or her creation, however, these rights are subject to the right of everyone to enjoy the benefit of cultural and scientific progress.

5.3.2 Critical examination of Article 15 of ICESCR

Article 15 of ICESCR has included identical norms in its text as it was in article 27 of UDHR. ICESCR is binding as well as enforces the rights mentioned in state parties. Text of article 15 (1) includes the following rights:

[69] Joo-Young Lee, *A Human Rights Framework for Intellectual Property* (Ashgate, 2015)151; Lee shaver, 'The Right to Science and Culture' (2010) 121 *Wisconsin Law Review* 121-84

[70] Lee shaver, 'The Right to Science and Culture' (2010) 121 *Wisconsin Law Review* 121-84

"The States Parties to the present Covenant recognize the right of everyone:

a. *To take part in cultural life;*
b. *To enjoy the benefits of scientific progress and its applications;*
c. *To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.*
d. *The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.*
e. *The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.*
f. *The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields."*

The United Nations Educational, Scientific, and Cultural Organisation (UNESCO) supported and advocated the provision and it was meant to make sure that everyone gets access to modern cultural and scientific progress.[71] There was opposition to the inclusion of this right in ICESCR by US-based on the complexity of the subject. As mentioned earlier, Article 15 is a continuation of Article 27 of UDHR that had very little opposition from state parties. However, in the process of framing article 15 of ICESCR, some reservations were made by developed states on account of intellectual property rights. The text of Article 15 includes three main norms such as the right of participating in culture, the right of everyone to participate in the benefit of scientific progress, and the right of the creator for its authorship.[72] A critical reading of the text reveals that not all these three elements focus on the possible equilibrium between the protection of rights of the author and access to the creation in sciences.

To elaborate the scope of the right to enjoy the benefits of scientific progress, the UN Special Rapporteur explains the basic formation of the right that includes access to everyone without discrimination, freedom for scientific research and innovation, the participation of everyone in

[71] Willian A. Schabas, '7 Study of the Right to Enjoy the Benefit of Scientific and Technological Progress and its application' in Yvonne Donders, Vladimir Volodin (eds), *Human Rights in Educaiton, Science and Culture: Legal Development and Challenge*s, *UNESCO* (Ashgate Publishing 2007) 281

[72] Audrey R. Chapman, 'Core Obligations Related to ICESCR Article 15(1)(C)', in Audrey Chapman and Sage Russel (eds), *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* (Intersentia 2002) 314

decision-making, and environment of development, conversation, and diffusion of science.[73] Freedom of scientific research and development has been explained in Article 15.3 stating, "The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity." In one way, the provision promotes scientific research by protecting both creation and process towards creation. Moreover, to connect the creator and user, it also enshrines the principle of including everyone towards the benefit of science by creating access to everyone for enjoying the benefits of scientific progress.

Access to medicines is a part of scientific research and development. In the view of Article 15 of ICESCR, the duties of state parties are two-fold. First, the state parties are bound to provide a legal and administrative framework for everyone to benefit from access to medicines, a part of scientific progress. The second part of the obligation is to ensure the right of everyone to benefit from their moral and material interest from their innovation or creation. Moreover, the state parties are under obligation to respect freedom for innovative activity related to access to medicines as part of scientific progress. Additionally, the provision calls for international building international cooperation for benefiting from scientific progress. The issue of access to medicines has been prominent where patent rights are under strict protection; however, access to medicines has enjoyed very little attention in the human rights framework. From the textual construction of article 15 (1), it is clear that the article calls all state parties to balance between the right of everyone to benefit from scientific progress and the right of individual creators for the development of science, culture, and art.

Article 15 (1) sets the protection of access to scientific progress as well as protection of research and development in science. However, the provision does not explain the possible interaction between the two rights. In case of access to medicines, the debate on the conflict between patents and access to medicines under patent monopoly has been under debate. Adding to the debate of interaction between intellectual property and human rights, CESCR has set criteria of their interaction in General Comment no. 17.

5.3.4 Balancing Patents and Access; General Comment No. 17 of the CESCR

[73] Joo-Young Lee (n-69) 162

The CESCR adopted General Comment 17 during 2005 to address the issue of interaction between intellectual property rights and human rights. The focus was on article 15 (1) regarding its scientific creation. The committee finds that everyone has the right for benefiting from moral and material interest from his or her scientific, artistic, or literary production as an author.[74] The comment distinguish between enforcement of intellectual property rights from human rights mentioned in article 15 (1) mentioning that it is significant not to equate enforcement of intellectual property rights with various human rights.[75] Regarding the conflict between human rights and intellectual property, the comment note:

"*States parties are therefore obliged to strike an adequate balance between their obligations under article 15, paragraph 1 (c), on one hand, and under the other provisions of the Covenant, on the other hand, with a view to promoting and protecting the full range of rights guaranteed in the Covenant … States parties should therefore ensure that their legal or other regimes for the protection of the moral and material interests resulting from one's scientific, literary or artistic productions constitute no impediment to their ability to comply with their core obligations in relation to the rights to food, health and education."*[76]

The committee has found that intellectual property rights are not similar to human rights mentioned in article 15 of ICESCR. The human right to access creations under monopoly as part of the right to benefit from scientific progress is towards fulfilling obligations mentioned in the provision. The comment call all members states that they must safeguard the rights of users while they are protecting the intellectual property rights of the authors. The comment further oblige state parties to avoid any conflict with access to food, health, and education. Paragraph 35 of the General Comment defines 'related obligations' to article 15 (1) (C).

5.3.5 Critical Analysis of General Comment No 17 of the CESCR

[74] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Para. 1 (c) of the Covenant)*, 12 January 2006, E/C.12/GC/17 Para 35. Hereinafter named 'General Comment No.17 of the CESCR'

[75] Philippe Cullet, 'Human Rights and Intellectual Property Protection in the TRIPS Era' (2007) 29 *Human Rights Quarterly* 403-430

[76] General Comment No.17 of the CESCR (n-74) Para 3

The text of general comment support human rights over intellectual property rights. It looks that the comment has missed explaining how states can achieve a balance of enforcing intellectual property rights.[77]

The findings of the committee clarify that there is a distinction between human rights and intellectual property rights. Moreover, the findings indicate that protection of intellectual property rights as explained in article 15 (1) (c) are connected to the right of everyone to enjoy the benefits of scientific progress.[78] Moreover, the same approach has been explained in paragraph 24 of the comment where limitations on intellectual property rights mention that the author of any form of intellectual property rights will get adequate compensation for his or her right against limitations applied by the state parties. Preferring human rights over the intellectual property will not be an easy task for the state parties to the ICESCR as the former enjoys protection through the TRIPS Agreement of the WTO.

The general comment differentiates between the origin of intellectual property and human rights. It says that human rights are rooted in the 'dignity and worth' of human life and intellectual property rights stem from state authority.[79] The nature of human rights is "timeless expression of fundamental entitlement of the human person".[80] Contrary to this, intellectual property rights are limited in time, amended, traded, and forfeited.[81] For this reason, intellectual property rights are distinct from human rights and human rights will always take precedence on all other rights. It is pertinent to quote paragraph 35 of General Comment No 17 that highlights the protection of the rights of authors along with the human right of access to health, education, and medicines. The paragraph says that state parties are under obligation to strike balance between protecting the intellectual property rights of the author and other human rights provided by the covenant. Additionally, it adds that in striking balance intellectual property rights may not take undue favouritism and due consideration to access and production of product under intellectual property

[77] RD Anderson, H. Wager, 'Human Rights, Development, and the WTO: The Cases of Intellectual Property and Competition Policy' (2006) 3 *Journal of International Economic Law* 721–3.

[78] General Comment No.17 of the CESCR (n-74) Para 3

[79] General Comment No.17 of the CESCR (n-74) Para 1

[80] Ibid.

[81] Ibid.

protection.[82] In this way, it demands state parties to protect material and moral rights of authors from their scientific, artistic, or literary production that they do not impede in performing core obligations of state parties towards the right to health, food, education, and the overall idea of the right of enjoying benefits of scientific progress. The comment interprets intellectual property as the mean and overall realisation of human rights as an end. The fundamental rationale for intellectual property is for the larger benefit of society. Therefore, intellectual property may not have triumphed over the core human rights mentioned in ICESCR. However, it is clear from the rationale of the comment that the state parties are under obligation to find balance. Meaning to understand is that the states are not free sacrificing one right over other rather attaining balance in the enforcement of both rights. The language of general comment focuses on public interest as the benefit of the society protecting intellectual property rights. The following text from the comment explain the same idea as under:

"Ultimately, intellectual property is a social product and has a social function. States parties thus have a duty to prevent unreasonably high costs for access to medicines, plant seeds or other means of food production, or for schoolbooks and learning materials, from undermining the rights of large segments of the population to health, food and education. Moreover, States parties should prevent the use of scientific and technical progress for purposes contrary to human rights and dignity, including the rights to life, health and privacy, e.g. by excluding inventions from patentability whenever their commercialization would jeopardize the full realization of these rights. States parties should, in particular, consider to what extent the patenting of the human body and its parts would affect their obligations under the Covenant or under other relevant international human rights instruments. States parties should also consider undertaking human rights impact assessments prior to the adoption and after a period of implementation of legislation for the protection of the moral and material interests resulting from one's scientific, literary or artistic productions."[83]

General Comment No 17 started with analysing right of the author concerning protecting the enjoyment of creation in artistic, cultural, and scientific knowledge. Later, it has also explained the interaction between the right of the author and the protection of other human rights. The comment have highlighted the issue of access to medicines and have called state parties to protect patent rights in a way that they do not jeopardize access to medicines. The state parties need to protect core obligations under ICESCR while they are enforcing intellectual property rights.

[82] General Comment No.17 of the CESCR (n-74) Para 35

[83] Ibid.

5.4 Impact of the TRIPS Agreement on access to medicines

Adoption of the TRIPS Agreement introduced a new era for the protection of intellectual property rights. The agreement required all WTO member states to introduce minimum standards of protecting intellectual property rights. This has led to the obligation to provide patent protection to all types of inventions, including medicines. The introduction of patents on medicines can affect access to medicines. Before the adoption of the TRIPS Agreement, patents on medicines were not available in many jurisdictions, including many developing and least developed countries.[84] The absence of patents on medicines, allowed governments to reduce spending on medicines by procuring generic versions of expensive drugs. After the adoption of the TRIPS Agreement, however, the WTO members are under obligation to grant both product and process patents on medicines. This often impacts the government's ability to control the various parameters of access to medicines. This section will examine how post-TRIPS Agreement standards of patent protection affect access to medicines.

5.4.1 Impact of the TRIPS Agreement on Access to Medicine

The population in developing countries is almost 4.8 billion and it is estimated that 2 billion of the population face difficulty in accessing medicines.[85] The enforcement of the TRIPS Agreement standards of protecting patent monopolies on medicine is raising the prices of medicines causing impact upon availability, accessibility, and affordability of drugs.[86] Apart from poverty and lower hygienic condition, patent protection leads to higher prices, a great blow to local pharmaceutical

[84] Naomi A. Bass, 'Implications of the TRIPs Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century' (2002) 34 *George Washington International Law Review* 191-222, 191.

[85] Thomas Pogge, 'Montreal Statement on Human Right to medicines' (2007) *Cambridge Quarterly of Health Care Ethics* 16 (1) 97-108.

[86] F M Scherer and Jayashree Wata, 'Post-Trips Options for Access to Patented medicines in Developing Countries' (2001) CMH Working Paper Series < http://icrier.org/pdf/jayawatal%20.pdf> accessed 12 January 2018.

production, generic competition, and quality of drug and local innovation of medicines.[87] Developing countries often face pressure from developed countries to align their laws with the TRIPS Agreement standards.[88] To illustrate further, the case of *Big Pharma versus Nelson Mandela* is an example from South Africa, a developing country. The government's efforts to ensure the availability of lifesaving drugs were opposed by the patent holder. The case was withdrawn on public pressure.[89] Similar reaction of the patent holder occurred as a result of Brazil's efforts to regulate access to medicine in the case of AIDS.[90]

Profitability or service in medical research is the main paradox debated for decades to address access to medicine by people who cannot afford it.[91] The aforementioned statement of the CEO of Novartis explains the stance of pharmaceutical producers:

"We have no model which would meet the need for new drugs in a sustainable way. You can't expect for-profit organisations to do this on a large scale. If you want to establish a system where companies systematically invest in this kind of area [low-cost medicines for developing-countries], you need a different system." - Former Novartis CEO, Daniel Vasella, in the Financial Times, September 2006[92]

The fundamental aim of the pharmaceutical companies remains the profit as the standards of access to medicines do not fit in their framework. This affects access to medicines in developing and least developed countries. For example, hepatitis is a widely spread disease in developing countries like India, Pakistan[93], and others, and one of the most effective drugs for the disease is known as sofosbuvir. While this drug is sold for the price of US $84000.[94] It is estimated that its production cost is not more than US$ 68-136.[95] Similarly, Gleevec is the drug effective for treating cancer that costs US$ 3,227 for a dose of one month in South-Africa where it is protected by the

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[87] Ellen 't Hoen, 'TRIPS, Pharmaceutical Patents, and Access to medicines: A Long Way From Seattle to Doha' (2002) 3 (1) *Chicago Journal of International Law* 27-46, 44

[88] Ibid.

[89] Ibid.

[90] Jennifer l. Rich, 'Roche Reaches Accord on Drug With Brazil' The New York Times (12 January 2018) <http://www.nytimes.com/2001/09/01/business/roche-reaches-accord-on-drug-with-brazil.html> accessed 12 January 2018

[91] Ellen 't Hoen (n-87) 27

[92] Ellen F.M 'T Hoen, Private Patents And Public Health: Changing Intellectual Property Rules For Access To medicines (Health Action International, 2016) <http://accessto medicines.org/wp-content/uploads/private-patents-and-public-health.pdf> accessed 12 January 2018

[93] Ibid.

[94] Ibid.

[95] Ibid.

patent, while the same drug is available in India for US$ 170 in its generic version, as no patent exists in this jurisdiction.[96]

Infectious diseases kill almost 10 million people in developing countries every year.[97] Moreover, diseases like HIV/AIDS, tuberculosis, malaria, and respiratory infections are major causes of death for the reason of the accessibility of medicines.[98] Concerning AIDS only, estimates show that more than 8000 people face death every day for lack of treatment.[99] Moreover, neglected diseases are also affected, as the absence of research and development makes the situation graver. Before the adoption of the TRIPS Agreement and patent protection of medicines, the treatment for HIV/AIDS virus was discoursed by the name of *Azidothymidine* (AZT).[100] The patent for the treatment is owned by GlaxoSmithKline, a pharmaceutical giant that priced the treatment for US$ 10,000 for a yearly dosage.[101] The price was openly in contrast with the question of the affordability of people living in developing countries such as African nations.[102] The estimates show that approximately 34 million are infected from the AIDS virus and many people died for non-availability of treatment and many others cannot afford the drug.[103] All these facts demonstrate that patent protection of medicines affects the access to medicines in developing and least developed countries.

The price of essential lifesaving medicines has surged in the past twenty years.[104] Contrary to this, the poverty index is raising higher making purchasing power of people in developing countries to lower levels. In this case, medicines are vital for saving lives. Lower health care facilities, worst cleanliness conditions, and states' incapacity to deal with health care challenges are killing millions in developing countries.[105] Only AIDS is causing 3 million deaths per year, tuberculosis leaves 1.39

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[96] Ibid.

[97] Ellen 't Hoen (n-87) 41

[98] Ibid.

[99] Ibid.

[100] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicine* (Oxford University Press 2008) 29.

[101] Ibid.

[102] Ibid.

[103] Access to Medicine Foundation, 'Access to Medicine Report 2018' < https://accesstomedicinefoundation.org/media/uploads/downloads/5c1a82b34aa87_Access-to-Medicine-Index-2018.pdf> accessed 21 December 2018.

[104] Dr Veronika J Wirtz, 'Essential medicines for universal health coverage' 389 (10067) The Lancet 337-339

[105] Elizabeth Siew Kuan, 'Balancing Patents and Access to Medicine' (2009) 21 *Singapore Academy of Law Journal* 457-484, 461.

million deaths every year, and malaria more than one million. It is worth mentioning that almost 90 percent of these casualties are recorded in developing countries.[106] This global health crisis has many reasons, and among them is patent protection of medicines under the WTO standards of protecting trade in isolation to human rights ideals. The WHO calls for prioritising the right to health on patent rights as it mentions:

"[H]ealthcare considerations must be the main objective in determining what IP regime should apply to healthcare products. IP rights are not conferred to deliver profits to industry except so that these can be used to deliver better healthcare in the long term. Such rights must therefore be closely monitored to ensure that they do actually promote healthcare objectives and, above all, are not responsible for preventing poor people in developing countries from obtaining healthcare."[107]

Incapacity to develop a modern treatment for diseases is an issue having roots in economic, financial, industrial, scientific backwardness. It is important to note that most developing countries have signed international treaties that include the right to health such as UDHR and ICESCR. The right to health is a universal responsibility.

Members of the international community are under obligation to frame their legal systems in consonance with the protection of the right to life and health. In this regard, the term 'bottom floor' meaning a minimum standard for health protection is used from where the states may further improve their health care.[108] These minimum standards are explained by the WHO by various standards of facilities, services, and most significantly access to medicine. It is also worth mentioning that states are under obligation to ensure these minimum standards of protection of health to people without any discrimination.[109] The state must sustain the available standards of health and do all its effort to save them from any deterioration. The protection of health contains the following four elements such as availability, acceptability, accessibility, and quality of the health-care system. It may be understood that most of developing and least developed countries do not possess sufficient capacity to comply with the standards of maintenance of health-care standards. Moreover, the obligations to protect pharmaceutical patents further aggravate the situation in securing access to medicine, a vital part of the obligation to protect the right to health.

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[106] World Health Organization, 'Scaling up the response to infectious diseases : a way out of poverty : report on infectious diseases' (2002) < http://apps.who.int/iris/handle/10665/67248> accessed 26 December 2018

[107] Ibid.

[108] Andrew Chapman, S. Russel (eds.), *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* (Intersentia , 2002) 16.

[109] International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, Article 2.2.

5.4.2 Objectives of the TRIPS Agreement and Public Interest

The fundamental objective of the TRIPS Agreement is to introduce minimum standards of protection for intellectual property rights including patents. The TRIPS Agreement includes guideline for the member states for balancing protection of intellectual property with the public interest. Moreover, the Agreement introduces certain flexibilities in enforcing intellectual property rights to protect the developmental needs and public interest of the state parties.

In particular, the language of the TRIPS Agreement aspires to balance the enforcement of patent with the issue of access to medicines. Article 7 and 8 of the Agreement are designed at creating a balance among various conflicting rights mentioning that the enforcement of patents right will be "in a manner conducive to social and economic welfare, and to a balance of rights and obligations". Moreover, Article 8 of the Agreement conditions protection of public health and nutrition in a way that conflicts with other provisions of the Agreement. The textual construction of the agreement can serve the purpose of harmonising the ideals of protecting the public health and nutrition with patents protection of medicines.

The developing countries also considered minimum standards of patents with a sceptical view keeping in mind their scientific and technological preparedness and opposed any form of enforcing intellectual property without discrimination of food and medicines.[110] While, the Agreement is often considered as a document mainly concerned with protecting the interest of a monopoly holder, the TRIPS provisions can be construed from a public interest perspective that may overweight intellectual property. With a specific view of access to medicines, the TRIPS Agreement is more positive to the public interest as compare to individual patent protection. The preamble of the TRIPS Agreement defines that the objective of the agreement is to protect the public interest in rem as a comparison with the protection of the personal right of the patent holder and it may be interpreted that in case of conflict of interest of patent holder and public interest such as access to lifesaving drugs, the former should prevail over the later.[111] The text points out that the intellectual property rights such as patent monopoly rights are only tools to achieve the

[110] Jayashree Watal, Leticia Caminero, 'Least-developed countries, transfer of technology and the TRIPS Agreement' (2018) Staff Working Paper ERSD-2018-01 < https://www.wto.org/english/res_e/reser_e/ersd201801_e.pdf> accessed 25 December 2018

[111] Ellen F.M. 't Hoen (n-21) 12

ideal to attain the highest purpose of public interest.[112] The fifth Clause of Preamble of the Agreement states: "Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives."[113] Hence, the text of the agreement points towards the national public policy of various parties to the agreement that includes the development of even the technological advancement of all parties to the agreement.

The objective and flexibility, in Article 7 of the agreement focus on the social and economic welfare of the parties to the agreement. The provision calls for harmonising between patents and public interest. The article states:

"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[114]

The aim and objective of enforcement of protection of intellectual property should not be the sole protection of monopoly of patent holder or the protection of commercial investment and profits rather the statement under the article demonstrates that the agreement aims to establish promotion, transfer, and dissemination of technology in a manner beneficial for social and economic welfare. The term welfare in no manner can be construed financial profit-based rather something more akin to the public interest. Moreover, the concerns presented by the developing countries with specific reservations on access to medicine and the right to health reflected in the text of Article 8 (1) of the TRIPS Agreement 1994 as:

"Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."[115]

The aforementioned text calls for the promotion and protection of public interest related to public health and nutrition, however the textual construction of the provision conditions the states' measures to rest of the provisions of the agreement. In this way, the state parties find it very difficult to protect public health in general and access to medicines in particular. In case of conflict

[112] Ibid.

[113] Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 1

[114] Ibid. Article 7

[115] Ibid. Article 8 (1)

between access to medicines and patent monopolies, the text of the objectives is convenient to patent protection in comparison with access to medicines.

5.4.3 Flexibilities for access to medicines in the TRIPS Agreement

As mentioned earlier, many countries objected to the inclusion of protection of patents on medicines in the WTO framework of the TRIPS Agreement.[116] The negotiating states to the TRIPS Agreement tried their best to bargain maximum space for their national interests in terms of providing access to essential products. As a result of the efforts by the developing and the least developing countries, the draft of the agreement included certain flexibilities for the state parties to protect the national needs. The TRIPS Agreement includes various flexibilities for protecting access against patents. The flexibilities include the use of compulsory licensing, parallel import, and the authority to define patentability criteria. However, these flexibilities are not utilised effectively because of internal inability and external pressure. They have considered theoretical but practical enforcement of those flexibilities is not yet achieved. The same issue of utilising flexibilities with reference to access to medicine was discussed in the Doha Declaration.

For instance, the use of compulsory licensing was widely done by Brazil, South-Africa, and India and it helped them to cut the prices of many drugs to ensure the availability and accessibility of drugs to the patients. However, these measures were objected and challenged by the pharmaceutical companies. Although compulsory licensing is an effective tool to coup up with the issue of access to medicine developing countries lack the required capacity to produce the medicines because of the under-developed pharmaceutical industry. Moreover, the political pressure and diplomatic pressure in the shape of economic sanctions, use of foreign direct investment and other commercial games, the use of compulsory licensing is marginalised. The standards of patent protection have further strengthened by the Trade-Related Investment Measures and Free Trade Agreement. These agreements impede the use of the TRIPS flexibilities.

Moreover, the complex and technical interface of the TRIPS Agreement and patent-related laws makes it harder for developing countries to use the flexibilities. To understand this, the question of patentability is also left to national laws to decide in accordance with their needs but lack of

[116] Dianne Nicol, Olasupo Owoeye, 'Using TRIPS flexibilities to facilitate access to medicines' (2003) 91 *Bulletin of the World Health Organization* 533-539

technical human resources and establishment make it tough for states to codify their laws efficiently to support their local industry. Prof. Drahos states:

"Over the years the steady drip of technical assistance leads to the formation of technocratic trust in the EPO's system. A strong belief forms that the EPO's system produce quality results and that belief in turn forms the basis of decision-making y patent examiners in under-resourced developing country patent offices. Technocratic trust thus fosters a circle of decision-making in which the EPO trains developing country examiners to make decisions in their own countries that predominantly benefit foreign companies, including European companies."[117]

On the question of defining the patentability criteria, only a few countries have used the potential to coin the national patent system in accordance with the domestic needs. The use of defining patentability needs technical and legal knowledge of the patent system and the countries lack enough technical and legal capabilities. Using the potentials of patentability criteria, India has been effective in balancing the patent standards with local needs by introducing Article 3(d) to its patent laws.[118] The provision does not allow the grant of patents to the new forms or uses of known substance unless the invention proves a substantial efficiency comparing to the known substance. In this way, the patentability criteria halt the grant of the patent for incremental inventions.

The use of flexibilities under the TRIPS Agreement has not been effective.[119] The attitude of developed countries towards access to medicine is demonstrated from the 23rd Session of Human Rights Council where both the United States of America and the European Union did not support a resolution to protect the right to health and access to lifesaving medicine. The pressure from the developed nation is demonstrated in one way or another.[120] The United States of America through the United States Trade Representative (USTR) puts pressure on nations who do not provide US patent 'protection'. Moreover, Pharmaceutical Manufacturers Associations of America use

[117] Peter Drahos, '"Trust Me": Patent Offices in Developing Countries, Working Paper, Centre for Governance of Knowledge and Development' < https://link.springer.com/content/pdf/10.1007%2Fs40901-016-0022-7.pdf> accessed 25 December 2108; K. M. Gopakumar, 'Twenty years of TRIPS agreement and access to medicine: a development perspective' (2015) 53 *Indian Journal of International Law* 367-404

[118] Zoee Lynn Turrill, 'Finding the Patent Balance: The Novatis Glivec Case and the Trips Compliance of India's Section 3 (D) Efficacy Standard' (2012) 44 *Georgetown Journal of International Law* 1555-1588, 1565.

[119] Ellen F.M. 't Hoen, et. al., 'Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016' (2018) 96 (3) *Bulletin World Health Organisation* 185–193, 187.

[120] Ellen F.M. 't Hoen (n-21)12.

financial sanctions as a tool to press developed countries to protect their patent bypassing various TRIPS flexibilities.[121]

5.4.4 Conflict of patents with access to medicines

One of the main limitations to access to medicines is the enforcement of patents on medical inventions.[122] While, in general, patents were available before the adoption of the TRIPS Agreement, many jurisdictions did not provide product and process patent protection in the fields of medicines and food because of the fear that this may create monopiles with respect to these essentials.[123] Almost 40 countries did not provide patents on medicines before the adoption of the TRIPS Agreement.[124] However, the adoption of the TRIPS Agreement introduced the indiscriminate grant of patents in all fields of technologies, including medicines.[125]

The potential negative impact of the agreement on access to medicines was raised by the negotiating states and academic scholarship.[126] Before the adoption of the TRIPS Agreement, most of the countries only allowed process patents instead of product patents to deal with the issues of creating monopolies on essential products such as medicines.[127] However, the TRIPS Agreement obliges the state parties to grant both product and process patents in all fields of innovation without any discrimination. This caused concerns in developing and least developed countries in relation to access to medicines and other essential products. These countries raised their concerns during the TRIPS Agreement negotiation process. Considering the reservations from the objecting states, the TRIPS agreement includes flexibilities such as Article 31 that allows WTO members to grant compulsory licenses patents adversely affects the public interest.[128] However, the use of this flexibility is under strict conditions. The TRIPS Agreement also provides a transitional period for enforcement of patents for 10 years that expired in 2005. The countries

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[121] K. M. Gopakumar, 'Intellectual Property Issues Dominate the USITC Public Hearing on India' (2014) <http://www.twn.my/title2/health.info/2014/hi140201.htm > accessed 11 January 2018

[122] Philippe Cullet, 'Medical Patents and the Right to Health–From Monopoly Control to Open Access Innovation and Provision of Medicines' (2019) 61 *German Yearbook of International Law* 153-182.

[123] Yoshiko Kojo, 'Global issues and business in international relations: intellectual property rights and access to medicines' (2018) 18 (1) *International Relations of the Asia-Pacific* 5-23.

[124] World Health Organisation, 'WTO and the Trips Agreement; Essential medicines and health products' <https://www.who.int/medicines/areas/policy/wto_trips/en/> accessed 5 May 2020

[125] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) 1994, Article 27.

[126] Holger Hestermeyer (n-87)12-15.

[127] World Health Organisation (n-124).

[128] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) 1994, Article 31.

with the transitional period were required to improve research and development to comply with the TRIPS standards and later the transitional period was extended to July 2013.[129] The transition period was further extended to 1 July 2021 for the least developing countries.[130] The issue of uplifting developing countries in terms of research and development remained without any major progress even after the completion of the extended transitional period for enforcement of the TRIPS Agreement.

A debate regarding the impact of the TRIPS Agreement on the right to health and access to lifesaving drugs was heated soon after its adoption in 1994. Moreover, the issuance of compulsory licenses by developing countries concerning access to lifesaving drugs especially HIV/Aids treatment has not proven productive.[131]

Post-TRIPS Agreement concerns from the developing states about access to medicines led towards the Declaration on the TRIPS agreement and public health. The Declaration focuses on examining the issue of access to medicine in the preview of the TRIPS Agreement. The Declaration is one of the significant steps for harmonising patents with access to medicines. The Declaration recognises the importance of public health challenges concerning the implementation of the TRIPS Agreement. Para 6 of the Declaration states:

"We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under TRIPS Agreement. We instruct the Council of TRIPS to find an expeditious solution to this problem…"

The statement in this paragraph later facilitated the way for extension in the transition period for developing countries for capacity building in research and development in the field of science and technology. The decisions taken in the Declaration further helped the least developed countries in importing medicines using compulsory licensing.[132] However, the enforcement of the Doha Declaration has not yet achieved its efficacy.

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[129] World Trade Organisation, Council for TRIPS, 'Extension of the Transition Period under Article 66.1 for Least-Developed Country Members' IP/C/40.

[130] UN LDC Portal, 'TRIPS Agreement: Transitional period for pharmaceutical products' <https://www.un.org/ldcportal/trips-agreement-transitional-period-for-pharmaceutical-products/> accessed 18 May 2020

[131] Holger Hestermeyer (n-87) 72.

[132] Laurence R. Helfer, G.W. Austin, *Human Rights and Intellectual Property: mapping the global interface* (Cambridge University Press 2011) 123.

In contemporary debates, enforcing patent monopolies in the field of medicine is leaving a significant impact on access to medicine in developing countries and the debate is going on both at academic and judicial levels. The conflict of patents and access to medicine, and its impact on the standards of access to medicines in developing and least-developed countries, has been the main focus of state negotiations, national judicial findings, and academic writings. Although, the TRIPS Agreement and the Doha Declaration provide a workable mechanism for access to medicine, the effective enforcement of these instruments has not been achieved and the gap between life-threatening diseases and life-saving drugs is widening despite all pharmaceutical and technological advances of 21st century.

5.4.5 Resolving the conflict; Declaration on the TRIPS agreement and public health (The Doha Declaration)

The Fourth Ministerial Conference, on 14th November 2001, focused on the issue of the TRIPS Agreement regarding the right to health in Doha. The conference was convened after allegations of higher prices of medicine under patent and the use of compulsory licensing by the state parties.[133] The Declaration is aimed at helping developing countries fighting diseases like AIDS, malaria, tuberculosis, and other infectious diseases.[134] It is worth noting that the Declaration was the result of the move from African Members to balance the impact of the TRIPS Agreement.[135] The Declaration focused on defining the true objective of the TRIPS Agreement. i.e. to protect the public interest and the right to health instead of commercialisation of medicines curing life-threatening diseases. Therefore, the Doha Declaration emphasised that the Agreement should be interpreted to enhance the availability and accessibility of drugs instead of hindering it. The interpretation of various clauses should be done in a way that it protects the right to health in developing and least developed countries. It also reinforced the right of WTO members to use compulsory licensing provided in Article 31 TRIPS. As was mentioned above, this provision allows states to issue a compulsory license in relation to patent-protected medicine under certain

[133] The Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2,14 November 2001.

[134] Peter Drahos, 'Developing Countries and International Intellectual Property Standard-Setting', (2002) 5 *Journal of World Intellectual Property* 765, 781.

[135] Tshimanga Kongolo 'TRIPS, the Doha Declaration and Public Health', (2003) 6 *Journal of World Intellectual Property* 373,374.

conditions.[136] As a result, a patent-protected pharmaceutical invention can be used by a third party without the consent of the patent holder, which essentially priorities a public health perspective over the protection of patent rights.[137]

While, TRIPS provide such flexibility, some WTO members, developing countries, have been struggling to use it because of the lack of technological and manufacturing capabilities for the production of medicines. This is because one of the requirements under Art 31 is that such compulsory licenses must be issued predominantly for the domestic market.[138] To resolve this problem the Doha Declaration included paragraph 6 addressing the issue of lack of manufacturing capabilities and the use of compulsory licensing effectively. The paragraph asked the council of TRIPS to resolve the issue and submit a report in 2002. The council submitted its report, finding 'expeditious solution' to address the problem of public health and access to medicines, on 30 August 2013.[139] The decision eased in Article 31 (f) of the TRIPS Agreement that restricted the use of compulsory licenses to the local or domestic market. The condition was relaxed that the parties to the agreement may import the medicine under compulsory license and most significantly, the condition of adequate remuneration to patent holder imposed by Article 31 (h) will not apply to import state.

Advocates of prioritising public health, in the post-TRIPS regime, consider the Declaration a success for the first time recognises the significance and prioritisation of public health over patent monopolies in pharmaceutical patents.[140] Paragraph one of the Declarations talks about the convenient use of compulsory licenses by members of the WTO in case of access to medicine. The second paragraph talks about the provision of importing medicines from other countries. It mentions that exporting members will inform the TRIPS Council about the conditions of exporting the medicine. Paragraph 3 of the Declaration explains the providence of adequate remuneration to the patent holder where the compulsory license is used. It also explains the condition of waiving the importing condition of the TRIPS Agreements. Paragraph four of the agreement talks about the appropriateness of importing and fair use policy. Paragraph five of the Doha Declaration review process of importing medicine by TRIPS Council in case of violation of

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[136] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Article 31.

[137] Peter Drahos (n-134) 765.

[138] Sandra Bartelt 'Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health', (2003) 6 *Journal of World Intellectual Property* 283, 296.

[139] S.K Verma, 'TRIPS Agreement and Access to medicines' (2011) < http://www.kansai-u.ac.jp/ILS/publication/asset/nomos/29/nomos29-06.pdf> accessed 19 January 2018

[140] Ibid.

fair import policy. Paragraph 6 very significantly provide importing clause for regional agreement and protection of health such as the case of African countries where AIDS is a common challenge. Paragraph 7 of the Declaration defines the main objective of the standards of pharmaceutical patents and that is the transfer of technology to the least developing countries.

A consensus on prioritizing the right to health and public interest over patent monopolies in pharmaceutical patents developed through Doha Declarations and recommendations later on in 2003. The criticism of the TRIPS Agreement bases itself upon its complex nature in terms of the enforcement of intellectual property rights. Some of the scholars claim that Doha Declarations further make the standards of intellectual property rights more dubious. The question of health emergency, industrial and technological incapacity, and licensing generic products are the issues that make the question of compulsory licensing and importing medicine from other countries more complex.[141]

5.4.6 Jurisprudential Status of Doha Declaration

The Doha Declaration focused on access to medicine and public health, was adopted on 14th November 2001 in Ministerial Meeting.[142] The Declaration was the result of a concentrated effort from the developing countries to define the domain of the TRIPS Agreement and its impacts public health with special concerns about access to medicine. The history of the Doha Declaration demonstrates the context or intention of parties. It is well documented in negotiation proceedings and parties to the arguments such as United States of America, EU, and other developed countries on one side and other side was composed and led by South-Africa, Brazil, India, and other adversely affected developing countries from the standards of pharmaceutical patents under TRIPS Agreement.[143] Paragraph four of the Declaration states:

"4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

[141] Ibid.

[142] Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, WT/MIN(0l)/DEC/2, 20 November 2001.

[143] Frederick M. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) 5 *Journal of International Economic Law* 469.

In this connection, we reaffirm the right of WTO Members to 'use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

This paragraph takes the Doha Declaration significant from a jurisprudential standpoint of interpretation of the TRIPS Agreement. Moreover, Article IX:1 of the WTO Agreement explains that the decisions taken at ministerial levels can be taken as a source for interpretation for the TRIPS Agreement in case of dispute with public health and access to medicine. Abbot argues the Declaration has attained jurisprudential in interpreting the various provisions of the TRIPS Agreement.[144] Therefore, the interpretation of provisions of the TRIPS Agreement in case they conflicted with public health and access to medicine, the balance of interpretation will go towards text and context in Doha Declarations.

5.4.8 Why do the patent monopolies triumph over public interest?

The WTO theoretically brings the protection of public interest along with trade relevant to its operation in TRIPS Agreement, GATT, GATS, SPS, and other instruments. Practically, the operation of public interest is second to the protection of trade rights. For instance, Article XX of GATT provides non-economic exceptions but practically it is very hard for a state to contend intention of non-economic activity. The arguments differentiating both human rights from non-economic operation sometimes become very complex during dispute resolution proceedings and the convenience is always in favour of trade rights.[145] Human rights can be relevant to the WTO dispute resolution system but it can be only possible if they are construed as public interest instead of promotion of trade interests. The WTO regime cannot accommodate the ideal or perfect interpretation of human rights as it will defeat the standards of global trade regulation. Another issue is the division of states ratifying different treaties of human rights. For instance, the USA has

The WTO and Human Rights regimes possess distinct objectives that do not share the legal frameworks. It has been argued that bring human rights under the WTO enforcement system will not be productive as it will impact the effective working style of the WTO regime. Movement for protecting human rights should be focused inside its regime as the WTO regime pursues its ideal of promotion of global trade. Article XXI of GATT recommends remedying potential human

[144] Ibid.

[145] Francesco Francioni, 'Environment, Human Rights and the Limits to Free Trade', in F. Francioni (ed.), *Environment, Human Rights and International Trade* (Oxford University Press, 2001) 14, 1-26.

rights violations with the help of the Security Council of the UN.[146] The possibility of direct enforcement of human rights in the WTO regime is very restrictive.[147] Article 3.2 of Dispute Settlement Understanding (DSU) answers the question of the relevance of external source in the WTO regime in the following text:

"2. The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements."[148]

It points out that the dispute resolution system will follow exiting laws or provisions of the WTO based instruments in deciding issues between the member states. In cases where external interpretations are required, international legal norms come relevant but they remain under the rights and obligation covered by the agreements between states party to dispute. The case of Codex Alimentarius is a relevant example, a document explaining the conditions of food-producing and processing standards.[149] While deciding *US Shrimp Case*, the DSU relied on the Convention on International Trade in Endangered Species of Wild Fauna and Flora to ascertain the question of statutes of sea turtles as endangered species.[150]

Arguments suggest that room for human rights protection in WTO is very limited.[151] Protection of global trade is the prime goal of the WTO regime and every other concern like environmental, labour, or health are secondary.[152] These public interests can only take relevance once it is contended that it will not impact the smooth running of global trade.

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[146] General Agreement On Tariffs And Trade (GATT), Article XXI.

[147] Ellen 't Hoen (n-17) 32.

[148] Understanding On Rules And Procedures Governing The Settlement Of Disputes, Article 3.2.

[149] Gudrun Monika Zagel, 'WTO & Human Rights: Examining Linkages and Suggesting Convergence' (2005) *2 Idlo Voices Of Development Jurists Paper Series* <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=740265 > accessed 6 April 2018.

[150] Dr. Pallavi Kishore, 'Revisiting the WTO Shrimps Case in the Light of Current Climate Protectionism: A Developing Country Perspective' (2012) 3 *George Washington Journal of Energy and Environmental Law* 78-90, 89.

[151] Ibid.

[152] Ellen 't Hoen (n-17) 32.

5.5 Access to medicines in Millennium Development Goals

The issue of COVID-19, HIV/AIDS, and other pandemics interferes with the right to life and health. The WHO and other international organisation started campaigning for universal protection of the right to health as closed knitted with the right to life.[153] In 1987, WHO set for addressing the issue of access to medicines. Among other goals of effective strategies dealing with the issue, it included access to medicines.[154] To further, support the right to health against all other rights, the principle of human rights primacy came under discussion by various writers of the international human rights law.[155] The campaign for the right to health and access to medicines expanded its scope to other life-threatening diseases such as tuberculosis, malaria, and other infectious tropical diseases. During the 1990s, the focus of UN instruments was to expand the enforcement of the right to health for child mortality and other life-threatening challenges.[156] The struggle for the protection of the right to health universally took a tangible turn after the adoption of Millennium Development Goals (MDGs). The rules were aimed at indiscriminate universal progress across the world making state parties effectively pursue them.[157] It is worth noting that the right to health is integral to almost all goals taken in MDGs as it contains stress on the assurance of health care many times in the document. As a result of MDGs, many human rights documents adopt the same approach such as Convention on Disability and Convention on Migrants (Workers and Families) includes health care as a goal. The development of the right to health rose to adoption and enforcement issues at both national and international fronts. On the national level, the developing states feel under-capacity in terms of protection of the right to health on the level of standards mentioned in human rights instruments for the lack of economic, infrastructural, and technological progress. On the international level, the human right of health later became in

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[153] World Health Organisation, The Global Strategy for AIDS Prevention and Control, Document No. SPA/INF/87.1 (1987).

[154] Sofia Gruskin, Daniel Tarantola, 'Universal Access to HIV prevention, treatment and care: assessing the inclusion of human rights in international and national strategic plans' <http://www.who.int/hiv/events/artprevention/gruskin.pdf > accessed 2 March 2018

[155] Ibid.

[156] United Nations, General Assembly Declaration of Commitment on HIV/ AIDS <http://www.unaids.org/sites/default/files/sub_landing/files/aidsdeclaration_en_0.pdf > accessed 02 March 2018

[157] Ibid.

conflict with commercial rights under the standards of pharmaceutical patent protection under the WTO regime. Countries like South Africa, Brazil, India, and other developing countries have justified their divergence from the TRIPS Agreement and the pharmaceutical patent protection because of protecting the access to medicines as a public interest.[158]

5.6 Conclusion

The arguments find that access to medicines related human rights obligations face multi-facet limitations. Form a perspective of limitations on access to medicines, the state parties to human rights instruments find it difficult to comply with access to medicines related obligations for domestic limitations such as the scarce financial resources, incapacity to develop new medicines to deal with domestic disease-burden, the issues of poverty, sanitation, and unhygienic living conditions. Moreover, the obligations of access to medicines under the right to health are progressive and the state parties often give it less priority in comparison with other human rights challenges such as maintenance of law and order. The compliance of access to medicines under the human rights framework often face issues such as divisibility of treatment between various human rights, the question of justiciability, and less priority of state for access to medicines related human rights obligations. Among the economic and human rights enforcement limitation, the enforcement of patents on medicines further aggravates the issue of access to medicines by adversely affecting affordability in low-income countries. The chapter has presented an overall less-optimistic but practical picture of enforcing access to medicines as a part of human rights. The next part will exploit the potentials of enforcing access to medicines related human rights obligations.

[158] Hans V Hogerzeil, et. al, 'Is access to medicines as part of the fulfilment of the right to health enforceable through the courts? (2006) 368 *The Lancet* 305-311

When There Is A Will, There Is A Way; Towards Recognizing and Enforcing Access to Medicines as A Part of Human Rights

6.1 Introduction

The miserable have no other medicine

But only hope.[1]

The recent outbreak of COVID-19 pandemic is a wake-up call for recognising and enforcing access to medicines as a human rights. On 26 March 2020, almost 42 independent UN human rights experts working under the mandate of HRC acknowledge that "Everyone, without exception, has the right to life-saving interventions and this responsibility lies with the government".[2] The experts from the UN called all member states to revitalise the status of human rights, along with progress in science and technology, to deal with the challenges like a recent issue of COVID-19 pandemic. Specifically referring to the issue of access to medicines, the experts mentioned that "When the vaccine for COVID-19 comes, it should be provided without discrimination".[3]

The international community has progressed in the scientific and technological fields making itself more effective for dealing with the issue of access to medicines.[4] An unremitting competition of developing new medicines and vaccines has effectively dealt with the crisis of polio and reducing the impact of infectious diseases. Jonas Salk, the inventor of the polio vaccine, sets the ideals of human progress as something to benefit humanity at the large. In his words, "This is perhaps the most beautiful time in human history; it is pregnant with all kinds of creative possibilities made possible by science and technology which now constitute the slave of man - if man is not enslaved

[1] William Shakespeare, Measure For Measure, Act 3, Scene 1.

[2] UN Experts, 'Human rights must be maintained in beating back the COVID-19 pandemic, 'without exception" (UN News 26 March 2020) <https://news.un.org/en/story/2020/03/1060372> accessed 30 March 2020.

[3] Ibid.

[4] Brigit Toebes, 'International Health Law: An Emerging Field Of Public International Law' (2016) *Indian Journal of International Law* 299-328; Obijofor Aginam, *Global Health Governance: International Law and Public Health in a Divided World* (University of Toronto Press 2005) 16.

by it."[5] Jonas was one of the most prominent advocates of access to medicines for all who need it. He further added to the question of patenting his invention on polio disease by saying, "who owns the patent on this vaccine?' 'Well, the people, I would say. There is no patent. Could you patent the sun?"[6] The issue of access to medicines has taken global attention after the outbreak of HIV/AIDS disease in poverty-ridden African countries where a large number of population could not access the essential lifesaving medicines.[7] The issue became relevant to human rights demand for access to medicines in the current age of scientific and technical progress where necessary medicines are available but are not accessible and affordable.

Besides various challenges faced by the ideals of access to medicines, recent developments related to the issue provide hope that the international and national policy-makers are pragmatically adopting the vision of equity and human rights. The pragmatic approach towards access to medicines related human rights obligations would improve the access to health in general and medicines in particular. Access to medicines has been taking the status of an international legal norm. With improving the status of access to medicines in both national and the international human rights framework, the traditional approach of treating access to medicines as ethical demand needs to be replaced by the positivist right notion of access to medicines as part of human rights.[8] Interpretation of access to medicines related human rights obligations makes it a formal norm enforceable with a threat of sanction. The international human rights law calls all state parties to adopt common principles of protecting human rights ideals in their territories.[9] The ideals of human rights facilitate people living their lives with dignity, freedom, equality, where everyone can peruse their life goals.[10] The principles of human rights comprise indivisibility,

[5] Robert I. Haddad, *Multidisciplinary Management of Head and Neck Cancer* (demosMedical 2011) 9.

[6] Siang Yong Tan, Nate Ponstein, 'Jonas Salk (1914–1995): A vaccine against polio' (2019) 60 (1) *Singapore Medical Journal* 9-10

[7] Katharine G. Young, Julieta Lemaitre, 'the comparative fortunes of the right to health: Two tales of justiciability in Colombia and South Africa' 26 *Harvard Human Rights Journal* 179–216, 203.

[8] Stephen P. Marks, ' The Evolving Field of Health and Human Rights: Issues and Methods' (2002) *30 Journal of Law, Medicine & Ethic* 739-754, 752.

[9] International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, Article 12

[10] Linden Farrer, et al., 'Advocacy for health equity: a synthesis review' (2015) 93 (2) *The Milbank Quarterly* 392-437.

universality, interdependence, equality, non-discrimination, and accountability.[11] The state parties to the international human rights laws are under obligation to incorporate human rights principles into their domestic legislation.

The principle of the indivisibility of human rights further refines the idea of human rights obligations related to access to medicines. In case of access to medicines as a part of human rights, the state parties to the international human rights instruments are under a duty to adopt human rights approaches for facilitating their population in accessing medicines. Access to medicines forms part of various rights under the International Bill of Rights, international and regional treaties, national constitutions, and SDGs adopted during 2015. Goal no. 3 builds consensus of the state parties to ensure the health and promotion of the well-being of the people of all ages. The goal achieved consensus among the state parties to deal with diseases such as HIVAIDS, malaria, tuberculosis, hepatitis, communicable, and neglected disease. To deal with these diseases, the role of access to medicines is integral.[12] Access to medicines falls under various human rights in several international human rights treaties. The right to health, life, benefiting from scientific progress, and other multiple international human rights include access to medicines. The state parties owe obligations of respecting, protecting and fulfilling the access to medicines related human rights obligation in their territories.

The human rights approach to deal with the issue of access to medicines can effectively assist the state parties in prioritising access to medicines related human rights obligations. The human rights approach will guide the legislative and policy process giving due consideration to access to medicines related human rights. Moreover, the human rights space at legislative and policy levels will help law enforcement institutions in the states to enforce multiple laws and policies as per access to medicines related human rights obligations. The most significant contribution of access to medicines related human rights framework will guide the domestic courts in interpreting access to medicines as part of human rights.

This chapter aims at setting coherence among the human rights framework for access to medicines as a part of human rights. The arguments will focus on highlighting access to medicines-related human rights obligations from the framework of international human rights law. The aim is to

[11] Ibid.

[12] Maryam Bigdeli, et al., 'Access to medicines from a health system perspective' (2013) 28 (7) *Health and Policy Plan* 692-704

establish access to medicines as a legal entitlement under the framework of international human rights law.

6.2 An overview of the Access to medicines related human rights obligations

In the view of the HIV/AIDS crisis, the struggle for creating access to medicines mainly relied upon the moral basis where access to lifesaving medicines have been treated as a charity, not a legal entitlement. The same approach persists in the cases of other disease outbreaks such as recent COVID-19, Ebola virus, malaria, TB, and other infectious diseases.[13] The states and international organisations, working for the issue of access to medicines, ignored the human rights perspective that gives entitlement to the patients to access necessary medicines. However, the issue of access to medicines cannot be dealt with effectively only on ethical grounds as many people around the world still cannot access the necessary medicines.[14] Moreover, the gap between requirement and access to medicines is widening. To effectively deal with the issue of access to medicines, the suffering populations in various countries should have human rights entitlements for accessing necessary medicines under both national and international legal frameworks.

As argued in previous chapters that the issue of access to medicines has been part of various international and regional treaties. In addition to the international legal framework, almost 105 national constitutions include the reference to the right to health.[15] Regarding the International Bill of Rights, access to medicines falls under both binging conventions, ICCPR and ICESCR. Under Article 12 read with General Comment No. 14, the state parties' obligations towards access to medicines extend to ensuring availability, accessibility, acceptability, and quality of medicines. The enforcement of access to medicines as human rights under the ICESCR may be evolutionary for its progressive charter. However, the obligation of the state parties towards the right to life of the Article 6 of the ICCPR read with General Comment No. 36 requires prompt compliance.[16] The

[13] Ibid.

[14] Stephen P. Marks (n-8)752.

[15] Health and Human Rights Resource Guide, 'How is Access To Medicines a Human Rights Issue?' < https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/> accessed 15 November 2019

[16] United Nations Human Rights Committee, General Comment No. 36 on Article 6 of the International Covenant on Civil and Political Rights – Right to life, para 26; UN Human Rights Committee (HRC), *CCPR General Comment*

right to life has been part of major constitutions and inter-state agreements. Additionally, the obligations under the right to life are clear and certain. The enforcement of access to medicines under the right to life is developing as a practice in various states.[17] Furthermore, several regional treaties European Social Charter 1961, the Bangkok Charter 2005 for the promotion of health, the Ottawa Charter for Health, and international agreements make access to medicines as a part of the state's obligations.[18] Under one treaty or another, the obligations of access to medicines are part of the obligations for the majority of states. The arguments will focus on analysing a range of international human rights instruments to argue that the obligations related to access to medicines under the International Bill of Rights, CEDAW, CRC, ECHR, and other international and regional treaties.[19]

Treating access to medicines as moral demand has not rescued the HIV/AIDS infected people from their sufferings. Every year, millions of children are not making to their adulthood because of malaria, TB, and other life-threatening diseases. These issues directly relate to access to medicines and it creates a question on human rights commitments in national and international frameworks. The status and concept of access to medicines as human rights entitlements are developing and refining. The issue that was thought to have moral grounds, is evolving to the level of right by taking space within the normative domain of the right to life and health. The broad interpretation of the right to life can empower the normative scope of access to medicines and other aspects requiring positive obligations of the state parties to the international human rights instruments. The same approach is taking strength in national and international interpretative trends. Furthermore, the interpretation of scope and domain of human rights by the human rights bodies authoritatively guide the states in defining the scope of access to medicines related human rights obligations.

The domain and scope of access to medicines, in one way or another, become the obligation of the states around the world. For instance, the USA is not a member of ICESCR but it has ratified ICCPR and other regional and international treaties, which set the ground for access to medicines

No. 6: Article 6 (Right to Life), 30 April 1982 <https://www.refworld.org/docid/45388400a.html> accessed 16 September 2019. Hereinafter Called 'General Comment No. 36 of the HRCee'

[17] Health and Human Rights Resource Guide (n-15)

[18] Ibid.

[19] Ibid.

as a part of human rights. The discussion now will analyse the developing trends of interpreting access to medicines under the right to health, life, benefiting from scientific progress, and adequate standards of living.

6.3 How to enforce access to medicines under the right to life?

The right to life is the most prominent of all human rights. The content of the right to life does not mention access to medicines as part of the state parties' obligations.[20] However, in cases of a life-threatening disease such as the COVID-19, access to medicines becomes a necessary condition for survival.[21] In this way, the laws, policies, enforcement of various rights that restrict any aspect of access to medicines may affect the fundamental notion of the right to life.[22] The HRCee adopts the same approach by demanding state parties to avoid restrictive interpretation of human rights and asks state parties to take all necessary steps for increasing life expectancy, reducing child mortality, and elimination of epidemics.[23] In the view of the interpretation of HRCee, it is clear that access to medicines in cases of disease such as HIV/AIDS, cancer, TB, and other infectious diseases will contribute to dealing with the issues of child mortality and dealing with life expectancy. The domain of the right to life includes access to medicines as part of the obligations of the state parties to ICCPR.[24]

Recently, General Comment No. 36 of the HRC start a new era for enforcement of access to medicines as part of human rights obligation under the scope of the right to life.[25] The committee

[20] Ibid.

[21] Stephen P. Marks, 'Access to Essential Medicines as a Component of the Right to Health" in Health: A Human Rights Perspective' <https://cdn1.sph.harvard.edu/wpcontent/uploads/sites/580/2012/10/marks_access_to_essential_medecines-2009.pdf> accessed 16 November 2019., Alicia Ely Yamin, 'Not Just a Tragedy: Access to Medications as Right under International Law', (2003) 21 *Boston University International Law Journal* 325–371, 331

[22] General Comment No. 36 of the HRCee (n-16) para 5

[23] Ibid.

[24] Ibid. para 26

[25] Ibid.

has the mandate to supervise and facilitate enforcement of rights under ICCPR in the state parties. As explained in previous chapters that the committee asks all state parties to widen the interpretative scope of the right to life. The committee, with the fiat of authoritative interpretation, requires the state parties to abandon narrow interpretation of the right to life that only includes negative states' obligations. The committee finds that the scope of the right to life includes both acts and omissions causing premature and unnatural death. Moreover, the obligations related to the right to life extend to the sustenance of life with dignity.

The state parties, in the light of General Comment no. 36, are under obligation to protect the right to life with dignity through the positive steps that include access to medicines for people suffering from life-threatening diseases.[26] While interpreting the right to life with reference to access to medicines, the comment stress the text of the provision that includes that no one arbitrarily deprived of his life.[27] The comment interprets that denial of required medicines to a person suffering from life-threatening diseases to fall under the scope of the right to life. The state parties of ICCPR are under obligation to ensure they respect, protect, and fulfill their liabilities by legislating, enforcing, and interpreting access to medicines as part of the right to life.

Access to medicine, in some life-threatening cases, may fall under the right to life. The right to life may enhance the enforcement standards of access to essential medicines. The ICCPR is effective for its Optional Protocols which enhance its enforceability. The text of the ICCPR regarding the right to life provides universal protection of human life and calls all signatories to protect an individual against arbitrary deprivation of it.[28] The right to life is the prime of all human rights and is substantively explained and granted by the ICCPR. Moreover, the right to life is significant for enjoying other human rights. Moreover, the right to life is non-derogable. Text of Article 4 of the ICCPR calls it an inherent right that one owns with birth through the operation of nature and this why some of the writers recognise it as a *Jus Cogens,* a rule of international law that is compulsory for all states. [29]

Various writers have not recognised including access to medicine in the domain of the right to life of the ICCPR. They claim that the scope of the right to life only extends to state killing and

[26] Ibid.

[27] Ibid.

[28] Ray Monihan, Richard Smith, 'Too Much Medicine? Almost Certainly' (2002) *British Medical Journal* 324-859, 324

[29] Ibid.

individuals without due process of law.[30] Moreover, death by hunger, lack of food, health, and access to medicine does not fall under the scope of the right to life.[31] The restrictive interpretation of the right to life focus on keeping its effective enforcement as including housing, health, food, and other life necessities will make it domain-wide and less enforceable.[32] Moreover, these are conditions for life, not life in itself. Therefore, the domain of the right to life is the protection of life itself. Interpretative trends among human rights focus negative duty on states not to infringe on individuals the right to life. Positive aspects of duties such as providing all necessities of life will not fall under the domain of the right to life of the ICCPR.[33]

Contemporary interpretations of the right to life go a step ahead from classical approaches. For instance, Article 2 of the ICCPR put a positive duty on state parties to ensure and respect all human rights enumerated in the document. It is further stressed that state parties are under obligation to make their laws, executive set-ups, and judicial interpretations in line with the international human rights standards. The same article of the covenant puts duties on states to, "take necessary steps, under their constitutional processes and with the provisions of present convenient, to adopt those laws or measures to give effect to the rights recognised in the present covenant".[34] The following paragraph, if critically evaluated, puts positive duty to act beside negative duty to apply restraint on power. Positive duty is exploiting states' constitutional framework and making laws effective for the protection of the right to life. Moreover, life cannot be taken in isolation with access to medicine in case of lifesaving medicine. We may take the example of COVID-19, AIDS, Cancer, Malaria, and other life-threatening diseases where denial of medicine is the denial of the right to life.[35] Moreover, the right to life is accomplished by the protection of all other human rights

[30] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicine* (Oxford University Press 2008) 115–116

[31] Holger P. Hestermeyer, 'Access to Medicine as Human Rights' < http://www.mpil.de/files/pdf2/mpunyb_hestermeyer_8.pdf> accessed 6 November 2018

[31] Ibid.

[32] Holger Hestermeyer (n-30) 115

[33] Ibid.

[34] Ibid.

[35] Alicia Ely Yamin, 'Not Just a Tragedy: Access to Medications as Right under International Law', (2003) 21 *Boston University International Law Journal* 325–371, 331

enumerated in the ICCPR and the ICESCR. General Comment 6 of the HRCee reflected upon the flexible interpretation of the right to life in the following words:

"The Committee has noted that the right to life has been too often narrowly interpreted. The expression "inherent right to life" cannot properly be understood in a restrictive manner, and the protection of this right requires that States adopt positive measures. In this connection, the Committee considers that it would be desirable for States parties to take all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics."[36]

The comment call state parties for understanding the protection of rights through positive measures through their constitutional process. Among increasing life expectancy and reducing child mortality, measures to eliminate malnutrition, and the epidemic is relevant to the issue of access to medicine.[37] In the case of life-threatening diseases, the issue of access to medicines becomes relevant to the right to life. State parties to the ICCPR have a positive duty to respect, protect, and fulfil the right to life. Keeping in view these arguments, states are under obligation to legislate, administrate, and interpret the issue of access to life-saving essential medicines as a matter of protecting life itself.[38]

6.4 The right to life and dignity; a pursuit of access to medicines

In the case of the recent outbreak of the COVID-19, the inaccessibility to medicines and health-care facilities are a violation of the right to life, and human dignity. For example, during childbirth, a large number of women lose their lives for uncontrolled bleeding. To avoid the bleeding during childbirth, a drug namedprophylactic uterotonics may treat the blood loss that is the biggest contributor to maternal mortality.[39] In the same way, the issue of child mortality and after the birth disease is very significant. The issue connects access to medicines with the right to life and human dignity. Article 6 of the Convention on Rights of Child (CRC) includes the protection of the right

[36] UN Human Rights Committee (HRC), *CCPR General Comment No. 6: Article 6 (Right to Life)*, 30 April 1982 <https://www.refworld.org/docid/45388400a.html> accessed 2 September 2019

[37] Ibid.

[38] Ibid.

[39] Health and Human Rights Resource Guide (n-15)

of every child as an inherent right.[40] It is pertinent to mention that the provision calls all state parties to take all necessary positive steps for protecting the life of a child concerning both pre-birth and later issues.

Various cases from regional and domestic judicial forums indicate that the inaccessibility of health care facilities connects to the right to life. The decision based on ECHR in *Travares v. France* is very significant in explaining this.[41] The wife of the applicant died in a French hospital during childbirth for several medical issues. The claimant argued that the negligence of the hospital staff constituted a violation of Article 2 (1) of the ECHR that includes the right to life for everyone. Although, the case did not get the merits of remedies as the defendant contended that they followed all necessary medical standards.[42] However, the judge found that the state must take all necessary positive measures for protecting the right to health in connection to the right to life.[43] The judgment found that the states are bound to both positive and negative obligations which include avoiding loss of life as well as taking all necessary positive steps to save lives from arbitrary loss.[44] The provision grants everyone a guarantee of life and one will not be deprived of it arbitrarily. The examples from the European interpretation of human rights mention that the issue of health connect with life when it comes to life-threatening disease. Moreover, access to medicines is an integral part of health care and facilities related to health. This is why issues of accessing medicines fall within the scope of the right to life.

The same approach of wider interpretation of the right to life finds space in various other jurisdictions. In the *Social and Economic Rights Action Center & the Center for Economic and Social Rights v. Nigeria*, the decision included several human rights obligations and their interdependence. The commission fixed responsibility on the Nigerian government for failing to protect the right to life for its inability and violation of the right to health as the result of the activity of oil companies in

[40] Convention on the Rights of the Child (Adopted and opened for signature, ratification and accession by General Assembly resolution 44/25 of 20 November 1989), Article 6.

[41] Rebecca J. Cook, Bernard Dickens. 'Human Rights Dynamics of Abortion Law Reform' (2003) 25 *Human Rights Quarterly* 1-59

[42] Ibid.

[43] Ibid.

[44] Ibid.

Ogoniland.[45] The commission tested the obligation of the state on the criteria to respect, promote, and fulfil their commitments to guaranteed rights. Resultantly, the commission found that the state has violated its obligations by not protecting the domestic population from the oil exploration activities and their impact on the right to life, health, and other related rights.[46] The inability of Nigeria was interpreted as a violation of Article 4 (1) of the Banjul Charter that provides everyone the right to have respect for life. The commission ordered to stop the impact of oil exploration on the local population. The commission also ordered the government not only to protect the population from physical attacks to the lives of the people but also demanded government protecting the right to health along with life. These examples demonstrate that the African Commission on Human Rights does not segregate between the right to health and life. A similar approach is found by the IAHR in *Mendes v. Brazil* where the commission interpreted that the right to life is interconnected with all other human rights in the charter.[47] The commission found that it is a violation of Article 4 of the convention not to protect its populations from arbitrary loss of life.[48] The findings of the court demonstrate that the right to health and life are closely connected. One may construe that the issue of access to medicines when it leads to arbitrary loss of life, demands state parties to Banjul Charter to respect, promote, and fulfil their positive obligations.

On constitutional levels, the preamble of the Bolivian Constitution interconnects various human rights stating:

"A State based on respect and equality for all, on principles of sovereignty, dignity, interdependence, solidarity, harmony, and equity in the distribution and redistribution of the social wealth, where the search for a good life predominates; based on respect for the economic, social, juridical, political and cultural pluralism of the inhabitants of this land; and on collective coexistence with access to water, work, education, health and housing for all."[49]

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[45] *Social and Economic Rights Action Center & the Center for Economic and Social Rights v. Nigeria (Communication No. 155/96)* < https://www.escr-net.org/caselaw/2006/social-and-economic-rights-action-center-center-economic-and-social-rights-v-nigeria> accessed 17 November 2019

[46] Ibid.

[47] James L. Cavallaro, et al., *Doctrine, Practice, and Advocacy in the Inter-American Human Rights System* (Oxford University Press, 2019) 349

[48] Ibid.

[49] Bolivian Constitution 2009, Preamble

The text of the preamble finds that the existence of a good life depends on respect for various human rights by the state. The Bolivian Constitution of 1967 also includes various positive aspects of the state obligations related to the right to life. The Constitutional Tribunal of Bolivia interpreted access to medicines to HIV/AIDS infected patients under the scope of the right to life.[50] The tribunal found that it is the obligation of the state under the right to life to provide necessary medicines in chronic illness that may lead to loss of life.[51] The constitution of Columbia provides the right to health for everyone. The right also includes a guarantee of protecting life with dignity. The protection of dignity includes the obligation of the state to protect its population against diseases such as cancer, AIDS, and other health conditions that may impair the enjoyment of life with dignity.[52]

The ECtHR has interpreted Article 3 of the ECHR in its wider sense. The provision prohibits inhumane or degrading treatment along with torture. In *D v United Kingdom*[53], the ECtHR found that the deportation of an AIDS-infected person to a place where adequate treatment is not available is the violation of Article 3. The case sets the parameters for violation of Article 3 in relation to the health conditions that may impact the obligation towards the prohibition of inhumane or degrading treatment. The court held that a mere shortening of life, because of the unavailability of standards health-care, does not fall within the preview of Article 3 of ECHR. In this way, the court settles that in case of non-availability of necessary health-care facilities fall under the scope of inhumane or degrading treatment where the person is on the verge of dying.[54] The parallel approach was found in the cases of *N v United Kingdom*[55], *Savran v Denmark*[56], and the recent judgment of the Supreme Court of UK in the case of *AM (Zimbabwe) v Secretary of State for the Home Department*[57]. The House of Lords unanimously found in *N v United Kingdom* that, "It is perhaps

[50] Health and Human Rights Resource Guide (n-5)

[51] Ibid.

[52] Ibid.

[53] D v United Kingdom (1997) 24 EHRR 423

[54] D v United Kingdom (1997) 24 EHRR 423

[55] N v United Kingdom (2008) 47 EHRR 39

[56] Savran v Denmark [2019] ECHR 651

[57] AM (Zimbabwe) v Secretary of State for the Home Department [2020] UKSC 17

not, however, self-evidently more inhuman to deport someone who is facing imminent death than someone whose life expectancy would thereby be reduced from decades to a year or so".[58] However, the findings in on the interpretation of Article 3 of the ECHR, concerning the availability of medication, distinguished between the question of the relation between unavailability of necessary medication that may lead to death and the other health conditions. In the recent case of *AM v Secretary of state*, Lady Hale finds:

"In my view, therefore, the test, in this sort of case, is whether the applicant's illness has reached such a critical stage (ie he is dying) that it would be inhuman treatment to deprive him of the care which he is currently receiving and send him home to an early death unless there is care available there to enable him to meet that fate with dignity"[59]

The findings set the criteria for interpreting access to health care and medication under Article 3 of the ECHR. To interpret the access to health-care and medicines, the illness must be critical with the threat of death and the person cannot achieve the dignified if not given adequate access to health-care that includes access to medicines.

The arguments try to establish that the scope of the right to life is widening in both international and national frameworks. The courts in various developing countries must learn from the rationale of including access to medicines and healthcare under the domain of the right to health where it must be the obligation of the states to respect, protect, and fulfil its positive obligations related to the right to life. The obligations must include the positive obligation of providing access to medicines when it is a case of life-threatening disease.

6.5 Interpreting access to medicines under the right to health

In response to the recent COVID-19 pandemic crisis, UN experts find that everyone has a right to health.[60] The former UN Special Rapporteur makes it clear that the right to health is one of the

[58] N v United Kingdom (2008) 47 EHRR 39

[59] AM (Zimbabwe) v Secretary of State for the Home Department [2020] UKSC 17

[60] UN Experts, 'Human rights must be maintained in beating back the COVID-19 pandemic, 'without exception" (UN News 26 March 2020) <https://news.un.org/en/story/2020/03/1060372> accessed 30 March 2020.

fundamental human rights and declared that an effective health care system is significant for core social construct.[61]

The views on the status of the right to health are diverse. Goodman follows Lock's conceptualisation of public good, in defining his understanding of the postmodern orientation of rights as 'welfare rights'.[62] He does not accept the right to health as absolute without any limitation and control from the government.[63] His visualisation of right demands states to intervene once a right leads towards inequality or creates a barrier of access towards the public good. Talking specific to the right to health, Goodman attributes it as the primary manifestation of torture and slavery and tried to establish its non-derogable status.[64] He argued that international agreements recognising the right to health such as ICESR, through Article 12, pose duty on states to protect the right to health of individuals. N Swazo notes that the right to health is declaratory and that is why it does not enjoy normal enforcement mechanisms. He quotes that declaratory tradition:

"is not effectively binding on the states, despite their frequent attempts to give it obligatory force by saying that the fundamental principles that underlie the tradition are principles of law" even as "the appeal is almost always to conscience, not to courts."[65]

If the abovementioned opinion is analysed critically, N Swanzo highlights Imperative Theory of Law where Austin accepts that the rules made by the state authority are enforceable by the courts. To clarify this, ICJ and ICC adjudicate based on ICCPR and ICESCR. Lee Caplan explains this as:

"Under the normative hierarchy theory, a state's jurisdictional immunity is abrogated when the state violates human rights protections that are considered peremptory international law norms, known as jus cogens. The theory postulates that because state immunity is not jus cogens, it ranks lower in the hierarchy of international law norms, and therefore can be overcome when a jus cogen norm is at stake"[66]

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[61] Lee M. Caplan 'State Immunity, Human Rights, and Jus Cogens: A Critique of the Normative Hierarchy Theory' (2003) 97 *The American Journal of International* 741-781

[62] Norman K. Swazo, 'The Right to Health, International Law, and Economic Justice' (2006) *The Internet Journal of Law, Healthcare and Ethics* 2, 1-14

[63] Ibid.

[64] Ibid.

[65] Ibid.

[66] Lee M. Caplan (n-61) 741

Lee goes a step forward and counts the protection of human rights above state immunity. He considers human rights as *jus cogens*, the highest universal norms of international law that he considers prime important, and state violating human rights does not enjoy state immunity.

Dealing with the question of derogable rights construct in the ICCPR, one may consider that the cause for derogation is the protection of public interest. For instance, the right to freedom of expression may be restricted if it harms public order, safety, health, or morals. States are authorised to take unilateral action if some rights violate fundamental rights. On the same analogy, states may use these declaratory international obligations to restrict or limit any patent rights-violating fundamental right of life and health.

6.5.1 How the domestic courts learn from Columbian Success

Columbia remains a success story to consider access to medicines as part of human rights obligations especially the right to health. Under constitutional jurisdiction, the court ordered the Ministry of Health and other health establishments to provide health-related remedies to 22 claimants in different cases.[67] Along with ordering the treatment of the claimants, the court also asked the Columbian government to amend laws in a way that it does not obstruct the right to health of individuals. To deal with the issue in the transitional period, the court demanded the government to expedite investing resources and evaluating health-related services provided by the private companies.[68] The decision has helped in evolving the status of the right to health as constitutionally guaranteed right. The decision has convinced that judicial intervention because of constitutionally guaranteed rights may help to solve the issue of access to medicines.

In pursuance of the Columbian Constitution of 1991, the legislature has adopted Law 1751 during 2015 that includes the right to health as a constitutionally guaranteed right. The law was the product of a long struggle for enforcing health as one of the constitutional rights enforceable by the constitutional courts of the country. It is pertinent to note that the adoption of the law as a

[67] Aquiles Ignacio Arrieta-Gómez, 'Realizing the Fundamental Right to Health through Litigation: The Colombian Case' (2018) Health and Human Rights journal < https://www.hhrjournal.org/2018/06/realizing-the-fundamental-right-to-health-through-litigation-the-colombian-case/> accessed 20 November 2019

[68] Decision T-760 of 2008, <https://www.escr-net.org/caselaw/2009/decision-t-760-2008> accessed 20 November 2019

result of several dozen judicial interpretations of health-related state obligations during decades' long judicial activism. Resultantly, the court ordered the state of Columbia to include the right to health among constitutionally guaranteed human rights.[69] The court used its *tutela* action, a human rights jurisdiction, as its function to order the government to protect the right to health of the claimants effectively. The Columbian Constitution gives the power to the courts. By using the writ petition, an individual can invoke the jurisdiction of the court on the question of violation of human rights. The petitioner has to contend that no alternate remedy is available and the action or inaction may result in the violation of constitutionally guaranteed rights of the individual.[70] The special judges of the constitutional court of Columbia decide the *tutela* action.

Deciding 22 cases related to *tutela* action, the Columbian Constitutional Court made the famous decision T-760 during 2008.[71] The decision discussed several judicial interpretations related to various aspects of the right to health in the past. The court found that the *tutela* action of the plaintiffs is maintainable as the human rights are interconnected. The court found that there is a very multifaceted correlation between rights to the health of vulnerable people with the right to life. The judgment referred to various international legal instruments and the obligations of the state of Columbia towards these treaties.[72] The findings mentioned that the state, by the virtue of their obligations towards Article 12 of the ICESCR, is under obligation to respect, protect, and fulfil its health-related obligations. The decision also benefited from the interpretation of the right to health in General Comment No. 14 of the CESCR. The decision not only provides a remedy to the plaintiffs it also structurally settles the question of the status of the right to health and its related aspects that include access to medicines.

The decision of the Columbian Court remains a guideline for all developing and less-developed countries where the right to health is not part of the constitutionally guaranteed rights or its enforcement remains ineffective. The decision has significantly settled the principle of human rights indivisibility, interconnected charter, and core obligation of the developing countries towards human rights ideals.[73] The decision also stands an answer to many excuses for not

[69] Ibid.

[70] Ibid.

[71] Ibid.

[72] Ibid.

[73] Ibid.

prioritising the right to health because of scarce economic resources and progressive realisation of the right to health under economic and social rights. The judicial role of the Columbian Constitutional court remains an example for other countries where access to medicines and other health care services are not included in legally guaranteed rights. The litigation under various constitutional rights may act as an effective way of ensuring access to medicines as it falls under multiple human rights guaranteed by the constitution.[74] Moreover, the judicial role will further pave the way for legislative and policy reforms as it happened in the Columbian example.

6.5.2 The enforcement of access to medicines in Brazil and Argentina

Argentina: The case of *Viceconte, Mariela Cecilia vs the State Ministry of Health and Social Action* is very significant in setting guidance to interpret the right to health under Article 12 of the ICESCR.[75] The Federal Administrative Court of Argentina decided the claim of applying entitlement to health under international legal instruments.[76] The *amparo action*, a constitutional jurisdiction of the court, was raised for the issue of production of vaccine treating Hemorrhagic Fever, a disease that affected 3.5 million of its populations.[77]

Mariela Viceconte, one of the claimants, filed an *amparo* action to fix the state obligation towards facilitating the population with the required vaccine named Candid 1 to treat Hemorrhagic Fever. The case relied on Article 12.2 (c) of the ICESCR that states:

"2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases"

[74] Ibid.

[75] Viceconte, Mariela Cecilia vs the State Ministry of Health and Social Action < https://www.globalhealthrights.org/wp-content/uploads/2014/01/ENGLISH-Viceconte-Argentina-1998-English-2.pdf > accessed 27 November 2019

[76] Ibid.

[77] Ibid.

The claimant argued that the population suffering from the disease have legal entitlement under the international obligations of Argentina to the ICESCR. Moreover, it was argued that the vaccine Candid 1 is almost 95 percent effective to treat the fever and the vaccine is approved by the WHO.[78] The issue was the non-profitability of the drug and the manufacturing company abandoned its production. After hearing the arguments from both parties, the Federal Court found that the Argentinian government must arrange the vaccine for the effected population under its international economic and social obligations. The decision ordered the Ministry of Health to make sure that the production of the Candid 1 vaccine is resumed without any further delay in strict compliance of the order.[79]

The decision is very significant towards fixing the obligation of the state towards establishing the right to health as a guaranteed right instead of considering its moral or ethical demand. The court has been active in its later decisions about interpreting the right to health in consonance with the international human rights standards set by various treaties.[80] This example is good for all developing and less-developing countries courts where the states are parties to ICESCR and constitutional rights framework supports the right to health as a legal entitlement.

Brazil: The issue related to access to medicines and other health care services to the suffering population. The court found that it is the obligation of both state and federal government that the citizens have adequate access to necessary medicines and health facilities. The Brazilian Constitution states as under:

"Health is the right of all and the duty of the National Government and shall be guaranteed by social and economic policies aimed at reducing the risk of illness and other maladies and by universal and equal access to all activities and services for its promotion, protection and recovery."[81]

Under Article 196 of the Constitution of Brazil, the state has an obligation towards guaranteeing the right to health by utilising all possible economic, policy, social, and legal means.[82] Furthermore, the court found that the state must reduce the risk of falling ill along with facilitating the population

[78] Ibid.

[79] Ibid.

[80] Ibid.

[81] Brazil's Constitution of 1988 with Amendments through 2014, Article 196

[82] Brazil's Constitution of 1988 with Amendments through 2014, Article 196

who is suffering from various diseases and cannot access the medical services necessary for recovery.

6.6 Protection of Minorities for access to medicines

The issue of access to medicines is more serious for protecting the right to life and health of the minorities and indigenous peoples. In the times of outbreak of pandemics and epidemics, the minorities are the most vulnerable in terms of protection of their human rights. After the outbreak of COVID-19, the minorities around the world are facing challenges to safeguard the right to life and health. The same issue has been taken by the UN treaty bodies and several other human rights forums. The challenges faced by the minorities and indigenous groups include health crisis[83], loss of jobs, physical and verbal abuse, communication barriers, and access to adequate health-care facilities including access to medicines.

The minorities and indigenous people are more vulnerable to the impact of the outbreak of diseases like COVID-19 for uneven access opportunities to the health-care facilities. The fundamental barriers reported to the Minority Rights International include discrimination from the law enforcement agencies and health-care workers, fewer skills to access the necessary information on treatment and medical advice, economic challenges because of widespread lockdown, and lesser financial ability to pay for the necessary health-care services. For instance, in Kenya, the Borana community is receiving negligible support from the government to fight the outbreak of COVID-19.[84] Only one part-time doctor is available for a population of 200,000 people that endangers the right to life and health of the minority group. In Rwanda, the minority and indigenous groups did not receive the food and health-care supplies.[85] The sanitary staff and sweepers from the minority groups were forced to work in hospitals without the provision of protective measures during the outbreak of the COVID-19 outbreak.[86] The minority groups in India, especially Muslim populations, were under attack for being the source of the pandemic

[83] Alexandra Xanthaki, 'Indigenous rights in international law over the last 10 years and future developments' (2009) 10 Melbourn Journal of International Law 27-34, 28

[84] Minority Rights International, 'Report COVID-19 Discrimination' <https://minorityrights.org/coronavirus/report-discrimination/> accessed 7 May 2020

[85] Ibid.

[86] Ibid.

outbreak. All these issues put the minority and indigenous groups more vulnerable. The states need to do more in order to protect the right to life and health of the most vulnerable populations in their territories.

With specific reference to the protection of the right to life and health of minorities in the recent outbreak of COVID-19, the chairpersons of ten UN treaty bodies noted that:

"No one should be denied health care because of stigma, or because they belong to a group that might be marginalized…States need to provide targeted support – including financial, social and fiscal - to those particularly affected, such as those without health insurance or social security."[87]

The treaty bodies have called all members states to take all necessary measures to protect the right to life and health of their citizens with special focus on protecting the vulnerable groups such as disables, asylum seekers, indigenous minorities, homeless, prisoners, and refugees. Under the UN human rights framework, the members of the minority groups can seek the protection of their rights granted under relevant human rights treaties. The fundamental focus of human rights is the protection of the rights of everyone without any discrimination. The human rights treaties obligate the state parties to do more for the protection of vulnerable factions of the society that includes minorities and indigenous groups. On the issue of access to medicines and health-care, the state parties to the international human rights treaties are under obligation to protect the right to life and health of minorities and indigenous groups.

6.7 Access to medicines for Women

The female population in most of the developing and least developing countries face issues fo unequal access to health-care and access to medicines for various cultural, social, and economic reasons. The women, living in traditional societies, face restrictions on movement, lack of necessary health education, financial dependence, and independent access to health-care facilities. The state parties to CEDAW are under obligation to eliminate all kinds of discrimination against women. The women are often more vulnerable in the issues of access to medicines and other

[87] Office of the High Commissioner (UN Human Rights), 'UN Human Rights Treaty Bodies call for human rights approach in fighting COVID-19' <https://www.ohchr.org/en/NewsEvents/Pages/DisplayNews.aspx?NewsID=25742&LangID=E> accessed 7 May 2020

health-care facilities when it comes to pandemics like the recent COVID-19. The state parties to the CEDAW and other international human rights treaties need to protect the women population form any discrimination in relation to access to medicines and health-care facilities.

The state parties to CEDAW are under obligation to eliminate all kinds of discrimination against women to protect the right to life and health in relation to the recent outbreak of the COVID-19 and other pandemics and epidemics. The state parties are under obligation to allocate funds in a way that does not exclude or discriminate women from equal opportunity to access the necessary health-care and medicines. The women taking care of children and elderly people are more vulnerable to contract contagious diseases, therefore, the state authorities must consider the increased risk situation for the women by providing necessary preventive and curative measures. Women form a major portion of the health-care staff. This requires further action from the states that women do not face any discrimination in accessing protective equipment and medicines.[88] Moreover, the state parties to CEDAW are under obligation to provide required health-care facilities for women to protect their sexual and reproductive health.[89] In a situation like COVID-19, the issue of access to health-care facilities and medicines becomes more serious for women. This requires the state parties to the international human rights to extend the institutional response to protect women as a vulnerable group of their societies.

6.8 Access to medicines under Right of Children

Every child is entitled to access necessary medicines under both ICESCR and Convention on the Right of Children (CRC). Article 12 of the ICESCR obligates all state parties to ensure the reduction of the stillbirth rate, healthy development, and child infancy.[90] Article 6 of the CRC calls all members states that every child born has the right to life, survival, and development of every born child.[91] The same obligation is set under Article 24 of the CRC states that every child has the right to protection of health about treatment, health care facilities, and rehabilitation in case of any

[88] Niaz A. Shah, *Judicial Resource Book on Violence Against Women for Asia: Combating Violence Against Women and Girls for Cambodia, India, Pakistan and Thailand* (The Commonwealth 2018) 68,69
[89] Ibid.
[90] Viceconte, Mariela Cecilia vs the State Ministry of Health and Social Action (n-76)

[91] Health and Human Rights Resource Guide (n-5)

illness.[92] The provision further sets that all state parties will try their level best to provide health care to every child.

To elaborate the right of every child to access health care facilities including access to medicines, General Comment No. 14 of the CESCR interprets the wider scope of the right of the child that includes the protection of both child and maternal health, pre and post-natal health, access to necessary health information.[93] On the same notion, General Comment No. 15 of the CRC states that the children are entitled to the highest standards of health. In the view of Article 24 of the CRC, the state parties are under obligation to perform their duties to ensure that access to medicines for every child is ensured.[94] Moreover, the comment focuses on the WHO list of essential medicines to define the scope of state obligations towards ensuring access. Moreover, the CRC has effectively levelled concerns against various state parties concerning their obligations under the covenant. The countries include Portugal, Gabon, Uzbekistan, Armenia, Ethiopia, Lithuania, Mauritania, and Moldova. It is pertinent to mention that the performance of the committee on the protection of rights under the CRC has pursued communications and has helped in improving child rights. The activism of the committee indicates that access to medicines related demand is not mere moral demand rather it is legally guaranteed entitlement under the international human rights law. Moreover, the states are under obligation to protect access to medicines as a matter of right concerning every child born in the territory without discrimination.

Argentina (Ana Carina v. Ministerio de Salud): The litigation based upon *amparo* action jurisdiction of the constitutional court was initiated by the parents of a baby boy suffering from a bone-related disease. The boy needed necessary medicines named Newtromax. The medicines were available to the children with the help of the Ministry of Health of Argentina. Later, the provider (company) abandoned the provision of medicine.[95] The argument from the agency was that the provision of

[92] Health and Human Rights Resource Guide (n-5)

[93] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, 11 August 2000, E/C.12/2000/4, paras 3. Hereinafter named 'General Comment No. 14 of the CESCR'

[94] Convention on the Rights of the Child (Adopted and opened for signature, ratification and accession by General Assembly resolution 44/25 of 20 November 1989), Article 24.

[95] Ilias Bantekas, Lutz Oette, *International Human Rights Law And Practice* (Cambridge University Press, 2011) 367

medicines was not based on any legal entitlement rather it was provided on moral and humanitarian grounds.[96] This is why it is the sole discretion of the providing agency to stop its provision.

The parents of the affected child brought constitutional action against the action of the provider and the Ministry of Health. The legal action relied on Article 3 of the CRC along with Article 12 of the ICESCR.[97] The court accepted the claim and issued a declaratory order to require the Ministry of Health arranging the required medicines for the suffering children. The court further decided that the government of Argentina has positive obligations towards the fulfilment of the right to health as a matter of legal right. The court did not accede to the argument of treating access to medicines as a moral or humanitarian demand.

South Africa (Treatment Action Campaign v. Ministry of Health): An action was brought by several claimants against the Ministry of Health of South Africa against its move to restrict the availability of medicine nevirapine that prevents the transfer of HIV from mother to child. The case relied on the right to life, health, and equality challenging the limited availability of medicines in a few hospitals. The arrangement was challenged as it was claimed that it is against the dignity of human life. The arguments relied on both national and international laws establishing the obligations of the state towards access to medicines as a part of the right to life, dignity, health, and equality. The defendant argued that the provision of the medicines was under a pilot study. Hence, the effects of the medicines are not ascertained yet.[98]

The High Court of South Africa, after hearing the argument, decided that restricting the availability of the medicines is not justifiable or reasonable based on arguments from the defendants. Therefore, the government was under a constitutional obligation to make the medicine available to public health centers. Furthermore, the court requires the government to further improve its plans dealing with HIV transmission to children from mothers. [99]

Access to medicines concerning children is well established. The CRC, ICESCR, and other international legal instruments are very clear that the issue of access to medicines falls under

[96] Ibid.

[97] Health and Human Rights Resource Guide (n-5)

[98] Minister of Health v Treatment Action Campaign (TAC) (2002) 5 SA 721 (CC), < https://www.escr-net.org/caselaw/2006/minister-health-v-treatment-action-campaign-tac-2002-5-sa-721-cc> accessed 21 November 2019

[99] Ibid.

various human rights such as life, health, human dignity, and equality. Moreover, reducing child infant mortality has been the common goal of the international community. There are arguments from countries like the USA that they are not part of ICESCR and this why they are not under obligation to treat access to medicines as part of the international human rights entitlement. However, the USA and other countries have signed CRC and other international legal instruments guaranteeing access to medicines as a part of the international human rights entitlement.[100] The cases quoted above are some of the examples from various countries to establish that the issue of access to medicines concerning children is not considered as moral demand rather it has been interpreted under both national and international laws. All this means that the issue of access to medicines is not a mere charity rather it is a legal obligation.

6.9 Access to medicines as a right to enjoy the benefits of scientific progress

The right to benefit from scientific progress is often undermined because of the historical difference in lifestyles between poor and rich. However, the issue of access to medicines is not as normal as new computing gadgets, cars, luxury houses, etc. The scope of Article 15 of the ICESCR includes access to medicines as a part of enjoying the benefits of research and development in medical sciences. Moreover, General Comment No. 15 of the CESCR has made it clear that the monopolies over scientific invention should not be allowed to suppress the ideas of international human rights.[101] Thus it is obligations of the state parties to make sure that scientific progress is accessible to the people without any discrimination of economic status.

To illustrate the issue of conflict of right to benefit from scientific progress and patents on medicines, the case of Romania is a significant example where hepatitis C is affecting many populations. Sofosbuvir, the effective medicine to treat the disease is under patent protection and the price is set almost fifty thousand dollars for three-month treatment. The same issue persists in Asia, Africa, and other parts of the world. The same issue has been addressed by various UN Special Rapporteurs, the CESCR, WHO, and Doha Declaration during 2001. All these efforts

[100] Ibid.

[101] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Para. 1 (c) of the Covenant)*, 12 January 2006, E/C.12/GC/17 Para 3

recommend developing and less-developed countries to uplift the protection and enforcement of access to medicines against any other conflicting right. General Comment No. 17 calls all state parties that to ensure that protection of intellectual property do not jeopardise access to medicines whenever there is conflict.

Venezuela (Glenda López et al. vs Instituto Venezolano de Seguros Sociales): A total of 29 claimants, infected with HIVAIDS, initiated *amparo* action against the Social Security Institute of the government of Venezuela.[102] The claim was that the institute has not been successful in providing medicines (antiretroviral) in a manner prescribed. Moreover, the allegation against the center included denial of covering the cost of necessary testing for the assessment of the treatment. The claim relied on both national constitutional provisions and international laws.[103] The court affirmed that the institute has violated the rights of the claimants. Moreover, the court found that it is the obligation of the government and the bodies working to fulfil their human rights obligations towards people suffering from HIV/AIDS. Moreover, the court is also obligated to facilitate the infected population with laboratory testing to make the treatment more effective.[104]

The debate on the conflict between patent protection of medicines and access to medicines has mainly focused on creating human rights concessions. The arguments on the topic mainly follow the idea of bargaining space for access to medicines under the WTO charter. However, the scholar suggests developing an independent human rights framework for securing access to medicines as a matter of legal right. This work has followed the same suggestion of establishing access to medicines as a matter of right under the international human rights law. The same has been stressed recently by the UN High-Level Panel on Access to Medicines Report.[105]

[102] Hans V. Hogerzeil, et al., 'Ruling for Access Leading court cases in developing countries on access to essential medicines as part of the fulfilment of the right to health' (2004) World Health Organization Department of Essential Drugs and Medicines Policy < https://www.who.int/medicines/areas/human_rights/Details_on_20_court_cases.pdf?ua=1 > accessed 13 March 2020

[103] Ibid.

[104] Ibid.

[105] Ibid.

6.10 Obligations of the states towards access to medicines as a human right entitlement

The recent outbreak of the COVID-19 pandemic has forced the global community to crystalise the human rights responsibilities of the states in relation to protecting the right to life and health. Moreover, the issue of access to medicines has come to the attention where the states are trying their level best to prioritise the access to health and medicines over other conflicting rights. Depending upon the situation of an infected person, the state responsibilities fall within the scope of the right to life and health. The protection of one human right interlinks with the overall human rights framework. For instance, a person suffering from the COVID-19 not only needs access to health care and medicines but also requires protection of life, human dignity, the prohibition against torture, equality, non-discrimination, and other relevant aspects of human rights.

The issue of access to medicines is an element of the right to health, life, and other related human rights.[106] The state parties to various international agreements are under obligation to respect, protect, and fulfil their obligations concerning their promises in good faith.[107] General Comment No. 14 is a good source to understand these obligations. The comment have comprehensively set the normative domain of the obligations of the states and other actors concerning access to medicines. However, the following analysis will present the normative contents of the member states' obligations concerning the right to health and other relevant rights in general. The obligations are divided on the duties to protect, protect, and fulfil.

The state parties to international human rights are under obligation to respect access to medicines by abstaining from limiting or denying access to for everyone without discrimination to minorities, prisoners, illegal immigrants, or any other discriminatory steps to hinder access to curative, preventive, and palliative health care services.[108] In this way, it is the obligation of the state parties that the health care facilities are available equally to everyone living in the territory without one's status as a freeman, prisoner, or a person without legal immigration status. This marks the significance of access to medicines. The provision of health care facilities finds under the right to

[106] Lisa Forman, et al., 'Assessing the UN High-Level Panel on Access to Medicines Report in Light of the Right to Health' (2016) 5 (4) Laws <https://www.mdpi.com/2075-471X/5/4/43/htm> accessed 25 November 2019

[107] Vienna Convention On The Law Of Treaties (with annex).Concluded at Vienna on 23 May 1969, Article 26

[108] General Comment No. 14 of the CESCR (n-94) paras 34

health of ICESCR. Moreover, the same entitlement can also be interpreted under the right to life, dignity, women, child, and enjoying the benefit of scientific progress. Providing medicines to a limited or selected group can constitute a violation of state obligations concerning the right to health and other related rights. In case of an action by the state that may affect the access to medicines or other aspects of the right to health, the member states are under obligation to follow the due course of law and facilitate the affected population in alternate ways.[109]

During 2016, the UN High-Level Panel on Access to Medicines reported that access to medicines is an integral element of the right of everyone towards physical and mental health in the context of HIV/AIDS and other diseases challenging the enjoyment of health and normal life.[110] The same was included in the UN Human Rights Commission Resolution that respecting access to medicines as an international legal entitlement under the right to health.[111] The resolution has required all state parties to respect their obligations towards access to medicines. The obligation to respect include the indiscriminate access to medicines, non-interfering in access to medicines in any way, availability of both medicines and related technologies to treat pandemics. The resolution required the state parties to establish a framework to treat diseases like HIV/AIDS and other infectious diseases.[112] The UN High-Level Panel on Access to Medicines has pointed out that there is policy incoherence between access to medicines as human rights and other rights such as protection of patents. These incoherencies affect the accessibility and affordability of medicines. Moreover, these policy incoherencies result in contradicting rights at the national levels that create a violation of the obligation to respect.[113] The panel reported that:

"Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfil the right to health. As a first step, they must undertake public health impact assessments. These impact assessments should verify that the increased trade and economic benefits are not endangering or impeding the human rights and public health obligations of the nation and

[109] Alicia Ely Yamin, 'Challenges and Possibilities for Innovative Praxis in Health and Human Rights: Reflections From Peru' (2002) 6 *Health and Human Rights* 35, 40.

[110] Lisa Forman (n-107)

[111] Ibid.

[112] Ibid.

[113] Ibid.

its people before entering into commitments. Such assessments should inform negotiations, be conducted transparently and made publicly available"[114]

The member state governments are under obligation to make sure that both national and international agreements do not jeopardise the obligations related to access to medicines. Any domestic law or international commitment that impacts access to medicines counterproductively will be a violation of the obligation to respect.[115] The Doha Declaration mentions that "each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."[116] The obligation to respect calls all the state parties to align both domestic laws and policies to support their obligations under access to medicines related human rights.

Furthermore, in *Ana Carina v. Ministerio de Salud,* the Argentinian court found it a violation of the obligation to protect where the state was unable to procure the necessary medicines from a third party.[117] The court interprets that the state needs to protect its citizens from any adverse actions that may come from pharmaceutical companies, drug distributors, or other related parties. The state parties need to ensure that private parties playing their role in the health care system do not risk accessibility, acceptability, availability, and affordability of the access to medicines as a larger part of their obligation to the right to health. The inability to control third parties from threatening access to medicines will be a violation of the obligation to protect. The states need to regulate their laws in a way that they secure access to medicines to all their population without any discrimination.[118] The states must create fair competition among various pharmaceutical and medical companies in a way that does not allow them to abuse their dominant position. Additionally, the states may use their competition laws as an effective tool to deal with all anti-competitive practices of pharmaceutical and medical companies under the umbrella of patent

[114] Ibid.

[115] Ibid.

[116] The Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2,14 November 2001.

[117] Hans V. Hogerzeil (n-103)

[118] Lisa Forman, et al. (n-107)

monopolies. Effective enforcement of anti-competitive laws can help in reducing the unequal distribution of health services and goods.[119] Moreover, the laws will help in promoting the adequate quantity of sufficient medicines and health care services to deal with pandemics such as HIV/AIDS.[120] To deal with the abuse of the dominant power of the pharmaceutical companies, the Doha Declaration guides the member states to use the power of compulsory licenses for creating access to medicines for their citizens.[121]

The states are under positive obligations to adopt an effective health policy to ensure the right to health to everyone without any discrimination to the status of the people because of their social, economic, cultural, racial, or other issues. Moreover, the state parties are under obligation to spend adequate sources to deal with the challenges of disease like COVID-19, HIV/AIDS, malaria, cancer, and TB. The state parties to the international human rights instruments are under obligation to fulfil their part will maximum possible efforts. This shows that the obligations of the states are not absolute that they at once provide all required medicines to their public. However, the obligations require their willingness and efforts to meet the standards agreed in the international treaties. Therefore, there is a difference between unwillingness and inability of the state parties towards fulfilling their obligations concerning access to medicines.[122]

To mark the domain of duty to fulfil obligations of the state parties concerning access to medicines and the right to health, the CESCR has defined core obligations. The states are under obligation to create access to essential medicines as defined by the WHO.[123] The state parties to the international human rights treaties including the right to health need to justify the limitation to fulfil their obligations. The CESCR interpreted the justification as, "In order for a State party to be able to attribute its failure to meet at least its minimum core obligations to a lack of available resources it must demonstrate that every effort has been made to use all resources that are at its

[119] U.N. Declaration of Commitment on HIV/AIDS, June 25-27, 2001, U.N. GAOR, 26th Special Session, Resolution. 33/2001

[120] Ibid.

[121] Lisa Forman, et al. (n-107)

[122] The Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 3, 'The Nature of States Parties' Obligations' < https://www.refworld.org/pdfid/4538838e10.pdf> accessed 23 October 2019

[123] Ibid.

disposition to satisfy, as a matter of priority, those minimum obligations."[124] The case of *Viceconte, Mariela Cecilia vs the State Ministry of Health and Social Action* is very significant in this regard where the court interpreted the core obligation of the state towards international treaty especially in the context of Article 12 of the ICSECE. The court found that the provision of Candid 1, a medicine, is almost 95 percent effective to treat the fever falls under the obligations of the Argentinian government to the right to health of ICESCR.

The violation of the duty to fulfil constitutes if the member state is unwilling to perform their obligations. General Comment No. 14 explain the idea of violation as under:

"In determining which actions or omissions amount to a violation of the right to health, it is important to distinguish the inability from the unwillingness of a State party to comply with its obligations under article 12. This follows from article 12.1, which speaks of the highest attainable standard of health, as well as from article 2.1 of the Covenant, which obliges each State party to take the necessary steps to the maximum of its available resources. A State which is unwilling to use the maximum of its available resources for the realization of the right to health is in violation of its obligations under article 12. If resource constraints render it impossible for a State to comply fully with its Covenant obligations, it has the burden of justifying that every effort has nevertheless been made to use all available resources at its disposal in order to satisfy, as a matter of priority, the obligations outlined above. It should be stressed, however, that a State party cannot, under any circumstances whatsoever, justify its non-compliance with the core obligations set out in paragraph 43 above, which are non-derogable."[125]

Paragraph 43 defines that the state parties to the ICESCR under obligation to ensure access to essential medicines, as defined by the WHO, as a part of minimum core obligations under Article 12 of the ICESCR. A state trying their level best to perform the obligations are deemed to fulfil the obligations. For instance, a developing state with limited financial resources may not adequately provide medicines to all suffering people. The state will only violate its obligations if it is unwilling to perform the possible part towards protecting access to medicines. The aforementioned cases from Argentina, Brazil, Bolivia, and other jurisdictions show that how national courts have interpreted and examined the performance of the states towards the right to health and access to medicines as part of both national and international laws. Another case from Costa Rica has interpreted the role of the state in fulfilling the obligations related to the right to health. The Supreme Court of Costa Rica, in *Alvarez v. Caja Costarricense de Seguro Social*, found that the scarce financial resources are not enough to contend that the state cannot perform its duties. The

[124] Ibid.

[125] General Comment No. 14 of the CESCR (n-94) paras 47

Supreme Court found that the disintegration of patients from the workforce is the actual loss to the economy. The court explained that:

"If we did an accounting of these costs and all of those associated [with their care], it seems reasonable to postulate that the country loses more in direct and indirect costs due to the state of incapacity of those who are prostrated by a disease, which alternatively could be invested providing treatment that would permit them to return to a productive life."[126]

The rationale provided by the apex court of Costa Rica stands guidance for those developing countries who often argue the scarce resources available for the protection of health. The inability to work because of diseases like COVID-19, HIV/AIDS, Cancer, Malaria, TB, and are counterproductive to the economy than spending on health.

The issue of access to medicines has become a matter of global goal under Sustainable Development Goals during 2015. The goals set 8 objectives. Among these goals, goal number three sets the challenge of ensuring healthy lives and promoting the well-being of all ages. The goal has included limiting water-related diseases, hepatitis, and other infectious diseases.[127] The same commitment came during MDGs those included combating COVID-19, malaria, TB, HIV/AIDS, and other infectious diseases.[128] Significantly, almost 191 states agreed to the goals. The UN Human Rights Commission Resolution is also called state parties of the UN to fulfil their obligation under International Law concerning combating HIV/AIDS.[129] The resolution required all state parties to ensure the availability of necessary medicines to the affected citizens. Moreover, the state should make the medicines and necessary medical technologies accessible to all its citizens without any discrimination.[130]

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[126] Hans V. Hogerzeil, et al (n-103)

[127] Health and Human Rights Resource Guide (n-5)

[128] United Nations Millennium Declaration, G.A. Res. 55/22, U.N. GAOR, 55th Sess., Item 60(b), U.N. Doc. A/Res/55/2 (2000). Millennium Development Goals

[129] Robin A. Weiss, 'HIV and AIDS in relation to other pandemics' (2003) EMBO reports < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1326444/> accessed 29 November 2019

[130] Ibid.

6.11 Obligations of third parties

Access to medicines related human rights obligations requires concentrated efforts from a range of stakeholders. A state cannot resolve the issue of access to medicines all alone. General Comment No. 14 mentions that the role of the United Nation, WHO, UNICEF, and cooperation in the international community of states can effectively deal with the issue of access to medicines in a well-coordinated fashion. The state parties to the international human rights instruments are under obligation to cooperate in the protection of human rights in general and access to medicines in particular.[131] The United Nations requires all state parties to work in a personal capacity and conduct all collective efforts for promoting high standards of living, social progress, dealing with the challenge of health problems, and creating universal respect for human rights.[132] The same principles of the UN Charter have been reflected in General Comment No. 03 that the state parties to ICESCR must cooperate to achieve the goals under the covenant. The comment states, "The Committee wishes to emphasize that in accordance with Articles 55 and 56 of the Charter of the United Nations, with well-established principles of international law, and with the provisions of the Covenant itself, international cooperation for development and thus for the realization of economic, social and cultural rights is an obligation of all States."[133] The comment explain that the obligations related to access to medicines bind individuals states and also obligate the international community as a whole.

The responsibilities of the pharmaceutical companies: The scope of access to medicines related human rights obligations also binds pharmaceutical companies. The former UN Special Rapporteur to The right to health mentions the submission of a report by the Institute for Human Rights and Business as under:

"where there are circumstances under which a company's activities are tied closely with the fulfilment and realization of specific rights — for example, companies running healthcare facilities, food distribution, water provision, power generation or telecommunication providers — it seems reasonable, at a minimum, to consider further whether

[131] Sarah Joseph, 'Pharmaceutical Corporations and Access to Drugs: The Fourth Wave of Corporate Human Rights Scrutiny' (2003) 25 *Human Rights Quarterly* 425-452

[132] Charter of the United Nations, Articles 55-56.

[133] The Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 3, 'The Nature of States Parties' Obligations' < https://www.refworld.org/pdfid/4538838e10.pdf> accessed 23 October 2019

companies involved in these or other services have responsibilities beyond the scope of the corporate responsibility to respect human rights."[134]

The responsibilities of the companies under human rights are not the well-settled principle of the international human rights law. However, recent trends have made the corporations accountable for human rights responsibilities. The case of Niger Delta is one of the illustrations where the oil exploration companies faced human rights litigations concerning the impact of oil exploration on the local population.[135] In the *Social and Economic Rights Action Center & the Center for Economic and Social Rights v. Nigeria,* the Nigerian government was found violating the rights of the population for not protecting them against adverse effects of actions of the oil company.[136]

The responsibilities of the business enterprise are explained by John Ruggie, the UN Secretary-General' Special Representative, stating that the responsibilities of the non-state actors and the state parties include the obligations of the state parties to respect human rights. This means the state parties are under obligation to not let any third party violate the human rights commitment. Moreover, the states are under obligation to protect their citizens from the adverse effect of business on human rights. Therefore, all corporations working in a state are under obligation to respect and comply with human rights. Last but not least, it is the obligation of the state parties that the effective remedial system is available in case of breach of duties related to respecting and protecting human rights ideals.[137] General Comment No. 14 also includes that the private business sector has responsibilities toward the right to health standards.[138] Later, the former UN Special Rapporteur, Paul Hunt, presented a detailed report on highlighting the obligations of the pharmaceutical companies about availability, accessibility, acceptability, affordability, and quality of medicines.

It may be argued that the corporations do not fall as subjects of international human rights. However, pharmaceutical companies indeed conduct their business under the aspirations of the national legal systems. Therefore, the state parties to access to medicines related human rights

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[134] Joo-Young Lee, Paul Hunt, 'Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines' (2012) 40 (2) *Journal of Law and Medical Ethics* 220-233

[135] Ibid.

[136] Ibid.

[137] Ibid.

[138] General Comment No. 14 of the CESCR (n-94) paras 42

obligations have the responsibility to make pharmaceutical companies respect human rights. Moreover, the states should take all necessary steps to protect their populations from the adverse impact of pharmaceutical business concerning availability, accessibility, quality, affordability, and acceptability of the medicines.

6.12 Conclusion

The status of access to medicines as a legal right is developing under the right to life, health, children, women, benefiting from the scientific progress, and rights included numerous regional and international human rights instruments. The progress on adopting access to medicines related human rights obligations in national legal frameworks are evolving. The examples from Argentina, Bolivia, Brazil, Columbia, Nigeria, India, South Africa, and other jurisdictions are guiding principles for other state parties to access to medicines related human rights instruments. In this regard, the role of national courts has been remarkable in interpreting access to medicines under national constitutional and legal frameworks. The role of the Columbian court remains noteworthy where the court relied on Article 12 of the ICESCR. The court not only found the duty of the government to provide necessary medicines under international legal obligations but also required the government to amend its laws in a way that they facilitate access to medicines as part of the right to health. The judicial role of the Columbian Constitutional Court establishes that it can guide the national legal framework towards respecting access to medicines related human rights obligations.[139] Moreover, the states are members of one or other international treaties containing the obligations related to access to medicines and health.

[139] Health and Human Rights Resource Guide (n-5)

Chapter 7: Conclusion

Summary and findings of the research

"COVID-19 is a test for our societies, and we are all learning and adapting as we respond to the virus. Human dignity and rights need to be front and centre in that effort, not an afterthought,"[1] *Michelle Bachelet, UN High Commissioner for Human Rights*

The analysis finds that the status of access to medicines is evolving as a legal right under the international human rights law. International human rights law includes access to medicines-related obligations under the right to life and health. Along with the International Bill of Rights, CEDAW, CRC, and WHO constitution supplement the human rights obligations related to access to medicines. However, the effective recognition and enforcement of access to medicines as a human right need both the will and solidarity from the state parties to the international human rights law.[2]

The research has endeavored to set coherence among access to medicines related human rights norms agreed and promised in several international human rights law instruments. The demand for access to medicines has been a matter of moral or ethical demand in social and academic debates. However, treating access to medicines as moral or ethical demand has not been effective in solving the issue of access to medicines in the case of COVID-19, HIV/AIDS, Malaria, TB, and other infectious diseases. Therefore, the study has argued that the status of access to medicines is developing as a positive international legal right under treaties, international customary law, and related norm-setting instruments of the international human rights law.

With reference to international and national response against the COVID-19, it demonstrates that the protection of access to medicines under the right to health and life is developing its status as a

[1] Michelle Bachelet (UN High Commissioner for Human Rights), 'Coronavirus: Human rights need to be front and centre in response' (6 March 2019) < https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=25668&LangID=E> accessed 17 March 2020.

[2] Michelle Bachelet, UN High Commissioner for Human Rights mentions, 'Given we are all operating in uncharted territory, I encourage States to establish ways of sharing information on good practices they are currently taking to alleviate the negative socio-economic effects of COVID-19 and the efforts to halt its spread. International solidarity and co-operation are more needed than ever. It is also clear that resources need to be directed to social protection so that people are able to survive economically during what may become a protracted crisis,"

legal entitlement instead of moral demand. However, the enforcement of access to medicines as a legal entitlement is still under progress. Not treating access to medicines as a human rights have consequences as during the year 2015, 5.9 million children died from preventable diseases around the world.[3] The treatment for serious diseases has not been adequately accessible in developing countries.[4] Low-income countries almost spend 40 percent of their health spending on procuring medicines that cut the overall efficiency of health care systems.[5] Dealing with the issue of access to medicines with charitable methods has been counterproductive, as it has hindered the establishment of enforceable human rights framework for access to medicines. The denial of necessary medicines is injustice and violation of rights included in the international human rights law.[6] For this reason, this research has tried to contend that access to medicines is a binding obligation of the state parties to various international and regional human rights treaties.[7]

Considering access to medicines as a human right will help the state parties of the international human rights law to effectively deal with the challenges of pandemics and endemics in their individual and collective efforts. The research has contended that access to medicines related human rights obligations mainly stem from the right to life and health. The interpretative trends from national and international adjudicatory forums have started including access to medicines as a part of obligations following domestic constitutional rights and the international human rights law. However, there was a gap in the literature on the consolidated account of access to medicines related human rights obligations. This research has defined the obligations of the states, their

[3] Report by UN Inter-Agency Group for Child Mortality Estimation, 'Levels and Trends in Child Mortality' (2015) < https://childmortality.org/files_v20/download/IGME%20Report%202015_9_3%20LR%20Web.p> accessed on 28 May 2019; Siva Thambisetty, 'Improving Access to Patented medicines: Are Human Rights Getting in the Way?' (2018) *LSE Law,* Society and Economy Working Papers *3/2018* 2

[4] Joint United Nations Program on HIV/AIDS (UNAIDS), 'Global Report: UNAIDS on the Global AIDS Epidemic (2013) 4-6; Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to medicines* (Ashgate, 2015) 121

[5] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to medicines* (Ashgate, 2015) 121

[6] Alicia Yamin, 'Not Just a Tragedy: Access to Medications as a Right under International Law' (2003) *Boston University International Law Journal* 325-71, 370

[7] Article 26 of the Vienna Convention on Law of Treaties, under Observance of Treaties, sets the principle of 'Pacta Sunt Servenda' mentioning, "Every treaty in force is binding upon the parties to it and must be performed by them in good faith". Now the elements of observance of treaties include both their binding charter and performance in good faith.

enforcement standards, the issues in the way of recognising and enforcing access to medicines related obligations, and the human rights treatment for the issue of access to medicines.

The state parties to the international human rights law have duties concerning access to medicines as a part of their human rights obligations at the national and international levels. Ensuring access to medicines includes availability, accessibility, acceptability, and quality of medicines. These legal obligations are tripartite in their essential nature; the duty to respect, protect, and fulfil. Under the duty to respect, the state parties to the international human rights law need to refrain from all measures undermining the access to medicines related human rights standards.[8] The state parties are under obligation to respect access to medicines vis-à-vis any conflicting rights or policies. The duty to respect also includes the provision of access to medicines in an indiscriminate way protecting all vulnerable factions of societies such as women, children, prisoners, and seriously ill people. The second part of the legal obligations of the state parties includes protecting access to medicines from all counter-measures by third parties. This includes ensuring the standards of access to medicines from all social, cultural, and corporate third parties that may impact access. The third tier of the legal obligations of the state parties requires the fulfilment of the obligations by recognising and enforcing access to medicines as a human right in their legal systems. This includes necessary legislation, enforcement, and effective interpretation by the respective state organs. Furthermore, it requires positive measures by the state parties to ensure that they take all necessary steps to realise the access to medicines as a part of human rights.

At the international level, the state parties to the international human rights law are under obligation to take all necessary steps to ensure the right to health which would also include access to medicines in their capacity as members of the international community and through international cooperation.[9] Among the international obligations, the state parties need to respect

[8] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, 11 August 2000, E/C.12/2000/4. Hereinafter named 'General Comment No. 14 of the CESCR'

[9] The Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 3, 'The Nature of States Parties' Obligations' < https://www.refworld.org/pdfid/4538838e10.pdf> accessed 23 October 2019; United Nations, *Charter of the United Nations*, 24 October 1945, 1 UNTS XVI, Article 55 states *"With a view to the creation of conditions of stability and well-being which are necessary for peaceful and friendly relations among nations based on respect for the principle of equal rights and self-determination of peoples, the United Nations shall promote:*

a. higher standards of living, full employment, and conditions of economic and social progress and development;

the access to medicines related human rights obligations in other states. The obligations would also include preventing third parties to create any impact on access to medicines. The state parties are also required to refrain from entering any international agreement that may adversely impact the national and international obligations related to access to medicines. With special reference to the recent COVID-19 and other pandemics, it is significant that the state parties must refrain from putting any sort of restrictions or embargoes on the supply of medicines and medical equipment to other states.[10] Moreover, the state parties are under the legal obligations to create an atmosphere of national and international cooperation towards protecting access to medicines.

The development of human rights has remained evolutionary.[11] The status of access to medicines as a human right is developing under the right to life and health among national and international legal frameworks. Moreover, the issue of access to medicines has been interpreted under the right to life[12] and the right to health[13] by international forms like the HRC and the CESCR. The same approach is taking root in interpreting access to medicines as a legal right by the national courts.[14] Furthermore, the recent outbreak of the COVID-19 pandemic further signifies the issue of recognising and enforcing access to medicines as a human right. The thesis finds that the status of

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b. solutions of international economic, social, health, and related problems; and international cultural and educational cooperation; and

c. universal respect for, and observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion."

United Nations, Charter of the United Nations, 24 October 1945, 1 UNTS XVI, Article 103 mentions, "All Members pledge themselves to take joint and separate action in co-operation with the Organization for the achievement of the purposes set forth in Article 55"

[10] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, 11 August 2000, E/C.12/2000/4, para 42

[11] Olivier De Schutter, *International Human Rights Law* (Cambridge University Press 2019) 35

[12] United Nations Human Rights Committee, General Comment No. 36 on Article 6 of the International Covenant on Civil and Political Rights – Right to life, para 26; UN Human Rights Committee (HRC), *CCPR General Comment No. 6: Article 6 (Right to Life)*, 30 April 1982 <https://www.refworld.org/docid/45388400a.html> accessed 16 September 2019

[13] General Comment No. 14 of the CESCR (n-8) para 42

[14] *Social and Economic Rights Action Center & the Center for Economic and Social Rights v. Nigeria; Viceconte, Mariela Cecilia v. the State Ministry of Health and Social Action*

access to medicines as a human right is of a developing right that needs urgent national and international attention.

Contributions and Recommendations

The research contributes to understanding the status of access to medicines as a human right under the international human rights law. Furthermore, the study examines the status of access to medicines related human rights obligations on both national and international levels. To assist the legislative, interpretative, and enforcement process, this research develops coherence in the international human rights framework for access to medicines. Bringing coherence and benefiting from the principle of indivisibility of human rights can synergies the recognition and enforcement of access to medicines related human rights obligations. The research contends that the status of access to medicines is well-defined beyond any doubt. Therefore, the states can not excuse their obligations. The state parties to the international human rights law need to perform their binding obligations towards recognizing and protecting access to medicines as a human right in good faith. The states need to show a certain level of will in good faith to find their way to protect access to medicines as a human right.

1- The research systematically contends that the status of access to medicines is of developing human rights instead of moral or ethical demand. The human rights perspective will help the state parties to the international human rights in prioritizing the status of access to medicines in legislative, interpretative, and implementation levels. The state parties can duly benefit from recognizing the status of access to medicines as a legal right. First, they can efficiently perform their human rights obligations under international human rights agreements. Secondly, the state parties can bargain the concessions for creating access to medicines against conflicting rights such as patent monopoly rights and other property rights.
2- The research comprehensively measures the domain of the international human rights framework for protecting access to medicines related human rights obligations. The examination has defined the status of access to medicines as a right, the obligations of the state parties concerning access to medicines, and finally the limitations and potentials for the state parties to perform their obligations effectively. The research finds that the status of access to medicines can be recognized and enforced at both national and international levels.

3- Last but not least, the research quotes the success stories of various low-income countries where the issue of access to medicines got treated by the use of human rights. The mentioning of success stories aims at cherishing and suggesting different approaches considering access to medicines as a human right under the international human rights law and domestic legal frameworks. The analysis suggests that various organs of the state parties, especially the judiciary, can become catalysts for elevating the status of access to medicines as a human right.

Further research on the area

This thesis has examined the status of access to medicines as a human right. Moreover, the research has confined itself to define the domain of human rights obligations of the state parties to the international human rights law. In light of analysis, the research contends that access to medicines is a developing human right in both national and international legal frameworks. The research has been doctrinal where the documentary legal analysis was used to contend that access to medicines is not a mere ethical or moral demand rather it is a developing international human right. Moreover, the research on access to medicines may also correlate with patents on medicines. In this regard, the research may focus on defining the competitive normative domain of access to medicines as human rights and patents on medicines as property rights.

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