THE NATIONAL UNIVERSITY OF ADVANCED LEGAL STUDIES Kalamassery, Kochi – 683503, Kerala, India

DISSERTATION

Submitted in partial fulfillment of the requirement for the award of the degree of

MASTER OF LAW (LL.M.)
(2021-2022)

ON THE TOPIC

"ACCESS TO ESSENTIAL DRUGS AND DRUG PRICING POLICY IN INDIA: A CRITICAL STUDY"

Under the Guidance and Supervision of

Dr. LIJI SAMUEL,

Associate Professor

The National University of Advanced Legal Studies, Kochi

SUBMITTED BY:
AKSHAYA.R. S

Register No: LM0321013

LL.M (PUBLIC HEALTH LAW)

CERTIFICATE

This is to certify that **AKSHAYA.R.S , REG NO: LM0321013** has submitted her Dissertation titled "**ACCESS TO ESSENTIAL DRUGS AND DRUG PRICING POLICY IN INDIA: A CRITICAL STUDY"** in partial fulfilment of the requirement for the award of Degree of Masters of Laws in Public Health Law to the National University of Advanced Legal Studies, Kochi under my guidance and supervision. It is also affirmed that the dissertation submitted by her is original, bonafide and genuine.

Date :30-07-2022

Dr. Liji Samuel

Place: Ernakulum

Guide and Supervisor
NUALS, Kochi

DECLARATION

I declare that this Dissertation titled "**ACCESS TO ESSENTIAL DRUGS AND DRUG PRICING POLICY IN INDIA: A CRITICAL STUDY"** is researched and submitted by me to the National University of Advanced Legal Studies, Kochi in partial fulfilment of the requirement for the award of Degree of Master of Laws in Public Health Law, under the guidance and supervision of Dr. Liji Samuel, Associate Professor and is an original, bona fide and legitimate work and it has been pursued for an academic interest. This work or any typethereof has not been submitted by me or anyone else for the award of another degree ofeither this University or any other University.

AKSHAYA.R.S

REG NO: LM0321013

LL.M., PUBLIC HEALTH LAW,

NUALS, KOCHI

Date: 30-07-2022

Place: Ernakulam

ACKNOWLEDGEMENT

I take this opportunity to express my profound respect and deep sense of gratitude to Dr. Liji Samuel, my guide and supervisor, for her support, guidance and encouragement throughout the course of my research work. She was always approachable, respected my ideas and gave me clear, cogent and meaningful suggestions, which has aided me profusely in completing this dissertation.

I would like to extend my gratitude to the Vice-Chancellor **Prof. (Dr.) K C Sunny** for his constant encouragement and support. I express my sincere thanks to **Prof (Dr) Mini. S** who is the Director of Centre for Post Graduate Legal Studies for her support and encouragement extended during the course. I would further extend my deep felt gratitude to all the Professors, NUALS for their guidance and support.

I would also like to convey my thanks to all the Library Staff and the Technical Staff for their timely assistance to carry out the work.

Words fall short of expressing love, appreciation and gratitude to my dear family and friends for their constant encouragement. With genuine humility, I am thankful to TheAlmighty for all his uncountable bounties and blessings.

AKSHAYA.R. S

ABBREVIATIONS

- AIR-All India Reporter
- AMRIT: Affordable Medicines and ReliableImplants for Treatment.
- API: Active Pharmaceutical Ingredients
- AWC: Allahabad Weekly Cases
- CDSCO: Central Drugs Standard Control Organization
- CLA: Central Licensing Authority
- CIOMS: Council of the International Organization of Medical Sciences
- CP: Ceiling Price
- CSIR: Council of Scientific and Industrial Research
- DCGI: Drug Controller General of India
- DGHS: Director-General of Health Services
- DPCO: Drug Price Control Order
- DPCRC: Drugs Price Control Review Committee
- EML: Essential Medicines List
- EMR: Exclusive Marketing Rights
- GMP: Good ManufacturingPractices
- HC: High Court
- HRBA: Human Rights Based Approach
- ICCPR: International Covenant on Civil and Political Rights
- ICESCR: International Covenant on Economic, Cultural and Social Rights

- ICH: International Conference on Harmonization
- ICLR: Indian Competition Law Review
- ICMR: Indian Council of Medical Research
- ICTRP: International Clinical Trials Registry Platforms
- IJARIIE: International Journal of Advance Research and Innovative Ideas in Education
- IPR: Intellectual Property Rights
- MAPE: Maximum Allowable Post- Manufacturing Expenses
- MBP: Market Based Pricing
- MLJ: Madras Law Journal
- MoHFW: Ministry of Health and Family Welfare
- NDA: National Drug Authority
- NDCTR: New Drugs and Clinical Trial Rules
- NGO: Non-Governmental Organization
- NHM: National Health Mission
- NHP : National Health Policy
- NIMS: National Institute of Medical Statistics
- NLEM : National List of Essential Medicines
- NPPA: National Pharmaceutical Pricing Authority
- NRHM :National Rural Health Mission
- NUHM: National Urban Health Mission
- OHCHR : Office of the High Commissioner for Human Rights
- Ori: Orissa

- OSDD: Open-Source Drug Discovery
- PIL: Public Interest Litigation
- PRDC: Pharmaceutical Research and Development Committee
- R&D: Research and Development
- SC: Supreme Court
- SCC-Supreme Court Cases
- SCR: Supreme Court Reporter
- TRC: Technical Review Committee
- TRIPS: Trade -Related Aspects of Intellectual Property Rights
- UDHR: Universal Declaration of Human Rights
- UHC : Universal Health Coverage
- U.N: United Nations
- W.B.: West Bengal
- WHO: World Health Organization
- WTO :World Trade Organization
- W.P: Writ Petition

TABLE OF CASES

25. State of Punjab vs. Mohinder Singh Chawla,1997 (2) SCC 83
26. Sunil Batra vs. Delhi Administration, (1978) 4 SCC 494
27. T. Damodar Rao and others vs. Special Officer, Municipal Corporation of Hyderabad, AIR 1987 AP 171
28. Union of India & Anr., v. Cynamide India Ltd & Anrs., 1987 AIR 1802, 1987 SCC (2) 720.
29. Union of India v. K.S. Gopinath and Others, SLP No. 3668/2003, dated 10.03.2003
30. Unni Krishnan vs. State of A. P, (1993)1 SCC 645
31. Vincent Panikulangara vs. Union of India ,AIR 1987 SC 990
32. Vikrant Deo Singh Tomar vs. State of Bihar, (1988) Suppl. SCC 734
33. Virender Gaur vs. State of Haryana, 1995 (2) SCC 577

TABLE OF CONTENTS

CHAPTER 1

INTRODUCTION

Health is a very important aspect of life for all individuals and nothing is more important than good health. A healthy body and mind are the very foundation for all human activities. Health does not only mean the absence of sickness, but it is a state of complete physical, mental and social well-being and therefore, it is considered as an integral part of the right to life, which is considered a basic human right. Human rights are the rights to which every human being is entitled, no matter who they are and where they belong. All human beings are equally entitled without any discrimination. Article 25 of the Universal Declaration of Human Rights (UDHR) provides that every individual has the right to a standard of living with good health and well-being of himself and of his family. The standard of living shall include access to food, clothing, shelter, health care and necessary social services. It also provides the right to security in case of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in situations that go beyond this India has also been made laws relating to protecting the health of the individual. The law of the land, i.e., the Indian Constitution, provides for the right to life under Article 21 of the Constitution, which also includes the right to health. Though the right to health has not been evidently mentioned under Article 21 of the Indian Constitution, the Supreme Court has clearly interpreted and said in many cases that the right to life also includes right to health. As the right to health is a basic human right, it shall be the obligation on the part of the state to protect the health of the citizen. The right to health can be assured through the right to access health care and affordable medicines, which are essentially required.

Those medicines or drugs which satisfy the priority health care needs of the population are considered essential medicines. These medications are designated with due regard to incidences of disease and public health relevance, proof of clinical safety and efficiency and relative costs and cost-effectiveness. These medicines are proposed to be always available in the healthcare system. It must be in adequate amounts and appropriate dosage forms; the quality must be assured and it must be available to all individuals and communities at an affordable price. Most of the countries have national lists for essential medicines and which closely relate to the domestic guidelines for

clinical health care practice, which are utilized for the training and supervision of health workers.

Ministry of Health & Family Welfare (MOHFW), the Government of India, is mandated to ensure a quality healthcare system by assuring the availability of safe and efficacious medicines for its population. The National List of Essential Medicines (NLEM) of India, initially prepared and released in 1996. The list of such medicines is revised in 2003, 2011 and 2015. The NLEM 2015 has been categorized as the essentiality of requirements of medicines, viz., Primary, Secondary and Tertiary levels. The list contains a total of 376 medicines as of NLEM 2015. Total 209 medicine formulations are listed in NLEM for all levels of healthcare; 115 medicine formulations are there for secondary and tertiary and 79 medicine formulations for the tertiary level.

The Indian government has taken many initiations in providing quality, affordable healthcare and drugs to the public. The main initiatives are the National Health Mission, AMRITH Pharmacies, Pradhan Mantri Bhartiya Janaushadhi Pariyojana and Ayushman Bharath. The government is encouraging people to use cost-effective, quality generic drugs. Any drug which is invented is initially marketed under the brand name and after the expiration of the patent period, it can be manufactured and sold under the name of generics. As the generics do not undergo repetitive expensive clinical research, it priced less than the branded drugs. The generics are the bio-equivalent of branded drugs. The generics are as safe and effective as branded drugs and benefitted to all, especially the poor and needy

The study relates to the regulation of essential drugs in India and drug pricing policy in India, and the inefficiency of the drug pricing policy in ensuring adequate access to medical care by all sections of the society, including the weaker sections.

1.1 SCOPE OF THE STUDY

Life is a precious gift that needs to be preserved and protected at all times through social, ethical and legal efforts. The right to health is an important and inseparable part of right to life. The Indian Constitution provides the right to health as an implied fundamental right under Article 21 of the Constitution. It is an obligation on the part of the State to protect the life and health of the citizen. There are a number of people who are suffering from many diseases and unable to access or afford essential drugs due to

the high cost of drugs. The high cost is due to the patent monopoly. There is a necessity to save the life of the individual by providing accessibility and affordability of essential drugs. Hence this research focuses on access regime and improving laws relating to access to essential drugs.

The scope of this research is to analyse regulation of drug pricing is sufficient for access to essential medicine. Impacts of these factors are analysed in depth by different chapters. This research is trying to evaluate the measures to be taken to minimize the negative impact of access to essential medicine. The study aims at identifying the issues relating to the regulation of drug pricing in India and the essential listing of drugs. India as a developing country, has one of the lowest drug prices in the world, yet many people are deprived of essential and lifesaving drugs. Due to the high pricing of many of the drugs, the poor people of the country are not in a position to afford drugs. The out-of-pocket expenditure on the health systems is very high. The people in India pay more than the people in developed countries (high income countries) in terms of the relative per capita income. The efficacy of the generic drugs is not up to the mark of company manufactured drugs, even though the drugs have same formulations, the quality of the generic drugs are not up to the mark. The bio-availability and bio-equivalence of the generic drugs are low when compared to non-generic drugs. As a result of the current drug price control policy, the profit margins of many pharmaceutical companies have decreased and they opted to go out of production thus leading to the substandard and spurious drug manufacturers dominating the pharma-market. Scope of this research is to evaluate all these factors, to analyse their impact on access to medicine and to find the solution to improve access of essential medicine to all patients in India.

1.2 RESEARCH PROBLEM

Even though India has one of the lowest drug prices in the world, the accessibility, availability and affordability of life-saving drugs still remain a challenge in India. Despite the efforts made at both the national and international levels, due to the inefficiencies in the present legislations many people in India are still denied of even essential life-saving medicines.

1.3 RESEARCH OBJECTIVES

1. To understand the importance of right to health and access to essential medicine.
2. To study on the regulation of drug pricing policy in India
3. To analyse the issues related to access to essential medicine
4. To identify the inefficiency in the drug pricing policies and regulations in India

1.4 RESEARCH QUESTIONS

1. What is the importance of access to essential medicine?
2. How right to health is connected with access to essential medicine?
3. What is the legal framework for access to essential medicine?
4. How are drugs regulated in India?
5. How is the drug pricing policy in India?
6. How far does drug pricing policy helps in access to essential medicine?
7. How inefficiencies in drug pricing violates the right to access medical care?
8. What are the issues relating to the essential listing of Drugs?
9. What are the suggestions for tackling the problems involved in drug pricing?

1.5 HYPOTHESIS

The access to essential medicine is an important element of the right to health which is protected under Art. 21 of the Constitution of India. Even though there are many legal frameworks, the regulation of drug pricing in India is not efficient in ensuring accessibility, availability and affordability of essential lifesaving drugs. The

inefficiencies in drug pricing violates the right to access medical care. Therefore, a more structured and comprehensive legislation is required to tackle the problem.

1.6 METHODOLOGY

The research methodology used in this work is doctrinal legal research as a means to establish the hypothesis in the best suitable way.

1.7 LITERATURE REVIEW

The research has depended on the primary sources including the Constitution of India, various legislations, executive orders, judgements of Supreme Court and High Courts, International treaties etc. The research has also used secondary resources like books, commentaries for the proper understanding of the subject and analysing the various topics. The research has extensively depended the electronic resources like online databases, websites for gathering resources.

- Jonathan.P.Caulkins &Peter Reuter, How drug enforcement affects drug prices,39CRIME&Just.(2010)

This article, the nation's drug problem, with its multiple causes, is beyond the reach of any existing intervention or strategy, but the decision-makers should not be prevented from realizing that money can be saved and justice improved by simply cutting in half the number of people locked up for drug offences.

- Renganathan R, Vijayabanu C, Srinivasakumar V& Vijay Anand V, Pharmaceutical Pricing Policy And Control: Indian Perspective, Asian Journal of Pharmaceutical and clinical research (2016)

This article says that Pharmaceutical companies can think of reducing the expenses to reduce the cost of drugs to comply with the government drug pricing policy. To ensure the affordability of medicines along with the pricing policy, the Indian Government may look and concentrate on the other important areas of pharmaceutical sectors.

- Hassoun, N., The Human Right to Health. Philosophy Compass, pp.275-283.((2015)

The human right to health and its foundations are discussed in this article. The disparities between legal and moral human rights, as well as rights to health vs. health care, are then highlighted. It then goes over the literature to see if there are any moral (and maybe legal) grounds for a human right to health. It finishes with responses to a number of typical denials of the existence of a human right to health.

- Shree Agnihotri & Sumathi Chandrashekaran, Drug Regulation In India: The Working And Performance Of CDSCO And SDRAs, Thakur Foundation(2019)

This report attempts to understand how drug regulation works in India through the lens of the performance of the regulatory bodies concerned, i.e., CDSCO and SDRAs. The dataset, based extensively on information sourced through RTI applications, reveals several concerns with current drug regulatory practices.

1.8 CHAPTERISATION

- CHAPTER I: INTRODUCTION

This chapter gives a brief idea about the research work by explaining what the research is about and the relevance of the topic. It provides the research questions and the hypothesis of the research. The chapter also says about the method used for research and gives a brief account about the literature used for research

- CHAPTER II: ACCESS TO ESSENTIAL DRUGS AND RIGHT TO HEALTH: A HUMAN RIGHT PERSPECTIVE

This chapter illustrates the human rights perspective, the constitutional perspective and the three A's of the essential drugs which is accessibility, affordability and availability of drugs. The chapter also includes various case laws that dealt with the importance of right to health.

- CHAPTER III: DRUG REGULATION IN INDIA: AN OVERVIEW

This chapter gives an overview about the regulation of drugs in India. The chapter explains various laws that regulate the manufacture, sale, distribution, export and clinical research of drugs in India.

- CHAPTER IV: DRUG PRICING POLICIES AND REGULATION

This chapter discusses the concept of essential drugs, selection of essential drugs and also gives an analysis on how the prices of drugs are controlled in India and its various pricing policies and regulations.

- CHAPTER V: CONCLUSION & SUGGESTIONS

The chapter says about conclusions arrived from the research and suggestion made for the tacking the problems involved in the existing Indian legal framework related to Drug pricing and Access to Essential medicine.

CHAPTER 2

ACCESS TO ESSENTIAL DRUGS AND RIGHT TO HEALTH: A HUMAN RIGHT PERSPECTIVE

2.1 INTRODUCTION

Health is a very important aspect of life for all individuals, and nothing is more important than good health. A healthy body and mind are the very foundation for all human activities. Therefore, one cannot achieve in life or lead a happy life without having a good health. Heath does not only mean the absence of sickness, but it is a state of complete physical, mental and social well-being and therefore, it is considered as an integral part of the right to life, which is considered a basic human right. Human Rights are the rights to which every human being is entitled, no matter who they are and where they belong. Article 25 of the Universal Declaration of Human Rights (UDHR) provides that every individual has the right to a standard of living with good health and well-being of himself and of his family[1]. The standard of living shall include access to food, clothing, shelter, health care and necessary social services. It also provides the right to security in case of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in situations that go beyond his control.[2] India has also been made laws relating to protecting the health of the individual. The law of the land, i.e., the Indian Constitution, provides for the Article 21 of the Indian Constitution[3], the Supreme Court has clearly interpreted and said in many cases that the Right to Life also includes Right Health. The right to health is the economic, social and cultural right to a universal minimum standard of health to which all individuals are entitled[4]. As the Right to Health is a basic human right, it shall be the obligation on the part of the state to protect the health of the citizen. The Right to Health can be assured through the Right to Access Health Care and Affordable Medicines, which are essentially required.

---

[1] Dr. Soumitra Kumar Chatterjee, *Right to Health, Constitutional Safeguards and Role of Judiciary, Odisha Review*,85,89(2016)

[2]United Nations, Universal Declaration of Human Rights, available at:http:/ /www.un. org/en/ universal declaration- human-rights/ (last visited on 16th April 2022)

[3]The Constitution of India (Ninety-Seventh Amendment) Act, 2011.

[4] Nisha K Jose-, *Right to health as human right*, (2017), available at https://www. researchgate. net/ publication / 319291598_Right_to_health_as_human_right

Access to essential medicines is an integral part of right to health[5].People are in need of drugs, from a simple cold to life-threatening diseases like Cancer, AIDS, Cardiovascular Diseases, Diabetes, Neurological Conditions and few newly found diseases like Nipah, Ebola, Dengue and H1N1, Covid-19 etc. Life-threatening diseases mean diseases that have the potential to cause the death of the patient. Those diseases are considered chronic and usually incurable diseases. It also effects limiting the life expectancy of the individual. The drug is necessary not only to cure the diseases but also to prevent diseases. The technologies have been developing day by day and many of the deadly diseases were found a cure. To cure these kinds of diseases, many research and developments have taken place.[6]

2.2 ACCESS TO DRUGS AS HUMAN RIGHT

Human rights have the potential to transform social, political, and legal norms for more equitable access to medicines[7]. Human rights are those basic standards without which people cannot live with dignity[8]. To interrupt someone's human rights is to treat that person as, however, she or he was not a human being. Human rights are a set of universal minimum standards that must be met. They are not only about the protection of individuals and groups in society but are a practical framework to protect the rights of everyone[9]. Health and Human rights has explicit intrinsic connections.[10]

Human rights affect medical practice in several ways. They influence ethical codes[11]; they justify each patient's claim to the best attainable physical and mental health

[5] Atharva Sontakke, *Right to Health and Access to Patented Medicines Toward Constitutionalisation of IPR*,,4International Journal of Legal Studies and Research 91(2015)

[6] Research and Reviews: Journal of Zoological Sciences, available at: https://www.rroij.com/ openaccess/prolonged-effects-of-an-antialzheimers-drug-galantamine-hydrobromide-on-morphometric-andbehavioural-aspects-of-albino-mice-1-6.pdf (last visited on 16th April 2022)

[7] Forman L, *Rights and wrongs: what utility for the right to health in reforming trade rules on medicines?,* Health and Human Rights Journal (2008), available at https://www. hhrjournal.org/2013/09/rights-and-wrongs-what-utility-for-the-right-to-health-in-reforming-trade-rules-on-medicines/

[8] UNPO: Human Rights. https://unpo.org/article.php?id=4956(last visited on 4th July 2022)

[9] Human Rights and Responsibilities Health & Social Care Essay Questions , https:// assignmenttask. com/answers/human-rights-and-responsibilities-health-social-care-essay-questions-and-answers/(last visited on 4th July 2022)

[10] The basic causes of morbidity and mortality in developing countries like malnutrition, inadequate access to clean drinking water, living and working conditions which are hazardous to health, lack of education and the exclusion of many poor and disadvantaged people from essential health service arise out of the failure to meet human rights commitments.

[11] World Medical Association, Medical Ethics Manual, The World Medical Association, Inc. (2005),p.11,viewed7thJuly2013, http://www.snabber.se/files/vardforalla/ wma_medical_ethics_ manual.pdf. (last visited on 08/07/2022)

through their emphasis on norms, obligations, and accountability; and health is jeopardized when generic human rights are violated.[12] At the same time, health is a basic requirement for enjoying other human rights and participating in social, economic and political life. For those already more vulnerable due to poverty, inequality or social exclusion, lack of respect or protection of human rights can actually cause or worsen poor health. Moreover, the values enshrined in human rights are a reliable guide for contemporary practice because they are universal and focus on people as rights holders rather than patients. Health is a basic human right and access to medicine is a basic tool to ensure health[13]. The right to health is a fundamental right of every human being and it implies the enjoyment of the highest attainable standard of health without distinction of race, religion, political belief or social condition. As it is one of the fundamental rights of every human being, governments have a responsibility for the health of their people which can be fulfilled only through the provision of adequate health and social measures.

The traditional notion of healthcare has tended to be individual-centric and has focused on aspects such as access to medical treatment, medicines and procedures[14] The field of professional ethics in the medical profession has accordingly dealt with the doctor-patient relationship and the expansion of facilities for curative treatment. In such a context, healthcare at the collective level was largely identified with statistical determinants such as life-expectancy, mortality rates and access to modern pharmaceuticals and procedures. It is evident that such a conception does not convey a wholesome picture of all aspects of the protection and promotion of health in society[15]. There is an obvious intersection between healthcare at the individual as well as societal level and the provision of nutrition, clothing and shelter. Furthermore, the term 'public health' has a distinct collective dimension and has an inter-relationship with aspects such as the provision of a clean living environment, protections against hazardous working conditions, education about disease-prevention and social security

[12] Eleanor D. Kinney, *The International Human Right to Health: What does This Mean for Our Nation and World?* , 34 Ind. L. Rev. 1457,1468(2001).

[13] Saeed Ahmadiani and Shekoufeh Nikfar, *Challenges of access to medicine and the responsibility of pharmaceutical companies a legal perspective*,13 DARU J Pharm Sci. 6 (2016)

[14] K.G. Balakrishnan, National seminar on the 'Human right to health' Organized by the Madhya Pradesh State Human Rights Commission (At Bhopal), September 14, 2008, http://supremecourtofindia.nic.in/speeches/speeches_2008/right_to_health_-_bhopal_14-9-08.pdf. (last visited on 08/07/2022)

[15] Impact of Mediation on Health & Social Welfare – Indian Context. https:// www.arbitrationindia. Com /pdf/mediation_health.pdf(last visited on 8th July 2022)

measures in respect of disability, unemployment, sickness and injury. While professional ethics in the medical profession have retained an individual-centric focus on curative treatment, the evolution of international human rights norms pertaining to health has created a normative framework for governmental action.

2.3 ACCESS TO ESSENTIAL DRUGS AND RIGHT TO HEALTH

The right to health is a vital part of human rights. It is the right of every person to enjoy and attain the highest standard of health. The right to health is essential for human existence and as a result it has acquired global significance.[16].Health services are meant for all and it's not charity or privilege for a few people.Each and every individual is entitled to access health care and services. The right to health is articulated in 1946, the Constitution of the World Health Organization (WHO), whose preamble defines health, which says not only the absence of sickness is enough to consider a person healthy, but it includes the overall well-being of an individual. The preamble further states that every individual has a right to enjoy the highest attainable standard of health and it is one of the essential rights of every human being. An individual shall not be discriminated against on the basis of race, religion, political belief, economic or social condition[17].

WHO is the dedicated agency of the United Nations, which is established for health. It is an inter-governmental organization that works in association with its member states regularly through the Ministries of Health. It is responsible for providing leadership on universal health matters, determining the health research program, setting norms and standards, enunciating evidence-based policy options, providing technical aid to countries and monitoring and assessing trends of health. India is also party to the WHO Constitution since 12th January 1948. The WHO head office, regional office and country office comprise health professionals, other experts and support staff to fulfil the objectives and also to carry out the activities. The WHO Country Cooperation Strategy – India (2012- 2017) has been mutually developed by the Ministry of Health

[16] SOUGATA TALUKDAR, RIGHT TO HEALTH IN INDIA, LAW, POLICY AND PRACTICE, 10,[Sage Publication (2022)]

[17] The Right to Health, Office of the United Nations High Commissioner for Human Rights, Fact Sheet No. 31,World Health Organization.

and Family Welfare(MoH &FW) of the Government of India and the WHO Country Office forIndia (WCO). The key purpose is to contribute to improving the health and equityin India. It has tried to solve the challenges faced internally relating to 'long-standing health, health services and delivery problems.' The Indian Constitution also provides its citizens a right to health and access to health care. Through various judgements, the Supreme Court of India says that right to health is an important and inseparable part of right to life which is guaranteed under Article 21 of the constitution of India.

The international organizations and institutions have made efforts to protect the right to health of an individual's considering it as one of the basic human rights. The right to health also includes the right to access health care,essential drugs, especially life-saving drugs and there are many efforts made in this regard. The Human Right, right to Health is enshrined and protected undervarious International Agreements, which are as follows:

1. Article 25 of the Universal Declaration of Human Rights[18]
2. Article 12 of the ICESCR[19]
3. Article 24 of the Convention on the Rights of the Child[20]
4. Article 5 of the Convention on the Elimination of All Forms ofRacial Discrimination
5. Articles 12 & 14 of the Convention on the Elimination of AllForms of Discrimination Against Women
6. Article XI of the American Declaration on Rights and Dutiesof Man[21]

[18] Universal Declaration of Human Rights, Article 25 states that "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control"

[19] International Covenant on Economic, Social and Cultural Rights, Article 12 states "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".

[20]Convention on the Rights of the Child, Article 24 " Children have the right to good quality health care, clean water, nutritious food and a clean environment, so that you they stay healthy".

[21] American Declaration on Rights and Duties of Man, Article XI "Every person has the right to the preservation of his health through sanitary and social measures relating to food, clothing, housing and medical care, to the extent permitted by public and community resources".

7. Article 25 of the Convention on the Rights of Persons withDisabilities.[22]

The access to essential medicines which is nested in the right to the highest attainable standard of health, is well founded in the international law. It was elaborated by the ICESCR, 1966 that the right to health includes "access to health facilities, goods and services". The CESCR noted that one of the core obligation of the state parties in relation to the right to heath, from which no derogation is permissible is the provision of essential drugs[23].The UDHR entitles every individual a right to a standard of living and adequate health. The adequate standard includes the health and well-being of the individual and also his family. Article 12 of the International Covenant on Economic, Social and Cultural Rights requires State Parties to identify the right to enjoy the highest attainable standards of both physical and mental health. It also asks the state parties to take suitable steps to achieve the full realization of the rights, which includes provisions relating to preventing, treating and to control epidemic, endemic, occupational and other diseases and also to create conditions which assuremedical service and attention in the case of sickness for all.[24] According to the International Covenant on civil and political rights , every human being has the inherent right to life. The concept of non-discrimination and equality which are two fundamental principles under the human rights law is central to the right to health. The ICESCR says that the access to medicines should be realized without any discrimination on any grounds[25].

The WHO, numerous national court cases and resolution of the Human Rights Council, and the Doha declaration on TRIPS and public health reaffirm access to essential medicines as a human right that must be available for all[26]. Even though the main responsibility with regard to the provisions of essential medicines lies with the states, these responsibilities are often shared with other non- state actors like pharmaceutical

[22] Convention on the Rights of Persons with Disabilities, Article 5 "States Parties recognize that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability"

[23] EMMANUEL KOLAWOLE OKE, PATENTS, HUMAN RIGHTS AND ACCESS T O MEDICINES ,8, [Cambridge University Press (2022)]

[24] Right to Health – WMA – The World Medical Association, https://www.wma.net/what-we-do/human-rights/right-to-health/, (Last Visited on April 16th , 2022).

[25] OHCHR and World Health Organization, The Right to Health, Fact Sheet No. 31, http://www.ohchr.org/Documents/Publications/Factsheet31.pdf.,(last visited on 28th July 2022)

[26] Access to Medicines and Human Rights, https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/ (last visited on 28th July 2022)

companies. As described by the former UN special rapporteur on the Right to Health , the pharmaceutical companies have the responsibilities towards the human rights which includes the duty to take all the reasonable measures to make new medicines 'as available as possible' for all those people who are in need[27]. Further, the private sectors were obliged by the UN guiding principles on Business and Human Rights, to take the responsibility for the violation of Human Rights related to the access to medicines[28].

A Human Rights Based Approach identifies that all human beings possess an interrelated and indivisible right to health and access to essential medicines. With related to access to essential medicines, a HRBA drawn special attention towards the disadvantaged, excluded and marginalized populations with the ability to achieve outcomes through an transparent , inclusive and responsive process[29]. The laws and national health policies should be shaped in such a way that it ensures universal and equitable access within the frame work of right to health.

If the access to essential medicines is recognized as a part of the right to health by the Domestic Constitutions, then it can support the claims of individuals for essential medicines in the National Courts[30]. The lack of access to essential medicines and the health care is the denial of the rights to health of the individuals and those communities who are living in relative poverty. Under the International Human Rights Law, all the states are obliged to protect, respect and fulfill the right to health, which also includes an obligation to adopt all the legislative, budgetary and administrative measures that facilitate affordable, accessible, acceptable and of good quality access to medicines. An obligation also lies with the Pharmaceutical companies to protect and respect the human rights.

The corporations have a duty to be careful not to cause any adverse human rights impacts through their own activities and if any such impact occurs. They should also have knowledge about those adverse human rights impacts that are directly connected

[27] UN General Assembly, The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Report of the Special Rapporteur, Paul Hunt, U.N. General Assembly, 63rd Session, Agenda Item 67(b), U.N. Doc, A/63/263

[28] John Ruggie, Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises: 'Protect, Respect and Remedy: A Framework for Business and Human Rights', A/HRC/8/5

[29] OHCHR/WHO, The Right to Health, Factsheet No. 31, 2008.

[30] Hans V. Hogerzeil, Melanie Samson, Jaume Vidal Casanovas, *Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable through the Courts?* 368,The Lancet pp. 305-11(2006)

with their operations and services and also should be careful about how to prevent it or mitigate such impacts[31]. These pharmaceutical companies bear a responsibility to avoid infringing the right to health of the individuals but these responsibilities are sacrificed when they give more importance or priority to the enforcement of their intellectual property rights rather than enforcing their right-to-health obligations. The medicines must be available , accessible, acceptable and of good quality[32]. The following four building blocks were outlined as essential by the WHO towards ensuring access to medicines in the Health systems of Nations.

1. Rational selection and use of essential medicines, based on national lists of essential medicines and treatment guidelines;
2. Affordable prices for governments, health care providers and individuals;
3. Fair and sustainable financing of essential medicines as part of the National Health Care system through adequate funding levels and equitable prepayment system in order to make sure that the poor people are not disproportionately affected by the prices of the medicines and
4. There should be reliable health and supply systems that ensure appropriate and sufficient combination of public and private service providers[33].

The Limburg principles on the implementation of the ICESCR suggests that the states should give more importance to the realization of the rights of the people regardless of their level of economic development[34]. So when comes to the context of access to medicines, the states must implement programs to continuously improve the access to essential medicines. The domestic law should recognize the responsibility of the states to provide essential medicines and public financing should be given priority through sufficient budget allocation. The government should be careful to properly utilize the

[31] John Ruggie, Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises: 'Protect, Respect and Remedy: A Framework for Business and Human Rights', A/HRC/8/5

[32] UN Committeee on Economic, Social and Cultural Rights (CESCR), General Comment No. 14, U.N. Doc. E/C.12/2000/4

[33] WHO, "Equitable Access to Essential Medicines: A Framework for Collective Action" in WHO Policy Perspectives on Medicines Bulletin(2004), http://apps.who.int/medicinedocs/pdf/s4962e/ s4962 e.pdf, 2. (last visited on 28th July 2022)

[34] Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights, https://www.escr-net.org/docs/i/425445(last visited on 30th July 2022)

trade options given under the TRIPS flexibilities to safeguard access to essential medicines.

The right to health is clearly recognized by the regional instruments and the documents that are agreed upon by the health community. The protocol of Sun Salvador[35], the European social charter, the African charter on human and people's rights ,the WHO Constitution[36] and the Ottawa charter for health promotion[37] all consider health as a fundamental right. In addition to all a clear link has been established between the provisions of primary health care and essential drugs by the declaration of Alma-Ata in the year of 1978.When comes to the Domestic law, more than 100 national constitutions has recognized a degree of protection of right to public health or medical care but only 13 constitution has included the right to access to medicines as a part of the right to health.

According to the office of the OHCHR, there is a primary responsibility upon the drug companies to invest in the R & D or support for external research. The 'Human Rights Guidelines for pharmaceutical companies' by OHCHR states that the accessibility of existing medicines is not only the thing that is required by the right to the highest attainable standard of health, but also requires that new medicines, which are much-needed are to be developed as soon as possible. When comes to the marginalized groups and vulnerable population , the access to medicines still remains as illusory goal.

2.4 CONSTITUTIONAL PERSPECTIVE AND RIGHT TO HEALTH

The Constitution of India is a public law, which governed the relationshipbetween the state and its citizens. The preamble of the Constitution reflects the goals set out for the welfare of the country and citizens to achieve the goals. It confers certain rights upon the people, imposes duties upon the citizens and issued certain directives to the state. From the perception of the right to health, following constitutional provisions carry importance.

[35] Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights "Protocol of San Salvador, http://www.oas.org/juridico/english/treaties/a-52.html.(last visited on 28th July 2022)

[36] Constitution of the World Health Organization, http://www.who.int/gb/bd/PDF/bd46/ebd46_p2.pdf. (last visited on 28th July 2022)

[37] WHO, Declaration of Alma-Ata, International Conference on primary health care, Alma-Ata, USSR, 6–12 September, 1978, http://www.searo.who.int/LinkFiles/Health_Systems_declaration_ almaata.pdf. (last visited on 28th July 2022)

Article 21 of the Indian Constitution guarantees the Right to Life and Personal Liberty, which also includes the right to health. According to Article 21,"No person shall be deprived of his life or personal liberty except according to the procedure established by law."[38] The right to life does not only mean mere animal existence[39], but it also includes the right to live with dignity, which contingently dependent upon the health of an individual. In *Bandhua Mukti Morcha v. Union of India*[40], the Supreme Court of India held that Article 21 is closely linked with Directive Principles of State Policy, particularly clause (e) and (f) of Article 39 and Article 42. It must comprise protection of the health andstrength of workers, men and women and tender age children against abuse. Theopportunities and facilities shall be provided for children to develop in a healthymanner. It shall provide conditions of freedom and dignity of life, educational facilities for children and just and humane environments of work and alsomaternity relief. These are minimum requirements that must exist in order to enable a person to live with dignity.

Only the absence of sickness is not considered as health; instead, it is a state of complete physical, mental and social well-being and thus, it is an integralpart of the right to life. Part IV of the Constitution also provides for the constitutional scheme of the right to health. Article 39(e) of the Constitution makes an obligation on the state to make policies to secure the health and strengthof workers, men and women and they must not be abused. According to Article 41, State has an obligation to make provisions to provide public assistance in times of 'unemployment, old age, sickness, disablement and in other cases of undeserved wants.' Similarly, as per Article 43, the State must provide a good environment for work and shall ensure decent standards of living. Article 47 imposes a duty on the State to 'raise the level of nutrition and improve public health[41].'

The Indian Judiciary has also played a dynamic role in protecting the health of the individual and also access to healthcare by shaping the Right to Health as a fundamental right under Article 21 of the Constitution.

[38] Article 21,Constitution of India,1950
[39] *Ibid*
[40]Bandhua Mukti Morcha v. Union of Indi*a* AIR 1984 SC 802, (1984) 2 SCR 67.
[41] Article 47, Constitution of India,1950

2.4.1 Public Health is State's Priority as a Constitutional Mandate:

In *Municipal Council, Ratlam v. Vardhichand & Ors*[42],The residents of Ratlam filed a complaint against the Municipality on issues like provision of sanitary facilities on the roads, public conveniences for slum dwellers who were using the road for that purpose and prevention of the discharge from the nearby Alcohol Plant of malodorous fluids into the public street.

The Court in their supplementary directions said that,

"The Ratlam Municipal Council was to take immediate action, within its statutory powers, to stop the effluents from the Alcohol Plant flowing into the street. It is also expected that State Government also shall take action to stop the pollution. Industries cannot make a profit at the expense of public health."

Further Justice Krishna Iyer observed:

"The State will realise that Article 47[43] makes it a paramount principle of governance that steps are taken for the improvement of public health as amongst its primary duties."

It is said that the local self governing bodies are responsible for protection and preservation of human life. All these institutions are under principal duty to preserve public health. They shall not take defence of financial inability. It was rightly said that decency and dignity are non- negotiable aspects.

In *Mohd. Ahmed (Minor) v.. Union of India & Ors.*[44] the issue in the present petition is whether a minor child born to parents belonging to economically weaker section of the society suffering from a chronic and rare disease, gaucher, is entitled to free medical treatment costing about rupees six lakh per month especially when the treatment is known, prognosis is good and there is every likelihood of petitioner leading a normal life[45].

It was felt that sufficient recognition to Right to Health is required and it is possible with the enactment of special law on this subject. A national health policy should be adopted to provide Right to Health to all. A reasonable and equitable access to life

[42] Municipal Council, Ratlam v. Vardhichand & Ors ,1980 Cri LJ 1075; AIR 980 SC 1622

[43] Article 47 of the Indian Constitution deals with the duty of the State to raise the level of nutrition and the standard of living and to improve public health.

[44]Mohd. Ahmed (Minor) v. Union of India & Ors. W.P.(C) 7279/2013

[45] IN THE HIGH COURT OF DELHI AT NEW DELHI - globalhealthrights.org. https:// www. Global healthrights.org/wp-content/uploads/2015/04/Mohd-Ahmed-v.-Union-of-India-2014.pdf(last visited on 28th July 2022)

saving medicines is critical to promoting and protecting the right to health[46]. It is unfortunate that even after sixty-six years of independence; universal medical healthcare is still a distinct dream. Even today, economically weaker sections of the society do not have access to free medical treatment.

Just because someone is poor, the State cannot allow him to die. In fact, the Government is bound to ensure that poor and vulnerable sections of society have access to treatment for rare and chronic diseases, like Gaucher especially when the prognosis is good and there is a likelihood of the patient leading a normal life. After all, health is not a luxury and should not be the sole possession of a privileged few[47].

2.4.2 Right to Health is A Fundamental Right of Workmen:

In *C.E.S.C. Ltd. v. Subhash Chandra Bose*[48], the Supreme Court of India has considered two important provisions namely, Article 25(1)[49] of Universal Declaration of Human Rights, 1948 and Article 7(b)[50] of the International Convention on Economic, Social and Cultural Rights, 1966.

The Court held that,

"Article 39(e) of the Constitution enjoins the State to direct its policies to secure the health and strength of workers. The right to social justice is a Fundamental Right. The Right to Livelihood springs from the Right to Life guaranteed under Article 21. The health of the worker is a basic part of Right to Life and liberty as because of Fundamental Rights the people can live freely without any coercion and harm to their freedoms.

The Court further observed that:

The concept of health is inclusive one and covers many other rights and not only

[46] Just because someone is poor, the State cannot allow him to die Delhi , http://www. Legal servicesindia .com/article/1653/Just-because-someone-is-poor,-the-State-cannot-allow-him-to-die-Delhi-HC-landmark-Judgment.html(last visited on 28th July 2022)

[47] Vagish Yadav, *Rare Diseases in India: Analysis of Laws and Policies,(2020)*, available at https://www.legalbites.in/rare-diseases-in-india-laws-and-policies

[48] C.E.S.C. Ltd. v. Subhash Chandra Bose, AIR 1992 SC 573, 585

[49] Article 25 (1) of UDHR reads as, Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

[50] Article 7 of ICESCR reads as, the State parties to the present Covenant recognize the right of everyone to the enjoyment of just and favorable conditions of work which ensure, in particular:(b) Safe and healthy working conditions;

absence of illness and medical care. The workers are required for economic growth of the country. In the light of Articles 22 to 25 of the Universal Declaration of Human Rights, the International Convention on Economic, Social and Cultural Rights and in the light of socio-economic justice assured in our Constitution, the Right to Health is a fundamental human right to workmen."

It was resolved that in every scheme for medical care in any Asian country the need for the prevention of disease and the improvement of the general standard of health must be considered as of extreme importance.[51]

The Apex Court has rightly stated that the health of the workmen is a significant aspect which enables them to work efficiently and helps to improve national productivity. It has placed reliance on international policy documents and the concept of socio-economic justice enshrined in the preamble of the Constitution. The creative role of the Supreme Court in interpreting Articles 21 and 39 significantly made it possible to establish social justice.

2.4.3 <u>People are Entitled to Adequate Health Care</u>:

In *Mahendra Pratap Singh v. State of Orissa and Ors.,*[52] the petitioner, an Ex-Sarpanch of Pachhikote Grama Panchayat on behalf of public of the aforesaid Grama Panchayat had approached this Court in a writ application for issuance of appropriate writ commanding the opposite parties. to take effective measures to run the Primary Health Centre at Pachhikote within Korei block in the district of Jaipur by providing all amenities and facilities for proper running of the said health centre. On the basis of demands of the local people and public at large, the Government of Orissa and the Department of Health and Family Welfare decided to open certain primary health centres in different areas for the year 1991-92 subject to fulfilment of these two conditions. Firstly the local people should provide at least one acre of land for medical institution within one month and Secondly the local people should provide permanent buildings for the medical institutions and staff within 6 (six) months from the date of issue of this order.The grievance of the petitioner was that though the Doctor, pharmacist, health worker and attendant had been posted yet, the Primary Health Centre is not functioning and no steps have been taken to make the centre run and the situation

[51] I.L.O. Asian Regional Conference, Delhi, 1947

[52] Mahendra Pratap Singh v. State of Orissa and Ors.,AIR 1997 Ori 37

has affected public interest and caused public jeopardy.

Further, the Apex Court has observed that,

"Life is a glorious gift from God. It is the perfection of nature, a master-piece of creation. Human being is the epitome of the infinite prowess of the divine designer. Great achievements and accomplishments in life are possible if one is permitted to lead an acceptably healthy life. Health is life's grace and efforts are to be made to sustain the same. We have seen that the Grama Panchayat had transferred the land measuring one acre in favour of the Department of Health but still insistence is being made to pledge it in favour of the Panchayat Samiti. It is true that violation has occurred but the violation of this nature should not be utilised against the public at large. This should be regarded as substantial compliance of condition no. (i) with regards to condition no. (ii) we are surprised to note that in spite of permission being granted by the competent authorities to run the hospital in the building of the Grama Panchayat and the staff having been posted because of this provisional arrangement no positive efforts were made to make the health centre run at the appointed building but staff were diverted to Korei. Whatever might be the reasons ascribed by the authorities, we are constrained to hold that they are neither genuine nor sanguine. It is not expected of a welfare State to play hide and seek with its citizens."

The Supreme Court here in this case highlighted the issue of Right to Health of villagers in India and said that Primary Health Centre should be provided for the protection of their life. There should be no technical obstacles to establish PHCs for villagers as rightly observed by the Court. The present case is a good example where the Supreme Court is very keen on the health of the general public. The issue of establishment of PHC and maintenance by the concerned Government department has been resolved with the directions given by the Court.

2.4.4 Health and Health Care of Workers is an Essential Component of Right to Life:

In *Consumer Education and Research Centre v. Union of India*,[53] the issue of occupational diseases and other health hazards was put before the court. The workmen working in modern industries are exposed to various occupational health hazards such as in asbestos industries. It may cause deadly diseases like cancer to the workmen. Besides judgments of the Supreme Court and various legislations, there are lacunae in

[53]Consumer Education and Research Centre v. Union of India**,** (1995) 3 SCC 42

providing remedial measures to the affected people.

The Court has relied upon the provisions of Convention 162 of ILO, Charter of UNO and UDHR. There are various provisions on health and safety. Article 1[54]of the UDHR particularly deals with the State responsibility to maintain and to protect human rights and human dignity. The Charter of UNO also speaks about fundamental human rights which are envisaged in Part IV of the Constitution.

The ILO Convention is more significant as India is a signatory to the same.Further the Supreme Court observed that, the Preamble and Article 38 of the Constitution of India the supreme law, which aims to establish envisions social justice to ensure dignified life. Jurisprudence is the eye of law giving an insight into the environment of which it is the expression[55]. The concept of Social Justice is discussed and it is stated that these are the supreme values. Social justice Equality and Equity are the important aspects to provide social security to workmen.

The Court has mentioned Justice K. Subba Rao, the former Chief Justice on the concept of social justice. He has stated in his 'Social Justice and Law' on page 2 "Social Justice is one of the disciplines of justice and the discipline of justice relates to the society." The constitution, therefore, mandates the State to accord justice to all members of the society in all facets of human activity. The concept of social justice embeds equality to flavour and enliven practical content of 'life.'[56]

The Court discussed the core values enshrined in the Preamble of the Constitution and various provisions of part IV of the Constitution along with important provisions of international policy documents to give recognition to the Right to Health of the Workmen.

The Right to Life under Article 21 does not mean mere animal existence. Health of the workmen is significant as they are compelled to work for economic necessity. Therefore, facilities should be provided to protect their health for higher production or efficient service.

Therefore, continued treatment, while in service or after retirement is a moral, legal and

[54] Article 1 of UDHR reads, "All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood."

[55] Personal Dignity: Tracing The Role of Indian Judiciary In Its Interpretation,https://www.legalserviceindia.com/article/l74-Personal-Dignity.html(last visited on 2nd July 2022)

[56] University of Minnesota Human Rights Library, http:// hrlibrary.umn. edu/monitoring/ adminchap14. html (last visited on 2nd July 2022)

constitutional concomitant duty of the employer and the State. Therefore, it must be held that the Right to Health and Medical care is a Fundamental Right under Article 21 read with Articles 39(c), 41 and 43 of the Constitution and makes the life of the workmen meaningful and purposeful with dignity of person. Right to Life includes protection of the health and strength of the worker is a minimum requirement to enable a person to live with human dignity[57]. The State, be it Union or State Government or an industry, public or private, is enjoined to take all such action which will promote health, strength and vigour of the workman during the period of employment and leisure and health even after retirement as basic essentials to live the life with health and happiness. The health and strength of the worker is an integral facet of Right to Life. Denial thereof denudes the workman the finer facets of life violating Article 21. The right to human dignity, development of personality, social protection, right to rest and leisure are fundamental human rights to a workman assured by the Charter of Human Rights, in the Preamble and Articles 38 and 39 of the Indian Constitution. Facilities for medical care and health against sickness ensure stable manpower for economic development and would generate devotion to duty and dedication to give the workers' best physically as well as mentally in production of goods or services[58]. Health of the worker enables him to enjoy the fruit of his labour, keeping him physically fit and mentally alert for leading a successful life, economically, socially and culturally. Medical facilities to protect the health of the workers are, therefore, the fundamental and human rights of the workmen[59].

Finally, the Court held that the Right to Health, medical aid to protect the health and vigour of a worker while in service or post retirement is a Fundamental Right under article 21, read with articles 39(e), 41, 43, 48A and all related to articles and fundamental Human Rights to make the life of the workmen meaningful and purposeful along with dignity of the person[60].

The Court also held that the State or its Undertaking including private employers are under obligation to follow all the directions issued under Article 32 and Article 142 to protect Right to Health and to live decent and dignified life.

---

[57] Riya Jain, *Article 21: Understanding The Right to Life and Personal Liberty from Case Laws*,(2015),available at https://www.lawctopus.com/academike/article-21-of-the-constitution-of-india-right-to-life-and-personal-liberty/

[58] The Right To Health – Uneasy Silence - Live Law. https://www.livelaw.in/right-to-health-uneasy-silence/(last visited on 4th July 2022)

[59] Dr. K.C. Malhotra v. State Of M.P. And Ors, AIR 1992 SC 573

[60] Consumer Education and Research Centre v. Union of India AIR 1995 SC 922,

The writ petition is allowed and Court issued following directions to Union Government, State Governments and all the industries on the subject of health of the workmen.

Olga Tellis v. Bombay Municipal Corporation[61], This case was related to forcible eviction of pavement and slum dwellers and removal of their hutments under the Bombay Municipal Corporation Act. The procedure followed by the Government and Bombay Municipal Corporation was challenged as *ultra vires*. It was argued by the petitioners that it deprived them of their means of livelihood and consequently right to life.

There can be no estoppel against the Constitution[62]. The Constitution, apart from paramount law of the land but, it is also the source and sustenance of all laws. Its provisions are intended to serve a public purpose. Fundamental Rights are undoubtedly conferred by the Constitution upon individuals which have to be enforced by them, if there is any violation of their rights. But, the high purpose which the Constitution seeks to achieve by conferment of Fundamental Rights is not only to benefit individuals but to secure the larger interests of the community[63].

The Apex Court while deciding the question whether Right to Life includes Right to Livelihood has observed that,"The sweep of the Right to Life conferred by Article 21 is wide and far reaching. It does not mean merely that life cannot be extinguished or taken away as, for example, by the imposition and execution of the death sentence, except according to procedure established by law. That is but one aspect of the Right to Life. An equally important facet of that right is the Right to Livelihood because; no person can live without the means of living, that is, the means of livelihood. If the Right to Livelihood is not treated as a part of the constitutional Right to Life, the easiest way of depriving a person of his Right to Life would be to deprive him of his means of livelihood to the point of abrogation. Such deprivation would not only denude the life of its effective content and meaningfulness but it would make life impossible to live[64]."

The role of Court is paramount if there are issues involved in a case are of public importance. The view of the Supreme Court is clear that right life is not absolute but

[61] Olga Tellis v. Bombay Municipal Corporation ,1985(3) SCC 545

[62] Human Rights and Jurisprudence: Right to Life / Livelihood Archives, https://www.hurights .or.jp/english/human_rights_and_jurisprudence/right-to-lifelivelihood/(last visited on 4th August 2022)

[63] Olga Tellis v. Bombay Municipal Corporation , https://www.elaw.org/content/india-olga-tellis-v-bombay-municipal-corporation-19850710-right-life-and-livelihood-homeless(last visited on 3rd July 2022)

[64] Ibid

the procedure established must be due, reasonable and fair.

The expanded connotation of life would mean the tradition and cultural heritage of the persons concerned. In *State of H. P. v. Umed Ram Sharma*,[65] the Supreme Court held that the Right to Life includes the quality of life as understood in its richness and fullness by the ambit of the Constitution. Access to roads was held to be an access to life itself in that state. In *Sunil Batra v. Delhi Administration*,[66] considering the effect of solitary confinement of a prisoner sentenced to death and the meaning of the word 'life' enshrined under Article 21, the Constitution Bench held that the quality of life covered by Article 21 is something more than the dynamic meaning attached to life and liberty. The same view was reiterated in *Board of Trustees of the Port of Bombay vs. D. R. Nadkarni*,[67] *Vikrant Deo Singh Tomar v. State of Bihar*[68] and *R. Autyanuprasi vs. Union of India.*[69] In *Charles Sobraj vs. Superintendent Central Jail, Tihar*,[70] the Supreme Court held that the Right to Life includes Right to Human Dignity. The right against torture, cruel or unusual punishment or degraded treatment was held to violate the Right to Life. In *Bandhua Mukti Morcha v. Union of India*,[71] the Court held that,

"The right to live with human dignity enshrined in Article 21 derives its life-breath from the Directive Principles of the State Policy and particularly Clauses (e) and (f) of Article 39 and Articles 41 and 42 and at the least, therefore, it must include protection of the health and strength of workers, men and women, and of the tender age of children against abuse, opportunities and facilities for children to develop in a healthy manner and in conditions of freedom and dignity, educational facilities, just and humane conditions of work and maternity relief."[72]

As stated above we can say that the directives issued under Part IV of the Constitution are significant which are necessary to live life with human dignity. The specific provisions under Part IV of the Constitution are required to be followed by Central and State Governments.

---

[65] State of H. P. v. Umed Ram Sharma, (1986)2 SCC 68

[66] Sunil Batra v. Delhi Administration, (1978) 4 SCC 494

[67] Board of Trustees of the Port of Bombay v. D. R. Nadkarni, (1983) 1 SCC 124

[68] Vikrant Deo Singh Tomar v. State of Bihar (1988) Suppl. SCC 734

[69] R. Autyanuprasi v. Union of India. (1989)1 Suppl. SCC 251

[70] Charles Sobraj v. Superintendent Central Jail, Tihar,AIR 1978 SC 1514

[71] Bandhua Mukti Morcha v. Union of India,AIR 1984 SC 802

[72] Riya Jain, *Article 21: Understanding The Right to Life and Personal Liberty from Case* Laws,(2015),available at https://www.lawctopus.com/academike/article-21-of-the-constitution-of-india-right-to-life-and-personal-liberty/(last visited on 4th July 2022)

In *C.E.S.C. Ltd. & Ors. v. Subhash Chandra Bose*,[73] considered the gamut of operational efficacy of Human Rights and the constitutional rights, the right to medical aid and health and held that the right to social justice is a Fundamental Right. Right to free legal aid to the poor and indigent worker was held to be a Fundamental Right in *Khatri vs. State of Bihar*,[74]Right to education was held to be a Fundamental Right vide *Maharashtra State B.O.S. & H. S. Education v. K. S. Gandhi*,[75]and *Unni Krishnan v. State of A. P*.[76]

Right to Health and Medical Care have been held as Fundamental Right under Article 21. In *Kirloskar Brothers Ltd. v. Employees' State Insurance Corporation*,[77] the Supreme Court held that the Right to Health and Medical care is a Fundamental Right under Article 21 read with Article 39(e), 41 and 43. The Constitution envisages the establishment of a welfare state at the federal level as well as at the State level. In a welfare State the primary duty of the Government is to secure the welfare of the people. Providing adequate medical facilities for the people is an essential part of the obligations undertaken by the Government in a welfare State. The Government discharges this obligation by running hospitals and health centres which provide medical care to any person seeking to avail of those facilities. Article 21 imposes an obligation on the State to safeguard the Right to Life of every person. Preservation of human life is thus of paramount importance. The Government hospitals run by the State and the medical officers employed therein are duty bound to extend medical assistance for preserving human life. Failure on the part of a Government hospital to provide timely medical treatment to a person in need of such treatment results in violation of his Right to Life guaranteed under Article 21.

2.4.5 Right to Health Care of Government Employees is Integral to Right to Life:

In *State of Punjab v. Mohinder Singh Chawla*,[78] issues like non- availability of special facilities for the treatment in the State Hospitals in Punjab and permission of treatment outside the State and subsequent rejection of reimbursement claims filed by

[73]C.E.S.C. Ltd. & Ors. v. Subhash Chandra Bose,1992(1) SCC 441
[74] Khatri v. State of Bihar, (1981)1 SCC 627
[75] Maharashtra State B.O.S. & H. S. Education v. K. S. Gandhi,1991(2) SCC 716
[76] Unni Krishnan v. State of A. P (1993)1 SCC 645
[77]Kirloskar Brothers Ltd. v. Employees' State Insurance Corporation, (1996) 2 SCC 682
[78] State of Punjab v. Mohinder Singh Chawla,1997 (2) SCC 83

Government employees were discussed.

The Supreme Court held that, "It is now settled law that Right to Health is an integral part of Right to Life. The Government has a constitutional obligation to provide health facilities. If a Government servant has suffered an ailment which requires treatment at a specialized approved hospital and on reference whereat the Government servant had undergone such treatment therein, it is but the duty of the State to bear the expenditure incurred by the Government servant. Expenditure, thus, incurred requires to be reimbursed by the State to the employee. The High Court was, therefore, right in giving direction to reimburse the expenses incurred towards room rent by the respondent during his stay in the hospital as an inpatient."

The present matter is closely related with the health rights of Government employees. The serving employee and retired both are entitled to reimbursement of medical expenses as per the policy of the Government. If special treatments are not available in the State controlled hospital then in the listed hospitals though private one, the State is under obligation to reimburse the cost of all medical expenses.

2.4.6 Environment Pollution is Linked to Health and as Violation of Right to Life with Dignity:

In *T. Damodar Rao and others v. Special Officer, Municipal Corporation of Hyderabad*[79], issue of use of land reserved for recreational zones for residential purposes which is contrary to the development plan of the Hyderabad City had come before the Court. This issue was taken up only on the ground that it will affect the health of the city's habitants as it will be difficult to provide civil amenities to the residents of the local area.In this case, the court observed that the Parliament with an objective to protect and improve our environment enacted the Environment (Protection) Act 1986.It mandate the state to improve and protect the environment and to safeguard the forests and wildlife of the Country (Article 48A) and also it is the duty of every one of our citizens to protect and improve the natural environment .

It is the duty of the Courts to take strict actions against those who are disturbing the ecological and environment balance. In *Virender Gaur v. State of Haryana*[80], the

[79] T. Damodar Rao and others v. Special Officer, Municipal Corporation of Hyderabad, AIR 1987 AP 171

[80] Virender Gaur v.. State of Haryana 1995 (2) SCC 577

Supreme Court held that environmental, ecological, air and water pollution, etc. should be regarded as amounting to violation of Right to Health guaranteed by Article 21 of the Constitution. It is right to state that a hygienic environment is an integral facet of the right to a healthy life and it would not be possible to live with human dignity without a humane and healthy environment. Therefore, there is a constitutional imperative on the State Government and the Municipalities, not to injure and to ensure and safe- guard proper environment, it is also an imperative duty to take adequate measures to promote, protect and improve both the man-made and the natural environment[81].

The Court has issued directives to the municipality to restore the position in the interest of environment health and human health.

In *M. C. Mehta vs. Union of India*[82], *Rural Litigation and Entitlement Kendra vs. State of U. P.*[83], the Supreme Court imposed a positive obligation upon the State to take steps for ensuring to the individual a better enjoyment of life and dignity and for elimination of water and air pollution[84]. It is also relevant to notice as per the judgment of the Supreme Court in *Vincent Panikulangara v. Union of India*[85] wherein the apex Court has observed that,

"In a Welfare state, therefore, it is the obligation of the State to ensure the creation and the sustaining of conditions congenial to good health. In a series of pronouncements during the recent years, this court has culled out from the provisions of Part- IV of the Constitution, several obligations of the State and called upon it to effectuate them in order that the resultant picture by the constitution fathers may become a reality."

In *Unnikrishnan, J. P. v. State of A. P.*,[86] the maintenance and improvement of public health is the duty of the State to fulfil its Constitutional obligations cast on it under Article 21 of the Constitution. All these cases prove that there is a close relationship between environment and human health. Therefore it can be said that the pollutant is equally liable for the violation of the Right to Health guaranteed under Article 21 of the Constitution.

---

[81] Ibid

[82] M. C. Mehta v. Union of India, AIR 1988 SC 1037

[83] Rural Litigation and Entitlement Kendra vs. State of U. P, AIR 1987 SC 359

[84] Constitution Of India And Environmental Concern ,https:// lawpage.in /environment /article / constitution-and-environmental-concern(last visited on 2nd July 2022)

[85] Vincent Panikulangara v. Union of India AIR 1987 SC 990

[86] Unnikrishnan, J. P. v. State of A. P., (1993) 1 SCC645

2.4.7 Adequate and Quality Medical Care is Part of Right to Health and Right to Life:

In *S. K. Garg v. State of U. P.*,[87] the petitioner S. K. Garg raised various issues regarding health and health care of public in the city of Allahabad. The unhygienic conditions of the public hospitals, inadequate drug supply refusal of treatment by doctors to indigent persons etc were the main issues. The Supreme Court has directed that a Committee be set up immediately for investigating the affairs of the Government Hospitals at Allahabad. Further, the Supreme Court in *Consumer Education and Research Centre and others vs. Union of India and others*,[88]held that, "The Right to Life with human dignity encompasses within its fold some of the finer facts of human civilisation which makes life worth living."

In *State of Punjab and others v. Mohinder Singh Chawla and others*[89], held that the Right to Health is a part of the Right to Life guaranteed by Article 21 of the Constitution. The issue of distressing sanitary and hygienic conditions at Government Hospitals came before the Court. The poor needy people neglected at such hospitals and they cannot afford treatment at private hospitals. Ours is the welfare State and people have right to have access to all medical facilities. The Court has observed that Article 21 of the Constitution, as interpreted in a series of judgments of the Supreme Court, has the same legal effect.

This is a clear incident of violation of Right to Health of poor people and the creative role of the Court to issue appropriate directives to the State under its constitutional mandate under Article 47.

In *Paschim Banga Khet Mazdoor Samiti v. State of W. B.*,[90]the issue of the obligation of the State to provide emergency health care to patients came before the Supreme Court. After refusal to admit an emergency patient in approximately 8 different hospitals a patient was admitted in a private hospital.

The patient Hakim Sheikh was taken to the Primary Health Centre at Mathurapur where necessary facilities for treatment were not available; then the patient was taken to N.R.S. Medical College Hospital near Sealdah Railway Station, Calcutta where he

[87] S. K. Garg v. State of U. P.,1999 (1) AWC 847
[88] Consumer Education and Research Centre and others v. Union of India and others ,1995 (3) SCC 42
[89] State of Punjab and others v. Mohinder Singh Chawla and others ,1997(2) SCC 83
[90] Paschim Banga Khet Mazdoor Samiti v. State of W. B., (1996)4 SCC 37

could not be admitted as no vacant bed was available in the Surgical Emergency ward and the regular Surgery Ward was also full. He was thereafter taken to Calcutta Medical College Hospital where no vacant bed was available, He was then taken to Sambhunath Pandit Hospital where he was not admitted and referred to a teaching hospital in the ENT, Neurosurgery Department on the ground that the hospital has no ENT Emergency or Neuro Emergency Department. He was later taken to the Calcutta National Medical College Hospital but there also he was not admitted on account of non-availability of a bed. He was then taken to the Bangur Institute of Neurology but on seeing the CT scan it was found that the case is an emergency case which could not be handled in the said Institute. Then he was taken to SSKM Hospital but there also he was not admitted on the ground that the hospital has no facility of neurosurgery. Ultimately he was admitted to Calcutta Medical Research Institute, a private hospital, where he received treatment as an indoor patient from July 9, 1992 to July 22, 1992[91].

In the present case there was breach of the said right of Hakim Shaikh guaranteed under Article 21 when he was denied treatment at the various Government hospitals which were approached even though his condition was very serious at that time and he was in need of immediate medical attention. Since the said denial of the right of Hakim Shaikh guaranteed under Article 21 was by officers of the State in hospitals run by the State the State cannot avoid its responsibility for such denial of the constitutional right of Hakim Shaikh[92].

In respect of deprivation of the constitutional rights guaranteed under Part III of the Constitution the position is well settled that adequate compensation can be awarded by the court for such violation by way of redress in proceedings under Articles 32 and 226 of the Constitution.[93] The Apex Court awarded Hakim Sheikh Rs. 25000/- as compensation against this violation of his Fundamental Right.

The notable suggestions made by the learned counsel are also significant. In situations like emergency medical treatment, the Court has accepted and in order that proper medical facilities are available for dealing with emergency cases it must be ensured

[91] Right to Health Facilities, Goods and Services - Icelandic Human Rights, https://www. Human rights.is/en/human-rights-education-project/comparative-analysis-of-selected-case-law-achpr-iachr-echr-hrc/the-right-to-health/right-to-health-facilities-goods-and-services(last visited on 4th August 2022)

[92] What did the Court say in the case of Hakim Sheik?https://www.vedantu.com/question-answer/did-the-court-say-in-the-case-of-hakim-sheik-class-12-social-science-cbse-5fc67926d58f2b581a13dcd4 (last visited on 27th July 2022)

[93] Rudal Shah v. State of Bihar, 1983 (3) SCR 508; Nilabati Behara v. State of Orissa, 1993 (2) SCC 746: Consumer Education and Research Centre v. Union of India, 1995 (3) SCC 42

that[94]:

1. Adequate facilities are available at the Primary Health Centres where the patient can be given immediate primary treatment so as to stabilize his condition;

2. Hospitals at the district level and Sub-Division level are upgraded so that serious cases can be treated there;

3. Facilities for giving specialized treatment are increased and are available at the hospitals at District level and Sub-Division level with regard to the growing needs.

4. In order to ensure availability of a bed in an emergency at State level hospitals there is a centralized communication system so that the patient can be sent immediately to the hospital where a bed is available in respect of the treatment which is required.

5. Proper arrangement of ambulance is made for transport of a patient from the Primary Health Centre to the District hospital or Sub-Division hospital and from the District hospital or Sub Division hospital to the State hospital.

6. The ambulance is adequately provided with necessary equipment and medical personnel.

7. The Health Centres and the hospitals and the medical personnel attached to these Centres and hospitals are geared to deal with a larger number of patients needing emergency treatment on account of higher risk of accidents on certain occasions and in certain seasons.

The Constitution provides positive policy called welfare State at both at Central and State level. It is duty of the Government to perform all obligations for welfare of the people. It includes establishment of hospitals under their control. Failure on the part of a Government hospital to provide timely medical treatment to a person in need of such treatment results in violation of his Right to Life guaranteed under Article 21[95].

[94] Paschim Banga Khet Mazdoor Samiti v. State of W. B., (1996)4 SCC 37
[95] Omprakash V. Nandimath, *Consent and medical treatment: The legal paradigm in India*, 25(3) Indian J Urol 343,346(2009)

The Court also observed that though the State of West Bengal is party to this petition still the other states are under obligation to take necessary steps and to implement the same and do whatever is necessary to be done by all States.

2.5 ACCESSIBILITY, AFFORDABILITY AND AVAILABILITY (THREE A'S) OF ESSENTIAL DRUGS

The principles of availability, accessibility, acceptability and quality are essential elements of the right to health[96]. It is very important that drugs must not only affordable but must also avail and can access by any person when he is in need of such drugs. These drugs may be essential or any other pharmaceutical drug. But if a person not able to access those drugs may be life-saving or other, it causes some loss or sometimes it may take away the life of the individual. Access to essential and affordable drugs and medicines is an integral part of the right to health[97]. Accessibility, Affordability and Availability of drugs are very much necessary in order to protect public health. The availability of and access to quality medical products, especially essential medicines, is one of the key element of good health care[98].

These three A's are very much necessary in a healthcare system. They are very much necessary in order to prevent, manage, prevent unnecessary disablement and helpful in the reduction of premature deaths. Accessibility can be defined as "the timely use of personal health services to achieve the best health outcomes[99]. Access to health care is very important in a country like India. Though we have adequate policies but because of the geographical vastness and diversity in religion, caste, social status some people could not access the health care services provided by the State. At the same time information is also not conveyed properly to alert people about health hazards. Media plays a very significant role in the spread of awareness and for the access of various facilities provided by the State but we find in India various villages where there is no electricity and the villages are unapproachable because of their remoteness.

---

[96] World Health Organization. Advancing the Right to Health: The Vital Role of Law. World Health Organization, 2017. JSTOR, http://www.jstor.org/stable/resrep39155. (last accessed 8 July 2022.)
[97] Atharva Sontakke, *Right to Health and Access to Patented Medicines Toward Constitutionalisation of IPR*,4International Journal of Legal Studies and Research 91,92 (2015)
[98] K.L. SHARMA, HEALING THE PHARMACY OF THE WORLD,10 [Notion press Pvt Ltd (1st Edi, 2021)]
[99] Institute of Medicine, Committee on Monitoring Access to Personal Healthcare Services

Whenever an individual feels sick first, he must able to access healthcare, which means locating a healthcare provider like Primary Health Care, Secondary Health Care and Tertiary Health Care on the basis of severity of the condition of health. Then the individual must trust such a healthcare provider and communicate with him about his condition. The accessibility of healthcare depends upon the location of the healthcare provider and where the patient in need is located. In some case, the distance of healthcare provider and patient seeking care prevent the patient from looking for the care they need. Availability can be understood as when a patient seeking healthcare goes for a healthcare provider and such a person/hospital must be able to provide the care sought by the patient. There must be the availability of healthcare professionals, the technology that helps to detect and diagnose the condition, treatment facilities etc. Affordability can be understood as the charges of healthcare which the patient is able to pay. The healthcare bill may differ from person to person depending upon the condition of the ailment, the treatment required and the cost of such treatment. Not that every person is in the position to pay off the charges of healthcare. Most of the time, the affordability of treatment made a person suffer.

2.5.1 Primary Health Care

This is the first tier in the healthcare system. These provide health care to the whole of society on the basis of the needs and preferences of the people, families and communities. PHC addresses the comprehensive health detriments and focuses on the wide-range and interrelated aspects of physical, mental, social health and wellbeing.[100] This healthcare provides an individual whole set of healthcare needs throughout life. In the International conference on primary health care held in 1978,the Alma-Ata declared health as fundamental human right[101]. PHC provides comprehensive care that ranges from 'promotion and prevention to treatment, rehabilitation and palliative care' that are viable to individuals in their everyday life. PHCs are well-positioned and they can quickly respond to the changes that occur, viz., economic, social, technological and demographic, those which impact the health and well-being of the individual. PHCs have been drawn the attention of the stakeholders in order to change the policies that address the economic, social, conservational and commercial factors that affect the

[100]World Health Organisation.
[101] Dinesh Kumar Meena, *Essential Medicines Research in India: Situation Analysis*,13(2) Journal of Young Pharmacists 82 (2021)

health and well-being of the individual. PHCs are also proven to be a highly effective and efficient way to address the different reasons and risks of poor health and wellbeing and also efficient in handling the evolving challenges that impend health and well-being. The investment in PHCs has been evidenced that these quality PHC providers lessens the cost of healthcare and also improves the efficacy by reducing hospital admissions. PHCs address complex health needs and also focuses on improving health security and also prevent health threats like epidemics and disinfectant resistance. The strong PHCs are necessary in order to achieve the Sustainable Development Goals (SDGs) relating to health and also Universal Health Coverage. PHCs are considered the most essential and easily available healthcare services. It does not need any sophisticated and specialized service, complex technology and infrastructure. These are considered cheaper and affordable to the people at large.

The Alma Ata Conference[102] has laid down eight aspects of PHCs. They are:

a) Adequate Supply of Safe Drinking Water and Basic Sanitation
b) Health Education
c) Nutrition
d) Immunization
e) Provision of Essential Drugs
f) Availability and Distribution of Medicines
g) Treatment of Communicable Disease. Immunization, which is necessary to protect a large number of the public from communicable diseases, is provided by the PHCs.

In developing countries like India, people are not in a position to afford sophisticated curative health services and treatment. Thus, immunization provides them the strength to fight against communicable diseases such as T.B., Tetanus, Diarrheal diseases, whooping coughs etc. The PHCs emphasize more immunization programs for the protection and development of public health.

The essential drugs which are required to meet the healthcare needs must be provided by PHCs. These distributions of drugs depend on the local needs and conditions of the public. For example, diarrhea, fever, common cold, pain etc., where these drugs need

[102]WHO called to return to the Declaration of Alma-Ata, International conference on primary health care, available at: https://www.who.int/teams/social-determinants-of-health/declaration-of-alma-ata, (last visited on April 22nd 2022)

very frequently. The drugs which are of local needs must be readily available at the PHCs to meet the health needs. Communicable diseases need proper and timely treatment or there may cause pre-mature deaths. PHCs provide drugs and treatment to these communicable diseases at the local level and managed to organize the short time training programs to treat and overcome the condition.

2.5.2 Secondary Health Care and Tertiary Health Care

Secondary Healthcare is referred to as the second tier of the health system in India. The patients are referred from primary health care to provide specialized treatments in higher hospitals. In India, District hospitals and Community Health Centre at the block level come under Secondary Health Care. The third level of the health care system in India is known as tertiary health care. The patients were usually referred from primary and secondary healthcare to provide the facilities of intensive care units, well and advanced diagnostic support services and also to get treatment and opinion from specialized medical professionals. In India, these services are provided by Medical Research Institutes and Medical Colleges.

Thus accessibility, availability and affordability of essential drugs can be understood as timely access to the drugs needed by the patient, availability of such drugs sought by the patient and also afford such drugs need for the treatment of the diseases suffered by the patient. The different level healthcare providers facilitate the public in order to access, avail and afford essential drugs. There are three levels of healthcare providers available to the public. The individuals, according to health needs, can seek and avail of medical services.

2.6 CONCLUSION

Access to essential medicines is a big problem for one third of all persons worldwide as the price of many medicines is not affordable to the majority of the population who is in need, especially in least-developed countries, but also increasingly in middle-income countries[103].Though India has made many progress in the field of pharmaceutical sector and medical tourism , the access to essential medicines remains

[103] Hilde Stevens and Isabelle Huys, *Innovative Approaches to Increase Access to Medicines in DevelopingCountries*,4Front. Med 1(2017)

limited and inequitable[104]. The right to adequate medical care and the opportunity to achieve and enjoy good health should be available to all the people[105].The right to access to medicine is an important aspect of human right which is a full realization of right to health. The Medical care which includes the prevention, treatment and control of diseases largely depends on the timely and appropriate access to quality medicines. The lack of accessibility to quality medicines in an affordable and timely way is a violation of human rights which is commonly seen in developing countries. This challenges the dignity of human beings including the rights to life , health and development of all persons.Every individual has Human Right to Health and it is the obligation on the part of the State to protect and provide good health to its citizens by providing easy access to health care and also to access essential drugs that are in need. Though WHO, UDHR and other international instruments provide that it is an obligation on the part of the state to protect health and shall take steps with regard to it, there is no uniform international law governing with this regard. Even though, right to health has been protected under Article 21 of the Constitution, no separate provision is provided for right to health under the Constitution. But hrough various judgements, the Supreme Court of India has protected the right to health of its citizens under Article 21(right to life and personal liberty) of the Constitution of India. Thus, the Right to health being a fundamental right; it includes the right to access life-saving drugs as a right under it. India, being a founder member of the United Nations has ratified various international conventions promising to secure health care right of individuals in society[106]. The Government of India has enforced several laws in order to provide its citizens with quality as well as affordable drugs. It has made efforts to bring drugs under the price cap but still not able to make a common price tag for a similar kind of drugs. For achieving the Constitutional obligation and also objectives of Health care for all there is a need on the part of the government to mobilize nongovernmental organization and the general public towards their participation for monitoring and implementation of health care facilities[107]. Domestic judges should familiarize themselves with the right to health and its interpretation in international human rights law, especially the concepts

[104] Sangeeta Sharma and Ranjit Roy Chaudhury, *Improving Availability and Accessibility of Medicines: A Tool for Increasing Healthcare Coverage*,7 iMedPub Journals 1(2015)
[105] JOHN TOBIN, THE RIGHT TO HEALTH IN INTERNATIONAL LAW,8, [Oxford university press (1st Edi, 2012)]
[106] Dr Amit Patil,*Right to Health and Healthcare*, 8(9)Indian Journal of Applied Research 67,68(2018)
[107] Baharul Islam, *RIGHT TO HEALTH: A CONSTITUTIONAL MANDATE IN INDIA*,3(3)IJARIIE 2627,2638 (2017)

of essential medicines selection and progressive realization.[108] The policies and initiatives by the Government of India are appreciable and always aimed at providing poor and needy people quality affordable health care and access to quality affordable drugs. But still, the lacunas in the enforcement of policies and schemes made it difficult to access essential drugs on time and people are suffering due to the non-availability of quality affordable drugs.

[108]Katrina Perehudof, Universal access to essential medicines as part of the right to health: a cross-national comparison of national laws, medicines policies, and health system indicators, 13(1) Global Health Action 1,12 (2020)

CHAPTER 3
DRUG REGULATION IN INDIA: AN OVERVIEW

3.1 INTRODUCTION

Every person who born as a human being is entitled to human rights which is necessary for an individual to lead a dignified life. The right to health is one of the basic human right, which is protected under Article 21 of the Constitution of India and various other international laws. In Vincent case[109] and Paramananda katara case[110], the SC clearly said that the right to life also comprises the right to health under 21 of the constitution of India. The right to health includes the accessibility, availability and affordability of individuals to quality health care and medicines. If the right to health of an individual is violated, then it is the violation of basic human rights. Drug regulation plays pivotal role in any country because the purpose of drug regulation is to promote and to protect public health by ensuring the safety, efficacy and quality of drugs[111]. It is the responsibility of the government to ensure its citizens with quality drugs in an affordable way. Since the drugs are essential for leading a healthy life, the quality of drugs cannot be compromised in any way. If the drugs are of not good quality or if it is spurious, adulterated or misbranded one, then it may lead to the loss of life of the individuals consuming it and affects the public interest. Also, the accessibility of essential drugs in an affordable way is very important to prevent the loss of life of the people due to the non-availability of the drugs. As the regulation of drugs is a complex process, the Indian government has taken many steps for the proper regulation of drugs.

3.2 REGULATION OF DRUGS.

As the drugs are very important in safeguarding the health and life of the individuals, the access to drugs are considered as a basic human right and it is protected within the purview of article 21 of the Constitution of India . Drug regulation plays pivotal role in

[109] Vincent Panikulangara v. Union of India AIR 1987 SC 990
[110] Paramanand Katara v. Union of India, A.I.R. 1989 S.C. 2039
[111] Priyanka V. Patel, *Drug Regulation in India: Swot Analysis*, 3(3) International Journal of Drug Regulatory Affairs 21(2018)

any country because the purpose of drug regulation is to promote and to protect public health by ensuring the safety, efficacy and quality of drugs. There have been incidents where counterfeit drugs were clearly responsible for deaths of several patients[112]. So the proper regulation of drugs are very necessary to safeguard the interest of the public and to make sure that no one is denied of access to quality and affordable drugs. So the government of India has enacted various legislation in this regard to regulate drugs in India. Some of the legislations that plays a very important role in the regulation of drugs are as follows:

3.2.1 THE DRUGS AND COSMETICS ACT, 1940

The Drugs and Cosmetics Act, which was passed in the year 1940 was entrusted with the main objective to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The main purpose of the act is to ensure people that the drugs are safe, effective and comply with the prescribed quality standards. The Act provides a good definition of drugs[113]. Under the Indian Constitution, the subject "Drug" comes under the concurrent list. Thus, the responsibility of enforcing the various provisions of the Act vests with the Central Government and the State/Union Territory Governments. The roles of Central and State Governments have been well defined.

The Central Government has got the power to constitute the Drugs Technical Advisory Board to guide the Central and State Governments on technical aspects that occur during the administration of the Act and to convey other functions entrusted by the Act. The Central Drugs Laboratory shall be established by the Central Government under Section 6 of the Act to perform the functions assigned in respect of any drug or class of drugs. The Drug Consultative

[112] Bhagya MANOJ Sattigeri, *Counterfeit drugs in India: significance and impact on pharmacovigilance*, 3(9) Int J Res Med Sci. 2156,2158 (2015)

[113] Drugs and Cosmetics Act,1940,Section 3(b)" "drug" includes—(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes (ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of 10[vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette(iii) all substances intended for use as components of a drug including empty gelatin capsules; and (iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board"

Committee might be constituted by the Central Government to guide the Central Government, the State Governments and the Drugs Technical Advisory Board on any aspect tending to secure reliability all over India in the management of this Act.

3.2.1.1 Regulation of Quality of Drugs, Import, Manufacture, Sale and Distribution of Drugs

The drugs are intended to save the life of human beings or animals, but the poor quality of drugs may lead to death than to save a life. Therefore, it is necessary to regulate the quality of drugs. For the purpose of import, [manufacture, sale and distribution of drugs], such drugs must comply with the standards set forth in the Second Schedule. During the import, manufacture, sale and distribution of drugs, one must satisfy that those drugs are of good quality. Those drugs must not be considered as a misbranded, adulterated, spurious drug that is unfit to use by human beings. Section 9 and Section 17 of the Act focuses on Misbranded Drugs[114]. The drug shall be considered as misbranded when it conceals the damage by its coated colour or if it is powdered or if it is prepared in such a way as to magnify the therapeutic value than the original. Those drugs may not be having the label in the prescribed manner or if it makes any false claim for the drug or misleading through its label or container. An adulterated drug is defined as a "drug which consists of any filthy, putrid or decomposed substance in whole or in part."[115] If the manufacture,

packing or storing of drugs is made in unhygienic condition, then it may get contaminated. The contaminated drug may turn injurious to the health of an individual. The drugs may be harmful when such container wholly or partly

[114] Drugs and Cosmetics Act,1940,Section 9 and section 17 "Misbranded drugs.—For the purposes of this Chapter, a drug shall be deemed to be misbranded(a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or(b) if it is not labelled in the prescribed manner; or(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular".

[115] Drug and Cosmetics Act, 1940,Section 9A ".Adulterated drugs.—For the purposes of this Chapter, a drug shall be deemed to be adulterated,(a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or (b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or (c) if its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to hea lth; or (d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or(e) if it contains any harmful or toxic substance which may render it injurious to health; or (f) if any substance has been mixed therewith so as to reduce its quality or strength".

contains any poisonous or deleterious substances or if it contains any harmful or toxic substances. If such drugs mix with that substance, which may, in turn, reduce its quality or strength are considered as an adulterated drug. Spurious Drugs[116] are those imported or manufactured under a name which belongs to another drug. The drug may be considered as spurious if it imitates or resembles in such a way which likely to mislead or if a drug has a name of the individual or company which claim itself as the manufacture of the drug, but in reality, such individual or company is fictitious or does not exist at all. If such drug is substituted wholly or in part by another drug or if it alleges that it is a product of a manufacturer of whom it is not truly a product, come under the meaning of spurious drugs. Hence, the import, manufacture, sale and distribution of substandard drugs, misbranded, adulterated, spurious drugs are prohibited under the Drugs and Cosmetics Act, 1940, in view to protect the health of an individual.

In the case *State of Maharashtra v. Jethmal Himatmal and Another*[117], it has been observed that special consideration is required in cases that involve the racketeering of essential drugs or trade of spurious medical preparations. Because there would be a compromise in the quality of drugs or adulteration of drugs. Due to spurious drugs or medical preparations, many lives have been lost and it is a matter of slight consequence whether the fault can be traced to the manufacture, to the intermediary or to the dealer. These kinds of crimes are against humanity and the law must deal with them with the utmost firmness if the rackets are to be controlled and quenched out. The Central Government has the authority under Section 12[118] of the Drugs and Cosmetics Act to make rules relating to the specification of drugs and the classification of drugs. It also has the power to

[116] Drugs and Cosmetics Act,1940,Section 9-B "Spurious drugs.—For the purposes of this Chapter, a drug shall be deemed to be spurious(a) if it is imported under a name which belongs to another drug; or (b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or (c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or (d) if it has been substituted wholly or in part by another drug or substance; or (e) if it purports to be the product of a manufacturer of whom it is not truly a product

[117] State of Maharashtra v. Jethmal Himatmal and Another, 1994 Cri.LJ 2613

[118] Drugs and Cosmetics Act,1940,section 12(1) "The Central Government may,[after consultation with or on the recommendation of the Board] and after previous publication,publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter"

prescribe the methods of test to be adopted or analysis to be employed in determining the standard quality of drugs, biological and organometallic compounds, the colour of drugs, specifications about the claims of imported drugs. It also regulates the places in which the drugs may be imported, manufacture and also mandates to mention the date of expiry of drugs, packing and labelling of drugs, display of the scientific name of the drug etc.

The Central Government under Section 26A[119] has the power to prohibit the manufacture of any drug if it is expected to involve any risk to human beings or animals. If such a drug manufactured does not have any therapeutic value which it claims or alleges to claim or if the components of such drugs do not have any therapeutic justification, then in the interest of the public, it can be prohibited. The drugs which are manufactured or imported must satisfy the prescribed standards. If any imported drugs are spurious or adulterated or contravene the provisions, then it is considered an offence and punishable under Section 13 of the Act. If any person manufactures for sale or for distribution or sells or stocks or exhibits for sale or for distribution, any drug which is deemed as spurious or adulterated is punishable under Section 27 of the Act.
It has to be noted that every drug manufacturing company must have a quality control chemist to test the quality of drugs. He has to test every batch which has been prepared for the purpose of sale. Then he has to allow only those drugs which fulfil the standards and have to reject those drugs which are substandard. The standards of drugs are prescribed under the Indian pharmacopoeia.
In *Armour Pharmaceuticals Ltd*. v. *Government of Andhra Pradesh & others*,[120] the Writ Appeal was dismissed and it has been observed by the court that, if essential drugs like anti-biotics are purchased from Small Scale Industries, then there is every possibility of supplying substandard drugs. These

[119] Drugs and Cosmetics Act,1940, Section 26A "Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, [regulate, restrict or prohibit] the manufacture, sale or distribution of such drug or cosmetic]"
[120] Armour Pharmaceuticals Ltd. v. Government of Andhra Pradesh & others, (1999) 4 ALD 24, (1999) 2 ALT 693

industries underquote the price, but it might endanger the lives of the people. With this regard, the Government does not want to take any risk in respect of antibiotics used by the poorer sectors of society. It has been observed that the discrimination, if any, is certainly justified in the interest of the public. The ultimate objective of the Drugs and Cosmetics Act is to prevent substandard drugs. The pharmaceutical industry has got the obligation to provide accurate

information and education about the products manufactured by them for the purpose of health care. It has to be done in order to establish a clear understanding of the appropriate use of prescribed medicines. The information must be provided with objectivity, truthfulness and in good taste and must conform to all relevant laws and regulations.

3.2.1.2. Central Drugs Standard Control Organisation (CDSCO)

At the central level, the Drugs and Cosmetics Act, 1940, has created the Central Drugs Standard Control Organisation (CDSCO), within which the Drugs Controller General of India (DCGI) is the key regulatory authority, acting under the advice of the Drug Technical AdvisoryBoard (DTAB) and the Drug Consultative Committee (DCC)[121].The Central Drugs Standard Control Organisation which is also known as the Central Drugs Authority, is entrusted with the duty of discharging functions assigned to the central government under the Drugs and Cosmetics Act, 1940. The CDSCO exercises control over the quality of imports of new drugs, its approval, clinical, trial and also lays down the standards for drugs , coordination of the activities of the State Drug Control Organisations and also provides an expert advice with a view to bring uniformity in the proper enforcement of the Drugs and Cosmetics Act. On the other hand , the state authorities are concerned with the regulation of manufacture , sale and distribution of Drugs licensing drug testing laboratories, approval of drug formulations and oversee the manufacturing process etc.

The CDSCO is controlled and governed by the DGHS, under the Ministry of Health

[121] Shree Agnihotri and Sumathi Chandrashekaran, *Drug Regulation In India: The Working And Performance Of CDSCO And SDRAs*, (2019),available at https://thakur-foundation.org/TFF%20State%20Drug%20Regulatory%20Authorities%20Capability%20Assessment%20Report.pdf(last visited on 4th July 2022)

and Family Welfare, Government of India. DCGI is the head of the department of CDSCO, who is responsible for approval for licence for specified categories of drugs and setting quality standards for manufacturing, sales, distribution and imports of drugs in India. The DCGI can decide on if there is any issue with regard to the quality of drugs[122].

3.2.2 THE DRUGS AND COSMETICS RULES, 1945

The Drugs and Cosmetics Rules, 1945, has been made under the Drugs and Cosmetics Act 1940. Hence the rules have full force and effect as if they were part and parcel of the Act itself. The Rules empowers to appoint the "Central Licence Approving Authority" for the purpose of grant or renewal of license for the purpose of import, manufacture for sale and distribution of drugs. "Central Licence Approving Authority" means "the Drug Controller, India or the Joint Drug Controller (India) or the Deputy Drugs Controller (India) appointed by the Central Government." The Central Drugs Laboratory has been established under the Rules to analyze or test samples of drugs. It is also entrusted to carry out other duties given by the Central or State Government after consultation with the Drugs Technical Advisory Board.[123] The functions of the laboratory are carried out at the different Research Institutes according to classes or types of drugs. For example, the analysis or test of drugs or classes of drugs such as Sera, Vaccines, Solution of serum proteins intended for injections, Toxins, Antigens, Anti-toxins, Sterilised surgical ligature and sterilized surgical suture and Bacteriophages are carried out at the Central Research Institute, Kasauli[124].

3.2.2.1 Grant of Licence to Import, Manufacture, Sale and Distribution of Drugs

One has to obtain a license from the Central Licence Approving Authority for the purpose of import, manufacture, sale or distribution of any drug. 'Import Licence' means a license required for the purpose of importing drugs from other

[122] Central Drugs Standard Control Organization, https://cdsco.gov.in/opencms/opencms/en/Home/(last visited on 4th July 2022)
[123] The Drugs and Cosmetic Rules, 1945.
[124] Central Drugs Laboratory (Kasauli), https://cdsco.gov.in/opencms/opencms /en/Departments/ Lab/ CDL _ Kasauli/(last visited on 4th July 2022)

countries. The manufacturer himself or any agent of such manufacturer shall also apply for a license by paying the prescribed fees, but it must accompany a copy of the Registration Certificate. In case of emergency, the licensing authority, with the approval of the Central Government, can issue a license without the issuance of a Registration Certificate under Rule 27-A[125] and have to record reasons in writing. Under Rule 25 of the Drugs and Cosmetics Rules, 1945, a single application and a single license are enough in respect of the import of two or more drugs or classes of drugs manufactured by a single manufacturer. The applicant has to satisfy the conditions provided under the rules or the issue of the license may be rejected by the licensing authority.

Rule 26 provides for the conditions of import license. The manufacturer must always oblige for the undertakings given by him or any person on his behalf[126]. The licensing authority or any inspector appointed on behalf of him shall inspect the premises and also take samples[127]. He may request the licensee to provide the sample from every batch or batches of substance for the examination[128] and the licensing authority has every right to direct the licensee not to sell until the issue of a certificate authorizing to sell[129]. If the licensing authority has not satisfied with the standard of strength, quality and purity of the drug, then he may direct to withdraw the remains of that batch or, in certain circumstances, may recall the issues already made from that batch. The licensee must maintain the record of all sales made by him of substances and to whom it has been sold and has to produce before the inspector during the inspection. The validity of the import license is for the period of three years from the date of issue unless it is preferably suspended or cancelled.

The import of small quantities of drugs may be done for personal use unless it is prohibited under Section 10[130] of the Drugs and Cosmetics Act, 1940. The imports of drugs for personal use are subject to the following conditions:

a. It must be part of the passenger's bonafide baggage and exclusively

[125] Drugs and Cosmetics Rules, 1945,Rule 27 A "On receipt of an application for Registration Certificate in the Form and manner specified in Rule 24A, the licensing authority shall, on being satisfied, that, if granted, the conditions of the Registration Certificate will be observed, issue a Registration Certificate in Form 4"

[126] Rule 26(1), Drugs and Cosmetics Rules, 1945

[127] Rule 26(2), Drugs and Cosmetics Rules, 1945

[128] Rule 26(3), Drugs and Cosmetics Rules, 1945

[129] Rule 26(4), Drugs and Cosmetics Rules, 1945

for the personal use of the passenger;

b. If Custom Authorities directs, then such drugs must be declared to such authorities;

c. The quantity of a drug that is imported must not exceed the average dose of one hundred.

In some exceptional cases, the licensing authority may allow a larger quantity of drugs to import.

As per the 1945 Rules, a Government Analyst shall be appointed for the purpose of analysing and testing the sample drugs sent by the inspector. He shall furnish the reports and then forward them to the Government from time to time. The Government Analyst has to furnish the complete details about the protocols of the test applied. For instance, where the test or analysis has been done according to the official pharmacopeia's for pharmacopeial drugs, then such references must be given in the report.

The application with the prescribed fee must be made under Rule 59 for the purpose of obtaining a license or for renewal of a license to sell, have a stock, exhibit or offer or sell or distribute drugs. A separate license must be issued under Rule 62[131] in case if sale has been done at more than one place. The license is issued only if the licensing authority has been satisfied with the conditions prescribed herein under this Rule. The premises must be adequate and well equipped with proper storage accommodations for preserving the drug[132] (Rule 62 B). The licensee must maintain the register, which consists of particulars about the serial number of entries, the date of supply of such drug, prescriber's name and address, name and address of the patient, name of the drug and particulars about the registered pharmacist on whose supervision it has been supplied etc. If the licensee failed to fulfil the conditions provided under Rule 65, then the licensing authority may

[131] Drugs and Cosmetics Rules, 1945,Rule 62 "Sale at more than one place. If drugs are sold or stocked for sale at more than one place, separate application shall be made, and a separate licence shall be issued, in respect of each such place:[Provided that this shall not apply to itinerant vendors who have no specifiedplace of business and who will be licensed to conduct business in a particular area"
within the jurisdiction of the licensing authority.]

[132] Drugs and Cosmetics Rules, 1945,Rule 62B(1) "A licence in Form 20A or Form 21A shall not be granted to any person, unless the authority empowered to grant the licence is satisfied that the premises in respect of which the licence is to be granted are adequate and equipped with proper storage accommodation for preserving the properties of drugs to which the license applies: Provided that this condition shall not apply in the case of licence granted to itinerant vendors"

cancel or suspend for such period the license and also give the licensee an opportunity to defend. A license must be obtained by the manufacturer for the purpose of the manufacture of any drug at any premises. The Central Licence Approving Authority appointed by the Central Government shall grant or renew the license for the purpose of manufacture for sale or distribution of drugs (Rule 68-A). The license shall be issued on the fulfilment of conditions prescribed under the Rules. The inspector appointed under the Rule shall examine all the portion of premises, plant and appliances and also process of manufacture to be employed for standardizing and testing the drugs to be manufactured. No new drug shall be manufactured for the purpose of sale unless the drug and its formulations are approved by the licensing authority. A drug is considered to be new if such a drug has not been used in the country to any significant extent and it is considered as new for the period of four years since the date of its approval or till its inclusion in the Indian Pharmacopoeia. The license for the manufacture or sale of drugs shall apply for a grant of approval for carrying out tests for identity, purity, quality and strength of drugs or raw materials used in the manufacture of the drugs. The approved institutions shall provide proper facilities for storage so as to preserve the properties of the samples to be tested. The licensee must maintain the records for the test carried out on all samples of drugs together with the results and protocols of tests. The record maintained by the manufacturer must produce it before the inspector during the inspection and he shall furnish the sample of every batch with protocols to the Licensing Authority on request. The licensee can sell any drug after he receives a certificate of authorization. If the licensing authority found if any of the batch drugs do not conform, the standards and purity specified in the Rules may withdraw or, if practicable, may recall the drugs sold. The extent of the license will be for the period of five years from the date of issue. The license may be cancelled or suspended at any time if the licensee has not been fulfilled the conditions of the license. The proper labelling and packing shall be done for each drug and must include the name of the drug, the manufacturer’s name and address, number of the license, batch or lot number, net content and expiry date of the drug etc.

3.2.3 PHARMACY ACT, 1948

Many of the time, the people buy drugs from the nearby medical shops. So it is necessary that the pharmacist should have sufficient knowledge about the drugs they provide.The Drug Enquiry Committee recommended that the persons practicing

pharmacy i.e. the persons responsible for compounding and dispensing of medicines should have a proper educational background[133]. Closely on the heels of the Drugs and Cosmetics Act, 1940, an upgrade and uplift for the profession of pharmacy was promulgated which result in the Pharmacy Act,1948. Before the enactment of Pharmacy Act, 1948, there were no restrictions on the practice of pharmacy so that any person without sufficient knowledge or qualification can practice the profession of pharmacy and sell the drugs. As a result of that, there were high chances of harm to the health of the people. Due to the absence of recognised curriculum, poor quality services were given to the people. So to regulate the profession of pharmacy and to ensure that the drugs are sold by the persons who has sufficient knowledge and skill on it, the Pharmacy Act, 1948 was enacted.

3.2.4 INDIAN PATENT LAW

In the year 1970, the Indian Patent Act was passed repealing all the previous legislations. However, in 1970, the government introduced the new Patents Act, which excluded pharmaceuticals and agrochemical products from eligibility for patents. This exclusion was introduced to break away India's dependence on imports for bulk drugs and formulations and provide for development of a self-reliant indigenous pharmaceutical industry[134]. The lack of protection for product patents in pharmaceuticals and agrochemicals had a significant impact on the Indian pharmaceutical industry and resulted in the development of considerable expertise in reverse engineering of drugs that are patentable as products throughout the industrialised world but unprotectable in India[135]. The Indian Patent Act, 1970 was amended in the years 1999, 2002 and 2005. The third amendment which was in the year 2005 explored the development of compulsory licencing.

Since independence, India emerged as a leading producer of generic drugs and thus plays a prominent role in ensuring that the poor people have access to affordable and

[133] DR.B.S.KUCHEKAR, PHARMACEUTICAL JURISPRUDENCE,9, [Nirali Prakashan Publishing Co. (13th Edi,2008)]

[134] Nilesh Zacharias and Sandeep Farias, *India: Patents And The Indian Pharmaceutical Industry*, (2019),available at https://www.mondaq.com/india/patent/8658/patents-and-the-indianpharmaceutical -industry(last visited on 14th July 2022)

[135]TRIPs and Pharmaceuticals: Implications for India, http://www.cuts-india.org/19978.htm# Pharmaceutical %20Industry%20in(last visted on 14th July 2022)

good quality essential medicines[136]. India signed the GATT on 15 April 1994, thereby making it mandatory to comply with the requirements of GATT, including the agreement on TRIPS[137]. The TRIPS Agreement harmonises the minimum standards for the protection of intellectual property across all the WTO members. TRIPs as an important part of WTO agreements intends to set an interpretative baseline to reconcile the interests of producers and consumers of intellectual property rights[138]. A number of provisions that deals with the health, public order, morality was included in the TRIPS Agreement. Most of the developed and developing countries under TRIPS excluded the pharmaceutical products from the purview of patent protection due to the fear that the grant of product patent to the pharmaceutical products would result in endangering affordability to general public. The monopoly in compulsory licence granted to pharmaceutical industry resulted in high prices for the innovated medicines. As a result, the right to the exclusive use of innovated drugs excluding potential competition violates the fundamental right to health. In 2005, as required by the provisions of the TRIPS Agreement, India revised its patent legislation and reintroduced product patents[139].The TRIPS agreement compels its all member countries to recognise and enforce product patent in their patent agreement in all fields of technology including the pharmaceutical sector[140].

The patent laws did not grant product patents before India accessed TRIPS Agreement. But after India accessed the TRIPS Agreement, the Indian patent laws undergone amendment and allowed the grant of product patents thus ensuring more flexibility to the patentees with availability, quality and price value of drugs. As a result of this, many provisions with regard to the grant of compulsory licencing were incorporated in the Indian patent laws with an objective to prevent the misuse of patent rights. Compulsory licence is an authorisation granted to a third party by the government to produce or manufacture a patented product without the permission of the patent holder or the patent

[136] Timothy Bazzle, *Pharmacy of the Developing World: Reconciling Intellectual PropertyRights in India with the Right to Health: TRIPS, India's Patent System and Essential Medicines*, 42, GEO. J. INT'l L. 785(2011).
[137] Nilesh Zacharias and Sandeep Farias, India: Patents And The Indian Pharmaceutical Industry, (2019), available at https://www.mondaq.com/india/patent/865888/patents-and-the-indian-pharmaceutical - industry
[138]Abu Saleh, *Pharmaceutical Patent and Right to Health: Seeking balance between IPRs and Human Rights* ,1 MLJ 17 (2015)
[139] YAEKO MITSUMORI, THE INDIAN PHARMACEUTICAL INDUSTRY-IMPACT OF CHANGES IN THE IPR REGIME,2, [Springer Singapore Pte.Ltd. (2018)]
[140] MAINAK MAZUMDAR, PERFORMANCE OF PHARMACEUTICAL COMPANIES IN INDIA,2, [Physica-Verlag HD (2012)]

owner. The compulsory licence is allowed if the patent owner tries to misuse his exclusive rights granted by patent. Thus the main purpose of the compulsory licencing is to avoid or prevent the misuse of patent rights by the patent holder in view of the public interest or anti-competitive practices which will otherwise result in the restriction of trade or hindering with the transfer of technology[141]. Compulsory licensing is not an absence of patent protection but merely a lessening of that protection.[142] In the pharmaceutical sector, 'compulsory licenses' can be employed by the government to allow generic pharmaceutical companies to produce and sell the patented essential medicines at a fraction of the price being charged by the pharmaceutical monopolists for meeting its twin objectives of ensuring accessibility and affordability of essential medicines for all[143]. Under the Indian patent laws, the compulsory licence is granted by the Indian patent office after 3 years of grant of patent. It is granted only if the patented product is not accessible to the public at a reasonable cost, not satisfying the requirements of the public and if the patent holder has not worked the patented product within the territory of India[144]. In the year of 2012, India granted the first ever compulsory licence to Natco Pharma for the manufacture of a generic form of Bayer's Nexavar, a drug for treating liver and kidney cancer[145]. The grant of a compulsory licence on Bayer's patented drug, Nexavar, was the world's first compulsory licence in the real sense of the word.[146] This was the first time a market-initiated compulsory licence was granted by an Agreement on Trade-Related Aspects of Intellectual Property Rights compliant patent regime, licensing a patented drug for a non-epidemic disease in the absence of a national emergency[147].The compulsory licence was granted on the ground that the drugs were not manufactured in India and it was sold at a very high cost which is not available by the public at a reasonable price. The was sold for 3200 EUR

[141]Obligationsandexceptions,https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm(last visited on 14th July 2022)

[142] IRINA HARACOGLOU, COMPETITION LAW AND PATENTS: A FOLLOW-ON INNOVATION PERSPECTIVE IN THE BIOPHARMACEUTICAL INDUSTRY, P.177[Edward Elgar Publishing Limited (1st Edi. 2008)]

[143] Rhyea Malik, *Striking a Balance between Patent Rights and Access to Essential Medicines through the Use of Compulsory Licenses - Comparative Study of Indian and Malaysian Patent Laws*, 42 JMCL 27 (2015).

[144] Hana Onderkova.,*Compulsory Licencing in India and changes brought to it by the TRIPS agreement*(2021),available at https://intellectual-property-helpdesk.ec.europa.eu/news-events/news/compulsory -licensing-india-and-changes-brought-it-trips-agreement-2021-10-12_en

[145] *Ibid*

[146] Natco Pharma v. Bayer Corpn, Order No. 45/2013 (Nexavar Licence) 38-39, Mumbai Patent Office, (2012) available at http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf

[147] Feroz Ali, *Nexavar: The First Market-Initiated Compulsory Licence*, 9 NUJS L Rev 295,296(2016)

for a monthly treatment. The compulsory licence that was granted to Natco assured that the generic version of Nexavar will be sold to the public at a reasonable cost of 100 EUR per month[148]. Thus the grant of compulsory licencing is an appreciated policy from the part of the government as it is effective in ensuring the availability of medicines to the public at a reasonable cost. As right to health is a fundamental right which is protected under the article 21 of the constitution of India, the access to essential medicines at an affordable cost is very important responsibility of the government as it is a part of right to health. The non-availability of essential lifesaving drugs violates the basic human rights and right to health of the individuals. The purpose of compulsory licence lies in access to affordable drugs[149]. The policies like drug price ceiling limit and the control on profit margin on big pharmaceutical firm may control the patent use[150]. The general public can access the medicines at a reasonable price with these policies. The provision of Doha declaration and TRIPS Agreement provides health benefits to the public without any discrimination. It is undisputed that compulsory licencing is a powerful tool that the developing countries can use to bypass the patent laws and increase the accessibility of medicines. There have been a handful of decisions that have the potential to foster the unique lines of Indian jurisprudence that projects access to essential medicines as a fundamental public health consideration. India as a developing country and also considering various decisions of the Honourable Supreme Court of India with regard to manufacturing of drugs at a reasonable cost, the Indian government should be careful to promote process patent rather than promoting product patent. If the product patent is granted, it creates more monopoly in the market that leading to higher prices of drugs and violates the right of access to medicines at reasonable cost which ultimately violates the human rights of the individuals seeking drugs.

3.2.5 THE DRUG PRICE CONTROL ORDER (DPCO)

The drug prices in India are controlled using Drugs (Prices Control) Order, an order issued by the government under Section 3 of the Essential Commodities Act, 1955

[148] Dealing with compulsory licensing in India, https://www.worldtrademarkreview.com/dealing-compulsory-licensing-india,last visited on 14th July 2022)
[149] Kiran Kumari and Ajay Sharma, *Doha Declaration:Compulsory Licensing and Access to Drugs*, 3(2)Amity Journal of Healthcare Management 43,52(2018)
[150] *Ibid*

empowering it to fix and regulate the prices of essential bulk drugs and their formulations[151]. The price of a drug plays an important role in access to drugs, especially essential drugs. In order to facilitate access to essential drugs, different countries have adopted different methods like "central procurement, health insurance, price regulation etc..." In Union of India v. K.S. Gopinath and Others[152], the Supreme Court has emphasized the need to "...consider and formulate appropriate criteria for ensuring essential and essential drugs not to fall out of price control..."

In India, we follow the "Cost Plus"[153] method. The Indian Government always made efforts to provide essential and essential drugs for poor and disadvantaged people at an affordable price. As its first attempt, the Indian Government included medicine under Section 3 of the Essential Commodities Act. It enabled the Indian Government to assert a "ceiling price"[154] for essential drugs and ensured the availability of essential drugs at a reasonable cost for the general public. The Drug Price Control Order (DPCO) was first introduced in the year 1979, where 347 drugs were identified as essential drugs and their formulations[155] and prices were going to be fixed by the Government. In 1987, the DPCO was revised and 142 drugs were brought under the control of the Government. The DPCO was further revised in the year 1995 and the 74 drug prices would be fixed by the National Pharmaceutical Pricing Authority (NPPA). The NPPA is an independent body that was set-up in the year 1997, which plays an important role in "fixing, revising and monitoring of prices" in terms of the Drugs and Prices Control Order, 1995. Only 20% of drugs come under price control and the remaining 80% don't have price control at entry-level. The NPPA was given the mandate of ensuring affordable drugs and was monitoring both scheduled and non-scheduled drugs. The NPPA is used to monitor the scheduled drugs through direct market surveillance as well as through survey reports, complaints and information received from individuals,

---

[151] Sandeep Narula, *Current Drug Pricing Status in India*, (2015),available at https://www.researchgate.net/publication/327181272_Current_Drug_Pricing_Status_in_India(last visited on 22nd July 2022)

[152] SLP No. 3668/2003, dated 10.03.2003

[153] The Cost-Plus Method compares gross profits to the cost of sales.

[154] Drug Prices (Control) Order, 1995, Section 2(c) "ceiling price" means a price fixed by the Government for Scheduled formulations in accordance with the provisions of paragraph 9.

[155] Drug (Prices Control Order) 2013, Section 2(h) "formulation" means a medicine processed out of or containing without the use of any one or more bulk drug or drugs with or pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or/and, but shall not include - (i) any medicine included in any bona fide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines. (ii) any medicine included in the Homeopathic system of medicine; and (iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply.

organizations, state drug control authorities and newspaper reports about over-charging and shortages etc. The NPPA would issue a show-cause notice to the company and direct them to deposit the amount overcharged. The prices of non-scheduled drugs were monitored by NPPA and they ensured that prices would not go up by more than 10 percent (20 percent before 1st April 2007) annually. The company would ask to reduce the price by NPPA if it has been noticed that they raise the price by more than 10 percent. If the company fails to reduce the price, then NPPA will fix the price of that medicine in the interest of the public by obliging to the conditions as empowered by DPCO. The Drug Price Control Order was again revised in the year 2013.

3.2.6 COMPETITION ACT, 2002

The Competition Act was enacted in the year 2002 to govern the commercial competition in India. The main objective of the act is to prevent those activities that have an adverse effect on the competition in India. The act further prohibits the anti-competitive agreements and prohibit the abuse of dominance. In the pharmaceutical industry, competition is necessary because it compels the industry to provide high quality of good and services to the people at reasonable or low costs. The pharmaceutical industry is an important source of healthcare for billions of people globally[156].The competition in the pharmaceutical sector motivate the brand companies to manufacture new and improved medicines and also encourage the generic companies to offer alternatives at low price. Through two core elements: enforcement and advocacy, the competition policy can improve both the consumer and government access to affordable drugs. Competition enforcement benefits consumers by detecting, halting and correcting anti-competitive practices[157]. Competition law policy is central to managing health care markets across the globe. The progress of pharmaceutical industry, though protected under a number of Intellectual Property laws, raises competition law issues. Competition law has to work in tandem with all such diverse set of laws, polices and regulation governing the pharmaceutical sector[158]. As it is for

[156] Dr. Gargi Chakrabarti, *Interface of IPR and Competition Law: Impact On Access to Medicine*, ICLR 87(2016)
[157] Manish Yadav and Sandip Sumbhate, *Critical Study of Competition Law with Reference to Patenting and Trade Secret in Pharmaceutical Products*,1(1) International Journal of Innovative and Informative Multidisciplinary Research 14,24(2017)
[158] Dr. Gargi Chakrabarti, Interface Of IPR And Competition Law: Impact On Access To Medicine, ICLR, available at http://www.iclr.in/assets/pdf/ICLR%20Issue%202%20(Gargi%20Chakrabarti).pdf

any other technology driven sector in the market, it's quite important to ensure competitiveness of the Indian pharmaceutical sector. Along with competitiveness, striking balance between the incentive for innovation in the pharma products and the freedom enjoyed by the market players while operating in the market is equally important. This calls for fine tune the anti-competitive agreement under section 3 of the Competition Act and section 140[159] of the Patents Act which deals with the avoidance of restrictive condition while entering into an agreement. An agreement for the lease or license of patent incorporating certain terms which are against or injurious to the public interest, whether they have been put knowingly or unknowingly will not be acceptable. However, the main lacuna of the Section 140 of Patents Act of 1970 is that it does not associate this section with compulsory license or else antitrust remedies. The only remedy provided under the Patent Act is that such conditions in a license can be used as a ground against infringement proceedings in the court of law. Consequently, there is a requirement to connect these provisions to compulsory license provisions of the Patents Act. The only two exceptions which are recognized under the Patent Act of 1970 are the Bolar exemption also referred as "experimental use exception" and the parallel import provisions as recognized under Sections 107A (a) and 107B (b) respectively. The basic notion behind the "Bolar exemption" is to make conditions, so that the generic pharmaceutical manufacturers can introduce their drugs immediately after the patent period on a drug lapse. While parallel importation is "Importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product"[160]. This provision was specifically incorporated to ensure availability of cheaper patented drugs. The requirement to extend protection to pharma enterprise for their innovation is well recognized under the Competition Act, 2002. However, the same is restricted by providing specific inclusions under Section 3(5) of the Act. Competition law has to ensure that the companies in pharmaceutical sector does not enter into anti-competitive agreement and also facilitate in achieving public health objectives. Competition Commission of India's analysis of the different aspects of the pharmaceutical industry may be categorized as following

A) Collusive conduct;

[159] Section 140: Avoidance of certain restrictive conditions.
[160] Section 107A(b), Patent Act ,1970

B) Abuse of dominance;

C) Conduct evincing both abuse of dominance and antitrust agreements;

D) mergers/acquisitions/amalgamations which are anti-competitive in nature.

The above-mentioned categories can be clubbed into two major agreements identified under Indian Competition Act of 2002 are horizontal and vertical agreements. Firstly, Horizontal agreements in the pharma sector would contain agreements entered at similar level between pharmaceutical companies to have an effect of restriction on supply or fix prices similar to situations including "payment of delay" which is most common in United States. Secondly, vertical agreements are entered between market players at diverse levels in the supply chain like being pharmaceutical companies and pharmacists or hospitals in the form of tie-in arrangements[161]. The clauses of sub (3) and (4) of Section 3 of the Competition Act relate to agreements entered between firm controlling purchase or sale prices, curtailing supply/production of goods and services as well as concluding exclusive supply or distribution arrangements, forming tie-in arrangements with the clear intention of adversely affecting the relevant market.

3.3 CONCLUSION

Drug discovery and access to generic drugs at affordable prices are so tightly inter-woven that it would appear that neither could exist without the other. Public health has been a major concern in India since the time of Independence and even after the advent of the Trade Related aspects of Intellectual Property Rights (TRIPS), it continues to be one[162]. Drug regulation plays pivotal role in any country because the purpose of drug regulation is to promote and to protect public health by ensuring the safety, efficacy and quality of drugs. Drug regulation should cover all products for which medicinal claims are made and all aspects of drugs like manufacturing, import, export, distribution, dispensing, promotion, sell and supply. But unfortunately drug regulation does not meet these requirements in India as legislation omits or exempts certain areas of pharmaceutical activity from the scope of control in India[163].

---

[161] Impact of Competition Law on Pharma Industry, available at http://www.nishithdesai.com/ fileadmin/user_upload/pdfs/Impact_of_Competition_Law_on_Pharma_Industry .pdf(last visited on 21st July 2022)

[162] Ritika Sharma, *Pharmaceutical Patents and Their Impact on Indian PharmaceuticalIndustry*, 2 INT'l J.L. MGMT. & HUMAN. 400(2019).

[163] Priyanka V. Patel, *DRUG REGULATION IN INDIA: SWOT ANALYSIS*,3(3), International Journal of Drug Regulatory Affairs 21(2018)

Every individual has Human Right to Health and it is the obligation on the part of the State to protect and provide good health to its citizens by providing easy access to health care and also to access essential drugs that are in need. Though WHO, UDHR and other international instruments provide that it is an obligation on the part of the state to protect health and shall take steps with regard to it, there is no uniform international law governing with this regard. Indian Constitution has provided its citizens the Right to Health under the Right to Life and Liberty under Article 21. The Right to Health has been protected under Article 21 of the Constitution, but there is no separate provision that enshrines the Right to health under the Constitution. But through various judicial decisions, it has been confirmed that the right to health is a fundamental right under the Indian Constitution. Thus, the Right to health being a fundamental right; it includes the right to access essential drugs as a right under it. The Government of India has enforced several laws in order to provide its citizens with quality as well as affordable drugs. It has made efforts to bring drugs under the price cap but still not able to make a common price tag for a similar kind of drugs. The policies and initiatives by the Government of India are appreciable and always aimed at providing poor and needy people quality affordable health care and access to quality affordable drugs. But still, the lacunas in the enforcement of policies and schemes made it difficult to access essential drugs on time and people are suffering due to the non-availability of quality affordable drug.

CHAPTER 4

DRUG PRICING POLICIES AND REGULATION

4.1 INTRODUCTION

Health Rights are fundamental essential rights of every individual. The Right to Health is attached to the Right to Life. Every individual in society enjoys a bundle of rights and the most important one is the Right to Life. The right to life does not only connote mere animal existence, but it entitles the person to live with dignity. Good health will make a way to live with dignity as a person with good health can earn and develop himself and not necessarily depend on others for his existence. The Right to Life also comprises the Right to Health. No man can deprive of this right. Both in national and international laws the health has been given more importance. The Universal Declaration of Human Rights under Article 25 clearly said that each and every person has a right to a standard of living with good health and accessibility to adequate health care services whenever necessary. Therefore, the Indian Constitution has put the right to health as a Directive Principle of State Policy and mandated Parliament to implement them while making laws. Medicines are the most important and basic element of health. Any system of medicine requires drugs of appropriate standard in order to treat the disease. Medicines have become an inevitable part of the day – to – day life of people. Drugs play a dynamic role in the life of an individual. It is chemical compositions that save the life of the individual as well as give strength to fight against the diseases. The largest share of out-of-pocket expenditure on health is due to medicines.[164] This is a major access barrier to healthcare, especially for the poor. It is very much necessary to regulate the quality of drugs and the price. The cost of healthcare and drug prices are major concerns in developed and developing countries[165]. Hence, the Indian government has enacted laws and policies regulating the manufacture, import, export, distribution, sale and price of the drug. The following are the analysis of relevant provisions of law and policies relating to the drugs.

[164] Aapproximately 70%, according to the NSSO.
[165] Venkatanarayana Motkuri and Rudra Narayan Mishra, *Pharmaceutical Market and Drug Price Policy in India*, 25(1)Review of Development and Change 30(2020)

4.2 CONCEPT OF ESSENTIAL DRUGS

People consume drugs even in the remotest areas of the world. These drugs are part of the armamentarium of medical practitioners and healers at all levels and are universally accepted to have and often do have powerful effects. The concept of essential drugs first evolved in a report made to the 28th World Health Assembly in 1975. The intention behind the report was to shoot up the scope and availability of medicines for populations with poor access. As a result of wide consultation, an "Expert Committee on the use of Essential Medicines" was formulated to assist member states in selecting and procuring essential medicines. In order to make the concept more specific, the WHO released an initial model list of essential medicines in 1977 with 205 items.[166] Most products on the list were known to be therapeutically effective and were no longer protected by patent rights. That step, according to the then WHO Program Manager of essential drugs, marked the start of 'a peaceful revolution in international public health'[167]. The WHO's goal of 'Health for All by the year 2000' included regular supply of certain essential drugs as a key indicator to evaluate progress[168]. The Declaration of Alma Ata on primary health care in 1978 identified the provision of essential drugs as a basic element.

Essential medicines are those that satisfy the priority healthcare needs of the population. These medicines are selected with due regard to the public health relevance, evidence on efficacy and safety and comparative cost – effectiveness.[169] Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford[170]. Essential medicines and medical technologies are the nucleus of a health system. The careful

[166]Essential Drug Concept and Rational Use of Drugs, https://www.researchgate.net/ publication/ 207423715_Essential_Drug_Concept_and_Rational_Use_of_Drugs (last visited 26th April 2022)
[167] Michael R Rech, Essential drugs: Economics and politics in international health, 1987 , https://cdn1.sph.harvard.edu/wp-content/uploads/sites/480/2013/01/essential_drugs.pdf (last visited on 28th May 2022)
[168] Centre for Environmental Health Activities ,https://applications .emro.who.int/docs /who_ em_ceha _55_e_en.pdf(last visited on 4th August 2022)
[169]World Health Organization, Who.int, https://www.who.int/topics/essential_medicines/en (last visited on 26th April 2022)

[170] Dipika Bansal and Vilok K. Purohit, Accessibility and use of essential medicines in health care: Current progress and challenges in India,4(1), J Pharmacol Pharmacother 13 (2013)

selection of a limited range of medicines ensures a higher quality of care, better management of medicines, including improved quality of prescribed medicines and more cost - effective use of quality medicines[171]. The concept of essential medicines has become one of the eight pillars of the World Health Organization's "Primary Health Care" strategy. In implementing of the concept of essential drugs the intention is to make it flexible and adaptable to different situations. Availability assumes not merely the physical presence of the drugs at the pharmacy but also includes economic factors. The purpose of such a model list is evident – to extend the accessibility of the essential drug to those populations whose health care needs cannot be met by the existing system[172].

The process of selection of essential medicines is very critical. An essential medicine list simply imposed by authorities will not be reflective of the needs of the people nor will it be acceptable. It is therefore very crucial that the selection procedure be transparent and consultative, selection criteria be explicit, selection of these medicines be linked to evidence-based standard clinical guidelines, the list be divided into different levels of care and be regularly reviewed and updated. The lists are flexible enough to accommodate new drugs. Nevertheless, in order to achieve the objective optimally, a review of the list at regular intervals is necessary. This is not only because of the advancements in the drug therapy but also to meet the needs of the practitioner considering experience. The WHO revises its Essential Medicines List every two years since 1977, the latest being the 21st EML released in 2019. The WHO also released the Essential Medicines List for Children in 2007. It was updated last in June 2019. A remark suggesting that a drug is complimentary can be seen on both the WHO adult and children's lists. Thus, the "core list" and the "complementary list" are effectively two lists. The core list is a list of the most efficacious, safe, and cost-effective medicines for priority illnesses that a basic health care system would require. Priority conditions are chosen based on their current and projected public health importance, as well as their potential for safe and cost-effective treatment. The complementary list includes necessary drugs for priority diseases that necessitate specialist diagnostic or monitoring

[171] Mukhopadhyay K, Singh R, *Essential medicine list 2011*,5 Muller J Med Sci Res 56 ,57 (2014)
[172] Kar SS, Pradhan HS, Mohanta GP, *Concept of essential medicines and rational use in public health,Indian*, 35(1)J Community Med10,11(2010)

facilities. The medicines may be labelled as complementary in a variety of circumstances due to greater costs or less appealing cost-effectiveness.

The essential medicines list consists of cost - effective and safe medicines, while the pharmaceutical market is flooded with a large number of medicines many of which are of doubtful value. The WHO model list ,2002 serves as a guide for the development of several national, regional and institutional list of essential medicines. Each country is encouraged to prepare its own National List of Essential Medicines, considering the local priorities and needs. The idea of essential drugs has now been accepted worldwide as a powerful tool that promotes health equity. Its impact is remarkable because essential drugs have proved to be one of the most cost - effective elements in healthcare. The Essential Medicines List help countries to rationalize the purchasing and distribution of medicines, thus lowering costs to the healthcare system. The idea of essential medicines is very progressive. It focuses on the need to regularly update new medicines selections to incorporate new therapeutic options and new therapeutic needs, the need to ensure drug quality and the need for continued development of new medicines, medicines for emerging diseases and medicines that meet changing resistance patterns. Clinical recommendations and lists of essential drugs, when appropriately designed, implemented, and supported, have been shown to enhance prescribing quality and result in better health outcomes. Once looked at as relevant only in resource-constrained settings, the WHO model of essential medicines is now viewed as equally important to high -, middle - and low- income countries, particularly after the inclusion of new, highly effective and expensive medicines in the most recent years. WHO recommendations are often referred to by many countries while making decisions on health spending. Over 150 countries now have an essential medicines list based on the local priorities and needs of the population.[173]

4.3 SELECTION OF ESSENTIAL DRUGS

The rationale for the selection and use of a limited number of essential medicines is that it leads to an improved supply of medicines, more rational prescribing and lower

[173] World Health Organization , Who.int, https://www.who.int/medicines/services/essmedicines_def/en/ (last visited on April 26, 2022)

costs[174]. In fact, proper utilization of vital pharmaceuticals is one of the most cost-effective methods that a government can implement. The concept of essential medicines is a worldwide notion and can be applied in any country, in both public and private sectors, at primary health centres and in referral hospitals, in urban as well as rural areas. The choice of which medicines are to be considered essential, however, is a national level responsibility. It means State decides which medicines are to be considered essential. The essential medicines list needs to be country specific addressing the disease burden of the nation and the commonly used medicines at primary, secondary and tertiary healthcare levels. The medicines in National List of Essential Medicines (NLEM) should be available at affordable costs and with assured quality. The medicines used in the various national health programmes, emerging and reemerging infections should be addressed in the list. The Government of India, Ministry of Health & Family Welfare (MOHFW) is mandated to ensure the quality healthcare system by assuring availability of safe and efficacious medicines for its population. Under ideal circumstances, the registration of essential medicines for the public and the private sectors should be based on an evaluation of efficacy, safety and quality assessment. In such instances, the selection of essential drugs takes place during medicine evaluation, approval and registration and hence is applicable to both public and private sectors. The selection of essential drugs is more commonly limited to public sector health facilities .A limited list of essential drugs is prepared as a basis for supplying pharmaceuticals, in each level of health care in the public sector, and for the purpose of training health professionals – the reason which is why such lists should be tightly linked to standard treatment guidelines for clinical health care practices[175].

There are several reasons to support the use of a limited list of essential medicines[176]. Firstly, basic health services are to be made accessible to everyone before more expensive services are made available to a small, usually urban proportion of the population. Secondly, neither the public sector nor health insurance systems can afford to supply or reimburse all medicines that are available in the market. Hence the list of essential drugs not only guide in procurement and supply of medicines in the public

[174] Managing medicine selection - msh.org. https://msh.org/wp-content/uploads/2013/04/mds3-ch16-selection-mar2012.pdf(last visited on 11th July 2022)
[175] World Health Organization ,Who.int, https://www.who.int/medicines/services/essmedicines_def/en/ (last visited on April 26, 2022)
[176] Rituparna Maiti, Vikas Bhatia,Biswa Mohan Padhy, and Debasish Hota,Essential Medicines: An Indian Perspective, 40(4)Indian J Community Med 223,227 (2015)

sector but also in schemes that reimburse medicine costs as well as those medicines that make sense for production by local manufacturers. Since the availability of pharmaceuticals in many countries is inconsistent, the regular supply of the products in the essential medicines list would aid in a well improved public health system and also boost the confidence of the general public in the health care system. Many organizations, including the UNICEF and other international non – profit supply agency organizations, have adopted the concept of essential medicines for their supply systems. Thirdly, the use of a limited list of essential medicines could improve the quality of care delivered by ensuring that patients receive the treatment of their choice as well as similar treatments from different providers because the list represents the consensus of prescribers on first choice pharmaceutical treatments. It also makes the prescribers more familiar with the selected number of medicines. This restricted possibility, in fact, contributes to an improved understanding of the actual benefits and limitations of specific medicines therapy, as well as in detecting and preventing adverse drug reactions. In the fourth place, for countries with scarce funds for health care expenditure, the limited lists of essential medicines act as a boon by promoting quality in care as well as cost control. As a result, the policy, which has now become a universally accepted tool, enables improved efficiency and effectiveness in patient treatment with reduced health care costs. Fifth in the row, it is advantageous to public sector supply programs in procurement and logistics activities because of the reduction in the number of medicines that needs to be stocked, distributed and monitored. Since essential drugs are available with multiple suppliers, increased competition facilitates negotiation for favorable prices. Additionally, the use of limited number of essential drugs creates potential opportunities to achieve economies of scale as larger quantities of the medicine will be required to treat a particular clinical problem. National pharmaceutical programs base their medicine donation programs on the national essential medicines lists, the reason for which is that it is easier to ensure the quality of a smaller number of pharmaceutical drugs. Lastly, the selection of limited number of essential medicines smooths the path for efforts to provide drug information and education, both of which facilitate rational prescribing and use of these drugs. Since objective drug information is very rare some in most developing countries, their provision is considered extremely beneficial by the physicians and other health care professionals.

4.3.1 Criteria for the selection of essential drugs

WHO Expert Committee on the Selection and Use of Essential Medicines employs the following criteria for the selection of essential drugs:[177]

- Only those medicines with sound and adequate evidence of safety and efficacy in a variety of settings are chosen.
- Another major consideration for choosing medicines within the same therapeutic category is relative cost-effectiveness. While contrasting between medicines of similar safety and efficacy, the total cost of the treatment - and not just the unit cost of the medicine - is considered and is compared to its efficacy.
- Other factors such as pharmacokinetic properties and local considerations such as availability of facilities for manufacture and storage also influence the choice of medicines.
- Each selected medicine shall be available in adequate quality in a form for which bioavailability is ensured; the stability under anticipated conditions for storage and use shall be determined.

Single compound formulations may be preferred for most essential medicines. Fixed - dose combination products may be selected only when such combinations have a proven advantage and special therapeutic effects, safety and adherence or decrease the emergence of drug resistance in TB, malaria, HIV/AIDS etc

4.4 CONTROL OF DRUG PRICES IN INDIA- AN ANALYSIS

The development of drug is a cost-intensive process, thus the pricing of drugs becomes a contentious issues in every jurisdiction .[178]The price of a drug plays an important role in access to essential drugs, especially life-saving drugs. In *Union of India v. K.S. Gopinath and Others*[179], the Supreme Court has emphasized the need to "…consider and formulate appropriate criteria for ensuring essential and life-saving drugs not to fall out of price control…"

[177] Pharmaceutical Management, Part II, Ch 16, Managing Medicine Selection, mds3-ch16-selection-mar2012.pdf(msh.org)

[178] Uday Shankar and Nidhi Mehrotra, *Patent Regime and Drug Pricing Regulations: An Intertwining Thread in Determining Accessibility and Affordability of Essential Medicines in India*, 12 RMLNLUJ 29(2020)

[179] *Union of India v. K.S. Gopinath andOthers* SLP No. 3668/2003, dated 10.03.2003

In India, we follow the "Cost Plus"[180] method. The Indian Government always made efforts to provide essential and life-saving drugs for poor and disadvantaged people at an affordable price. As its first attempt, the Indian Government included medicine under Section 3 of the Essential Commodities Act. It enabled the Indian Government to assert a "ceiling price"[181] for essential and life-saving drugs and ensured the availability of life-saving drugs at areasonable cost for the general public. The Drug Price Control Order (DPCO) was first introduced in the year 1979, where 347 drugs were identified as essentialdrugs and their formulations and prices were going to be fixed by the Government[182]. In 1987, the DPCO was revised and 142 drugs were brought under the control of the Government. The DPCO was further revised in the year 1995 and the 74 drug prices would be fixed by the National Pharmaceutical Pricing Authority (NPPA)[183]. The NPPA is an independent body that was set-up in the year1997, which plays an important role in fixing, revising and monitoring of prices in terms of the Drugs and Prices Control Order, 1995.Only 20% of drugs come under price control and the remaining 80% don't thave price control at entry-level. The NPPA was given the mandate of ensuring affordable drugs and was monitoring both scheduled and non-scheduled drugs. In order to safeguard the public health, National Pharmaceutical Pricing Authority (NPPA) is the watchdog in India, which controls the prices of drugs[184]. The NPPA is used to monitor the scheduled drugs through direct market surveillance as well as through survey reports, complaints and informationreceived from individuals, organizations, state drug control authorities and newspaper reports about over-charging and shortages etc.[185] The NPPA would issuea show-cause notice to the company and direct them to deposit the amount overcharged. The NPPA has

[180] The Cost-Plus Method compares gross profits to the cost of sales.

[181] Drug Prices (Control) Order, 1995, Section 2(c) "ceiling price" means a price fixed by the Government forScheduled formulations in accordance with the provisions of paragraph 9.

[182] Drug (Prices Control Order) 2013, Section 2(h) "formulation" means a medicine processed out of or containingwithout the use of any one or more bulk drug or drugs with or pharmaceutical aids, for internal or external use foror in the diagnosis, treatment, mitigation or prevention of disease in human beings or/and, but shall not include –(i)any medicine included in any bona fide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines. (ii)any medicine included in the Homeopathic system of medicine; and (iii) any substance to which the provisionsof the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply

[183] NPPA fixes the ceiling price of medicines. https://www.teamleaseregtech. com/updates/article / 18296/nppa-fixes-the-ceiling-price-of-medicines/(last visited on 14th July 2022)

[184] Renganathan R, Vijayabanu C, Srinivasakumar V& Vijay Anand V, *Pharmaceutical Pricing Policy And Control: Indian Perspective*, 9(6) Asian Journal of Pharmaceutical and clinical research 305 (2016)

[185] Bindhu Shajan Pareppadan, 'What is the National Pharmaceutical Pricing Authority's role in fixing drug prices?', https://www.thehindu.com/sci-tech/health/explained-what-is-the-nationalpharmaceutical-pricing-authoritys-role-in-fixing-drug-prices/article65240274.ece,(last visited 10th July 2022)

recovered Rs. 174.33 cores till 31st July 2009 on this account. The prices of non-scheduled drugs were monitored by NPPA and they ensured that prices would not go up by more than 10 percent (20 percent before 1st April 2007) annually. The company would ask to reduce the price by NPPA if it has been noticed that they raise the price by more than 10 percent. If the company fails to reduce the price, then NPPA will fix the price of that medicine in the interest of the public by obliging to the conditions as empoweredby DPCO.

4.4.1 DRUG (PRICES CONTROL) ORDER 1995

The Central Government, while exercising the powers bestowed in Section 3 of the Essential Commodities Act, 1955, made the Drug (Prices and Control) Order 1995 and it was revised in 2013. The Order empowers the Government to fix the "maximum sales price" for the "bulk drugs,"[186] which are specified under the First Schedule. The main purpose of fixing the price is to make the drug available to the public at a "fair price" from different manufacturers. Every citizen has a right to obtain essentialdrugs at fair prices and State has the power to fix prices and the obligation of theproducer is not to charge more than the price fixed.[187]

If any manufacturer wishes to revise the maximum sale price of a bulk drug, then he has to make an application to the government and after the due enquiry, the government may accept and fix a revised price or it may reject the application with reasons. It must be done within a period of four months and thereasons shall be recorded in writing[188].

The manufacturer shall furnish all the information in relation to the Scheduled bulk drug manufactured by him. The list of all scheduled drugs shall be produced with cost details to the government. The manufacturer shall furnish the details about non-

[186] Drug (Prices Control Order) 2013, Section 2(a): "Bulk Drug" means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeia or otherstandards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940) and which is usedas such or as an ingredient in any formulation.

[187] *Union of India & Anr., v. Cynamide India Ltd & Anrs.*, 1987 AIR 1802, 1987 SCC (2) 720.

[188] Drugs (Price Control) Order, 1995, Section 3(5): "Any manufacturer, who desires revision of the maximum sale price of a bulk drug fixed under sub-paragraph (1) or (4) or as permissible under sub-paragraph (3), as the case may be, shall make an application to the Government in Form 1, and the Government shall after making such enquiry, as it deems fit within a period of four months from the date of receipt of the complete information, fix a
revised price for such bulk drug or reject the application for revision for reasons to be recorded in writing".

scheduled drugs with cost details within thirty days of the commencement of the Order[189]. But if the Government, after due inquiry, finds if itis necessary to fix the revised price in the interest of the public, then such drug shall not be sold exceeding the fixed or revised price. The Government had the power to direct the manufacturer to sell formulations of any bulk drug to other manufacturers in order to achieve adequate production and regulate equitable distribution. While making such an order, the government shall consider factors such as the requirement for captive consumption of such manufacturer and the requirement of other manufacturers[190].

Section 7 of the Order empowers the government to Calculate the RetailPrice of a Formulation [191] in accordance with the following formula namely:

R.P. = (M.C. + C.C. + P.M. + P.C.) x (1 + MAPE/100) + ED[192].

Provided that in the case of an imported formulation, the landed cost shall form the basis for fixing its price along with such margin to cover selling and distribution expenses including interest and importer s profit which shall notexceed fifty percent of the landed cost.

Explanation - For the purpose of this proviso, landed cost means the cost of import of formulation inclusive of customs duty and clearing charges. [193]

---

[189] Drugs (Price Control) Order, 1995, section 5:"Every manufacturer, producing a non-Scheduled bulk drug shall furnish to the Government,-(a) a list of all such bulk drugs produced by him within thirty days of the commencement of this Order and indicate the details of the cost of each of such bulk drug in Form II.

[190] Drug (Prices Control) Order,2013.

[191] *Ibid.*

[192] Where R.P. means retail price;

M.C. - It means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss thereon specified as a norm from time to time by notification in the Official Gazette in this behalf ;

C.C. - Means conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf ;

P.M. - Means cost of the packing material used in the packing ofconcerned formulation, including process loss and shall be fixed as a norm everyyear by notification in the Official Gazette on this behalf;

P.C. - Means packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf ;

MAPE (Maximum A flowable Post-manufacturing Expenses)- Means all costs incurred by a manufacturer from the stage of ex-factory cost to retailingand include trade margin and margin for the manufacturer and it shall not exceedone hundred percent for indigenously manufactured Scheduled formulations ;

E.D. means excise duty :

[193] *Ibid.*

The retail prices[194] of Scheduled Formulations[195] were fixed by the government from time to time. The manufacturer has to make an application within thirty days of the fixation of the price of the bulk drug by the government to revisethe price of such formulation used by him in the bulk drug. Later, if theGovernment finds it necessary, then it fixes or revises the price of the formulation. Once the price has been fixed, it shall not be increased unless prior approval is taken from the government. There is a restriction for new formulation; unless it obtains the prior approval, no manufacturer/importer shall market a newpack. The imported formulation shall not be marketed without prior approval bythe government.

4.4.2 FIXING OF CEILING PRICE OF DRUG

The Price Ceiling is imposing price control or maximum price charged for a drug or a limit fixed by the government. The government does so for the purpose of protecting the consumers and providing the drugs at affordable prices.The government, under Paragraph 9 of the Order[196], has been empowered to fix the ceiling price for the Scheduled Formulations from time to time. While fixing suchceiling price, it shall consider the cost or efficacy or both fixed by the manufacturers of such formulations and the price fixed by it shall be the ceiling sale price for all, including generic name formulations.

The ceiling price may be revised by the government on its own motion orif any application is made by the person on behalf of the manufacturer. The ceiling price will be fixed for a particular pack size of any formulations[197]. If any manufacturer would like to sell similar formulations in different pack sizes, thennotified, shall fix the price according to the norms prescribed by the government.The person who fixes such price shall intimate such price to the government andafter expiration of sixty days of such intimation shall release it to sale[198]. The government may revise the price if it deems

---

[194] Drug (Prices Control) Order 1995,Section 2(s): retail price means the retail price of a drug arrived at or fixed in accordance with the provisions of this Order and includes a ceiling price.

[195] Drug (Prices Control) Order 1995,Section 2(v) : Scheduled formulation means a formulation containing any bulk drug specified in the First Schedule either individually or in combination with other drugs, including one or more than one drug or drugs notspecified in the First Schedule except single-ingredient formulation based on bulk drugs specified in the First Schedule and sold under the generic name.

[196] Drugs (Prices Control) Order, 1995

[197] *Ibid*

[198] Ibid

it necessary and such a manufacturershall not sell such formulations exceeding the price revised. The Scheduled Formulations mentioned under paragraph 9 includes "single-ingredient formulation based on bulk drugs specified in the First Schedule and sold under the generic name.

4.4.3 POWER TO FIX AND REVISE THE PRICE OF THE DRUG OR DRUG FORMULATIONS

The Government has got the power to revise the price of bulk formulations and drugs after getting hold of information from the manufacturer or importer. For one or more formulations, the government may fix or revise the retail price in such a way that "the pre-tax return on the sales turnover of such manufacturer or importer does not exceed the maximum pre-tax return specifiedin the Third Schedule." The government has the power to fix or revise retail prices in the interest of the public. The government has the power to include the non-scheduled formulations and also to include a bulk drug in the First Schedulewhile fixing the retail price of any formulations. The government will fix such aprice after getting information from the manufacturer or importer of such bulk drugs or formulations. If such a manufacturer or importer fails to submit it withinthe prescribed time, then the government can fix the price according to the available information. The government has the power to recover the dues accumulated under the "Drugs (Prices Control) Order, 1979". The dues collectedwill be deposited into the "Drugs Prices Equalization Account." The deposited money will be utilized for the purpose:

- To pay the manufacturer, importer or any distributor in case of the deficit between retention price and selling price in common or for the purpose of raising the production if the price has been pooled or to secureequitable distribution and to avail drugs at a fair price[199];
- To meet the expenses incurred by the government while discharging its function under Para 12[200];

[199] Drugs (Prices Control) Order, 1979, Section17(2)(a): "The amount credited under sub-paragraph (1) shall be spent only for paying to the manufacturer, importer or distributor, as the case may be, the shortfall between his retention price and the common selling price or, as the case may be, the pooled price for the purpose of increasing the production, or securing the equitable distribution and availability at fair prices, of drugs"

[200] Drugs (Prices Control) Order, 1979, Section17(2)(b): "The amount credited under sub-paragraph (1) shall be spent only for expenses incurred by the Government' in discharging the functions under this paragraph"

- To promote higher education and research in "Pharmaceutical Science and Technology" and any other purposes incidental thereto. If any manufacturer, importer or distributor has charged the price more than the price fixed, then the government has the power to recover the same by issuing notice to that effect. Once the government fixes the price, the manufacturer or importer must carry forward within fifteen days of such notification.

The manufacturer or importer must print legibly such price in the pack ofsuch drugs. The retail price of such drugs shall be mentioned with the words that'retail price not to exceed' and also "local tax extra." In the case of smaller saleable packs, it must display the price and it shall not exceed the allocated retailprice of the chief pack rounded off to the nearest paisa. It is the duty of the manufacturer or importer to issue the price list and supplementary price list to the dealers from time to time fixed or revised by the government[201].

The retailer and dealer shall display such a price list where it can be easilyaccessible for a person who desires to consult the same. It is also the duty of themanufacturer or importer or distributor to display the prices and price list of non-scheduled formulations. It is necessary to mention in the green strip that "Not under the Price Control" along with the retail price and taxes. Thus, no person shall sell the drug or bulk drug formulations to any customer at a rate higher thanthe price mentioned in the list or printed on the pack of such drugs. The drugs or formulations can be sold in split quantities and such price shall not exceed the actual price allotted to such formulation plus five percent thereof. If any consumer comes to a manufacturer or distributor or dealer with the intention to buy the drug, then he shall not refuse to sell the drug without sufficient reason. In view of controlling the sales of the drug, the government specifies to maintain records by the manufacturer and importer relating to sale and turnover.[202]

The provisions given under this Order shall not apply to the new drug (product or process) which has been patented under the Indian Patents Act, 1970and it has not been produced elsewhere. If such a new drug has been developed through indigenous Research and Development, then provisions under this Ordershall not apply for the

[201] The Drugs (Prices Control) Order, 1995

[202] Drug (Prices Control Order) 2013, Section 2(w) "sale turn-over" means the product of units of formulations sold by a manufacturer or an importer, as the case may be, in an accounting year multiplied retail price inclusiveof sales tax, if any, paid or direct sales by the manufacturer or importer but does not include excise duty and localtaxes if any

period of five years from the date of commencement of itscommercial production in the country.[203] If any new drug produced by themanufacturer involves a new delivery system developed through indigenous R&D, then provisions under this Order shall not apply for a period of five years as of the date of its market approval in India, provided documents relating to approval of new drug from Drug Controller General (India) must be produced before Government.[204]

4.4.4. DRUG POLICY, 1986

Indian Government, in order to meet the health needs of the people, has framed drug policies; and the existing drug policy was formulated in 1986 and several modifications have been made later. The policy provisions were implemented through the Industries (Development and Regulation) Act, 1951, with regard to the Industrial licensing aspects and through the Drugs (Prices Control) Order under the Essential Commodities Act for giving effect to the pricing mechanism. The Drug Policy has also provided the policy framework with regard to Quality Control and Rational Use of Drugs. The quality and standards in drugs have been enforced through the provisions contained in the Drugs and Cosmetics Act, which is administered by the Ministry of Health and Family Welfare.The chief objectives of the Drug Policy 1986 are as below:

- To ensure abundant availability of quality essential and life-saving drugsand prophylactic medicines at a reasonable cost;
- To strengthen the system of quality control over drug production and topromote the rational use of the drug in the country;
- In order to create an environment favorable to channelize newinvestment into the pharmaceutical industry and also to encourage cost-effective production with economic sizes. It also had an intention tointroduce new technologies

[203]Drug (Prices Control Order) 2013, Section 32 "Non–application of the provisions of this order in certain cases (i) The provisions of this order shall not apply to, - (i) a manufacturer producing a new drug patented under the Indian Patent Act, 1970 (39 of 1970) (product patent) and not produced elsewhere, if developed through indigenous Research and Development, for a period of five years from the date of commencement of its commercial production in the country"

[204] Drug (Prices Control Order) 2013, Section 32"Non–application of the provisions of this order in certain Cases (iii)a manufacturer producing a new drug involving a new delivery system developed through indigenous Research and Development for a period of five years from the date of its market approval in India"

and new drugs; and

- To strengthen the indigenous capability for the production of drugs.

The Government of India felt that there is a need for modifications to existing policy and made some modifications with regard to licensing for bulk formulations, price control by fixation of drug prices and decided to keep the drugunder price control, which has the annual turnover of Rs. 400 lakhs or more. However, the monopoly situation in cases of drugs with comparatively lower turnover has also been decided to keep in view, if any, bulk drug, having a turnover of Rs. 100 lakhs or more and there is a single formulator having 90% ormore market share in the Retail Trade (as per ORG), a monopoly situation would be considered as existing[205]. Drugs in which there is sufficient market competition, viz., at least 5 bulk drug producers and at least 10 formulators and none having more than 40% share in the market in the Retail Trade (as per ORG) may be kepton the movement of prices as it is expected that their prices would be kept in check by the forces of market competition.[206]

If the prices of drugs are raised unreasonably then, the government, which will be watching closely on prices of drugs, will take appropriate measures, including reclamping of price control. A uniform Maximum Allowable Post- Manufacturing Expenses (MAPE) of 100% will be allowed in all cases of drugs under price control. In order to achieve uniformity in prices of largely used formulations, the ceiling of prices for commonly marketed standard pack sizes of price-controlled formulations and it would be obligatory for all, including small scale units, to follow the prices so fixed. To encourage R&D in pharmaceuticals, apart from existing incentives, including tax incentives, an Inter-Ministerial Committee will be set-up under the Chairmanship of the Secretary, Department of Chemicals and Petrochemicals to provide further incentives. To do the work of price fixation, the Government would set up an independent body called the National Pharmaceutical Pricing Authority, which consists of experts. It would receive applications and make decisions on price approvals within a given set of the time limit, i.e., two months for formulations and four months for bulk drugs.It would also supervise the enforcement of the provisions of DPCO. To ensure

[205] Span of Control - National Pharmaceutical Pricing Authority. https://www.nppaindia .nic.in/en/ drug-policies /modification-in-drug-policy-1986/span-of-control/(last visited on 14th July 2022)
[206] Availability and Price Management of Drugs And Pharmaceuticals. http://164.100.24.208/ls/ CommitteeR/chemicals/7rep.pdf(last visited on 14th July 2022)

the quality of drugs, the Government would set up a National Drug Authority (NDA) through a separate Act of the Parliament and it would also responsible formonitoring standard practices in drug promotion and use. It must also clearly identify those which are acceptable and prohibit, which are unethical and againstthe consumers interest. It would also prepare and publish a National Formularyand also formularies which are relevant to various levels like district hospitals, community centre, primary health centre for the guidance of consumers as well as doctors. To strengthen the drug control system, including Good ManufacturingPractices (GMP) and to encourage R&D, access of 1% would be levied on the production of drugs and pharmaceuticals through legislation.

4.4.5 PHARMACEUTICAL POLICY, 2002

The Drug Policy 1986 has enumerated basic objectives relating to the drug and pharmaceutical sector and still remains largely valid. Due to globalization and liberalization of the economy, the Indian drug and pharmaceutical industry has been facing many challenges and also new obligations were undertaken by WTO Agreements which demanded changes in the current policy and there was a need for new initiatives beyond those enumerated in the Drug policy, as modified in 1994.[207] Thus, the policy inputs have directed it more towards promoting accelerated growth of the pharmaceutical industry and to make it more internationally competitive.[208] The pharmaceutical industry is recognized as one of the knowledge-based industry and to bring changes in that, the Prime Minister's Advisory Council on Trade andIndustry has made important recommendations.

The process of liberalization has been set for force in 1991, whichconsiderably abridged the scope of industrial licensing and devastated many non-tariff barriers to import. Many steps which have taken with this regard viz., the abolition of industrial licensing for all drugs and pharmaceuticals except for bulk drugs produced by the use of recombinant DNA technology, nucleic acids and specific cell/tissue targeted formulations, abolition reservation of 5 drugs for manufacture by public sector only and give way to private

[207] As published by the Govt. of India, Ministry of Chemicals & Fertilizers, Dept of Chemicals and Petrochemicals,vide pamphlet dt. September 1994.
[208] Pharmaceutical Pricing Policy, 2002.

sector also[209]. The foreign investment through automatic route was raised by 100%, automatic approval, encompassing the facility of weighted deductions of 150% of the spending on in-house research and development to cover as eligible expenditureon the filing of patents, obtaining regulatory approvals and clinical trials besides R&D in biotechnology. One more important step is the introduction of the Patent (Second) Amendment Bill providing 20 years of the term of the patent.

India has been recognized as a low-cost producer and supplier of qualitybulk drugs to the world. India, during 1999-2000 has exported drugs and pharmaceuticals worth Rs. 6631 crores out of the total production of Rs. 19,737 crores. But there found a need to bring Pharmaceutical policy 2002 on the basis of two issues. Firstly, to improve incentives to R&D in order to achieve sustainable growth and secondly, to bring down the rigours of price control[210].The main objectives which were enshrined under Pharmaceutical Policy 2002 are[211]:

- To ensure abundant availability of good quality pharmaceutical drugs for mass consumption at a reasonable cost within the country.
- To strengthen the indigenous capability of cost-effective quality production and pharmaceutical exports by reducing trade barriers in the pharmaceutical sector.
- To strengthen the system of quality control and to make quality an essential attribute in the Indian Pharmaceutical Industry and also to promote therational use of pharmaceuticals.
- To encourage R&D and also to make the pharmaceutical sector compatible with the country's needs. It shall make a special focus on diseases or epidemics or relevant to India and also create an environment that is favourable to make a high level of investment into R&D.

To create an incentive agenda for the pharmaceutical industry that promotes new investment and also encourage the introduction of novel technologies aswell as novel drugs.

---

[209]Indian Drug Policy - Economy Watch. https://www.economywatch.com/indian-drug-policy(last visited on 14th July 2022)

[210] Pharmaceutical Policy 2002, Department of Pharmaceuticals,https:// pharmaceuticals .gov.in/policy/pharmaceutical-policy-2002(last visited on 10h July 2022)

[211]*Ibid*

A committee was set up in 1999 in order to strengthen the pharmaceuticalR&D and to develop capabilities and also to identify the aid required to undertake R&D by the Indian pharmaceutical companies. The Committee was established by the name of the Pharmaceutical Research and Development Committee(PRDC) under the chairmanship of the Director-General of CSIR. The PRDC hassuggested a few conditions in order to qualify as an R&D intensive company in India. They are as follows (Gold Standards):

- Invest at least 5% of its turnover per annum in R&D,
- Invest at least Rs.10 Crore per annum in innovative researchincluding new drug development, new delivery systems etc. in India,
- Employ at least 100 research scientists in R&D in India,
- Has been granted at least 10 patents for research done in India,
- Own and operate manufacturing facilities in India[212].

The recommendations of PRDC are taken while formulating the proposals on pricing aspects. From time-to-time ceiling of prices can be fixed forany formulations and it would be obligatory to all, including small-scale units and those who are marketing under generic names. Any drug which has obtainedpatent protection under the Indian Patent Act 1970 shall eligible for exemption from price control for the period of 15 years from the date of commencement ofits commercial production. If it is with regard to the patented process or new delivery system, then the exemption will extend up to the expiry of the patent term. It has also been suggested that if any drug which has low cost, i.e., measuredin terms of cost per day per medicine can be taken out from the price control. Ifany formulator provides such proof to NPPA that such medicine cost not exceeding Rs.2 per day to a consumer-patient, then with the intimation to the government, such drugs can be taken out of price control. The government will have an overriding power to fix the maximum retail price of any bulk drug in theinterest of the public. The validity of Drug Policy 2002 was challenged as policy announced increasing the turnover limit of the producer of a bulk drug for price control fromRs. 4 crores to Rs. 25 crores. This was challenged before Karnataka High Court and it has stayed. This matter was taken to Supreme Court by the Union of India.It was directed that the Drug Policy 2002 shall be suspended. The court directedthe Union of India to

[212] Pharmaceutical Policy 2002 | Department of Pharmaceuticals., https:// pharmaceuticals. gov.in/policy/pharmaceutical-policy-2002(last visited on 14th July 2022)

consider and formulate appropriate criteria for ensuring essential and life-saving drugs not to fall out of the price control. The main object of the state to protect and preserve the health of the public and NLEM contains all such medicines which satisfy the priority health needs of the public.It must be made accessible to the public at all times in adequate quantities in theproper dosage formulae to serve the public. Afterwards, the Union of India, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals published a fresh policy called the National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012) vide notification dated 07.12.2012 in continuation of the 1994 Policy.[213]

The recommendations by DPCRC to have operative monitoring and enforcement scheme and to change from the controlled regime to a monitoringregime is, in the current context an extremely important as imports will increasingly contend with local drugs and pharmaceuticals in the domesticmarket. A new system based on solely market price data is required to be evolvedand controls are applied selectively only to cases where either profiteering or monopoly profit-seeking is noticed.[214] The NPPA, set up in August 1997, would need to be revamped and reoriented for this purpose. It will be continuing to entrusted with the task of price fixation/price revision and other related matters and empowered to make final decisions. It would also monitor the price of decontrolled drugs and formulations and oversee the execution of the drug pricecontrol orders. The Government would have the power to review the price fixation/and price revision orders/notifications of NPPA.[215]

4.4.6 NATIONAL PHARMACEUTICAL PRICING POLICY 2012

The objective of the NPPP 2012 was to make available the quality essential medicines to the masses at a reasonable price. The key principles of thispolicy are as follows:

- Essentiality of Drugs
- Control of Formulations of Prices only
- Market-Based Pricing

[213] Para 24 & 36.4, *Rockitt Benchiser (India) Ltd. v. Union of India and Another, High Court of Delhi*, CMNo.10105/2014 in W.P.(C)No.7705/2013.
[214] Supra 207
[215] *Ibid*

The price of drugs under NPPP 2012 was regulated on the basis of the essentiality of drugs. The drug must be on the list of National List of Essential Medicines to be considered for "Essentiality." The NLEM has been prepared by the Expert Core Committee, constituted by the Director-General of Health Services (DGHS). It also consists of medicines that satisfy the priority health needs of the people of the country. These listed medicines are required to be madeavailable all time at all functioning health systems with adequate quantity and dosage. In the case the *Union of India v. K.S. Gopinath and Others*[216], the SupremeCourt held that there must be the same criteria to be formulated to bring life- saving drugs under price control and no life-saving drugs shall go beyond the price control.

The NPPP 2012[217] would regulate only the prices of formulations and whichis different from that of the Drug Policy 1994, which was regulating the prices offormulations of the bulk drug. The regulation of prices will be on the basis of regulations of prices of formulations through "Market Based Pricing" (MBP). This is different from that of earlier, which was based on the principle of "Cost Based Pricing." The methodology used to fix the ceiling of the price of the drugwhich is listed under NLEM is by adopting the "Simple Average Price" of all brands which has a market share (on the basis of moving turn over) more than and equal to 1% of the total market turnover of the medicine is as calculated below[218]: (Sum of Prices of all the brands of medicine having market share more than andequal to 1% of the total market turnover of that medicine)/ (Total Number of manufacturers producing such brands of the medicine).

The formulations will be estimated only by fixing a Ceiling Price (CP), but the producers are allowed to fix any price for their products equal to or belowCP. It is based on the dosage basis viz., per tablet/ per capsule/standard injectionvolume as listed in NELM-2011. The CP will be fixed on the basis of readily monitoring market-Based Data[219] (MBD). Every year the pharmaceutical company is authorized to revise the

[216] Reportable Case, 5th September, 2013, *available at*: https://indiankanoon.org/doc/51249220/ (last visited on 26th April ,2022).
[217] National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012)
[218] National Pharmaceutical Pricing Policy, 2012.
[219] Data available with the pharmaceuticals market data specializing company- IMS Health (IMS). It gives price figures of stock list level prices hence in order to arrive ceiling price (which will be maximum retail price), the IMS price will be further increased by 16% as margin to the retailer so as to arrive at a reasonable ceiling price chargeable from the consumers

prices and it may increase or decrease according to the Wholesale Price Index for the previous year. If there is any reduction in the Wholesale Price Index, then it will be obligatory on the part of the company to make a reduction in the ceiling price. The Simple Average Price(SMP) of all the brands of the medicines having a market share[220] more than and equal to 1% of the total market turnover of that medicine. The Reference prices for calculations of SMP may also change on the basis of changes in MAT value. But there will be no revision in the ceiling of price on the basis of MAT value. Itwill be changed only for a period of five years or when NELM is updated or revised. Yet, the Government in between five years may revise the ceiling price of drugs under NELM if there are any notable variations in the market structure of any drug[221].

The cost of non-scheduled drugs does not come under price control and their prices are fixed according to market forces. If the price of such drug increaseby 10% in a year, then the government will fix prices for such medicines from time to time. The ceiling price of drugs that are imported shall be determined byadopting the Simple Average Price as discussed above and there will be no separate determination as to such. Any drug can be added in NLEM in the interestof the public and can bring those drugs under price control on therecommendations of the Ministry of Health and Family Welfare. The production levels, availability and accessibility to the NLEM drugs and formulations shouldnot fall after price control is introduced and the Department of Pharmaceuticals will ensure that production levels are maintained by an appropriate mechanism.[222] If any manufacturer who is into the manufacture of NLEM drug (dosages and strengths specified as per NLEM) launches a new drug with the combination of NLEM drug with another NLEM drug or Non-NLEM drug or changing the strength and dosages of NLEM drug, must seek permission from Government before such launch of the drug. There was a proposal to the Ministry of Health and Family Welfare to consider making mandatory prescription of drugs by its generic names. The distribution of generic drugs which is quality and affordableto the public through Janaushadhi Stores will be strengthened.

Price control, the ceiling of price, patents etc., all are very technical terms to be understood by a common man. He only knows that the drugs which are in need should

[220] On the Basis of Moving Annual Turnover (MAT).
[221] National Pharmaceutical Pricing Policy, 2012
[222] *Ibid*

be easily accessible, available and affordable to him. The Government of India indeed has taken several measures and thus found to implement the policy on account of public interest. The strategy of the policy is to provide quality affordable drugs to the public as well as to support the innovation of drugs. The strategy insisted on incorporating programs of affordable health care to the majority of the population through "Direct Government Programs or Insurance-Linked Programs and an overarching Pharma Control Policy etc."[223] There are several issues that are to be looked into and make suitable provisions in order to make health care affordable. Theprovisions relating to direct health care to its citizens would do it by expanding healthcare cover through the State Health care System jointly with an insurance cover-based health care system. Then thought about how to improve access to drugs for specialized treatment viz., anti-cancer, anti-HIV etc. and thus found thatit can be achieved through a special assistance scheme where it subsidizes the prices of such drugs, particularly for BPL and APL families. There was a need to streamline the system of procurement of drugs by the Government to ensure the procurement of quality affordable drugs. It would apply to both Central and State PSUs. There required a strong and transparent drug purchase policy for bulk procurement of drugs by the government. It also helps the government in determining reasonable Ceiling Prices for NLEM drugsin the future. The plan was also there to promote non-branded generic drugs andlow-cost drugs by creating low-cost pharmacies through Janaushadhi Scheme and to make accessible a low-cost essential drug to reach every village and town.The program will not see success if the doctors do not prescribe such non-brandedgeneric drugs. Thus, there was a need to give education for both public and medical fraternity and to make obligatory on the part of the doctors to prescribe it along with branded drugs. The CPSUs mandated for producing essential drugsas determined by the Government from time to time as required. The special schemes are thought to implement in order to provide accessibility of drugs to low-income families, especially BPL families and setting up drug banks and also strengthening the pharmaceutical industry. All the issues discussed above are required a detailed consultation and cooperation of all other departments of the government. The department of pharmaceuticals will take due steps to initiate a holistic policy on the Pharma sector in due course.[71] Soon after this New Drugs (Policy Control) Order 2013 was passed and the NPPA would be the implementation authority provided

[223] Supra n. 221

organizational and financial support in orderto implement the new policy in a speedy, effective and transparent manner.

The Draft Pharmaceutical Policy 2017 was drafted in order to contributeto the easing of doing business in the pharma sector and also to support the makein India program. The Pharmaceutical Policy 2017 was drafted with a few key objectives, such as:

- To make essential drugs accessible at affordable prices to the public;
- To make India sufficiently self-reliant in the end-to-end manufacture of indigenous drugs;
- To ensure the quality of drugs for domestic consumption and exports;
- To create an environment for R&D to produce innovative drugs.

As it already envisaged that the laws and policies were framed in such a way to make the life-saving drug easily accessible, available and affordable by the needy people. Before discussing government initiatives, the researcher herein makes a note of highlights of National Intellectual Property Rights Policy, 2016.

4.4.7 NATIONAL INTELLECTUAL PROPERTY RIGHTS POLICY, 2016

This policy has been formulated with the slogan "Creative India; Innovative India." Creativity and innovation are very much required for the growth and development of any knowledge economy. Creativity and Innovations are stimulated by Intellectual Property and it is for the benefit of all. The intentionof the policy is to foster innovation and creativity and, in that way, promote entrepreneurship and also to enhance socio-economic and cultural development.The policy also aimed at enhancing access to health care. It lays down seven objectives.[224] They are:

IPR Awareness: Outreach and Promotion- It is for the creation of awareness among the public about the economic, social and cultural benefits of the IPRs.

- Generation of IPRs- In order to stimulate the Generation of IPRs.
- Legal and Legislative Framework- to have a strong and effective IPR law, which balance the interests of rights owners with the larger public interest.

[224] National Intellectual Property Rights Policy, 2016.

- Administration and Management- To modernize and strengthen service-oriented IPR administration.
- Commercialization of IPR- Get value for IPRs through commercialization.
- Enforcement and Adjudication- To strengthen and expand human resources, institutions and capacities for teaching, research and skill-building in IPRs.
- Human Capital Development- To strengthen and expand human resources, institutions and capacities for teaching, training, research and skill-building in IPRs.

India has strong Intellectual Property Laws and also Intellectual propertyJurisprudence. The policy orientation and national priorities which have emergedduring the time will be reflected in the legal framework. The needs for development and international commitments will be kept in mind while framingthe law. The IPR Policy has drawn a roadmap for IP protection in India as well as protect and promote the public interest. The policy had made it clear that stepsmust be taken with regard to encouraging researchers in public-funded academicand R&D institutions and also to link it with research funding and career progression. It also wanted to take steps towards formulating uniform guidelinesin the distribution of royalties between organizations and the individual researchers and innovators who are in public-funded academic and R&D organizations. The policy is aimed at encouraging R&D institutes which are run by the public fund and to insist them to support the development of affordable drugs for neglected diseases. To encourage R&D, which also includes source- based research like Open-Source Drug Discovery (OSDD) by the Council of Scientific and Industrial Research (CSIR) for new inventions for prevention, diagnosis and treatment of diseases, particularly those that are life-threatening and those that have a high incidence in India.[225]

This policy has also focused on the accessibility of affordable medicines and also streamlining the regulations on the process of timely approval of drugs.The policy made efforts to reduce depending on API imports (Active Pharmaceutical Ingredients); it also supports incentivise manufacture in India. Itwas also taken a step to revitalizing public sector undertakings in the health caresector. There is a big problem with generic drugs

[225] *Ibid*, Objective 2.10.

to cherish is considering them as spurious and counterfeit drugs; thus, the policy had an objective to bring strong measures against such acts. The policy also endorsed to undertake stringent measures to restrict the manufacture and sale of misbranded, adulterated and spurious drugs.

The following are few initiatives taken by the Government of India to make sure that each and every individual can afford, access and avail of the life-saving drugs in time and also to eliminate discrimination.

4.5 GOVERNMENT INITIATIVES

4.5.1 National Health Mission

The National Health Mission was launched by the Indian Government in2013 in order to address the health needs of under-served rural areas. It was extended in 2018 to continue till March 2020. The National Health Mission (NHM) encompasses its two Sub-Missions[226], i.e., the National Rural Health Mission (NRHM) and the newly launched National Urban Health Mission (NUHM). The chief programmatic components include Health System Strengthening in rural and urban areas-Reproductive-Maternal- Neonatal-Child and Adolescent Health (RMNCH+A) and Communicable and Non- Communicable Diseases. The NHM envisages the achievement of universal access to equitable, affordable & quality health care services that are accountableand responsive to people's needs.[227] One of the major initiatives under this Missionis to provide free drug and diagnostic services with an intention to reduce the outof pocket expenditure on health. The initiatives were taken to strengthen the District Hospitals to provide multispecialty health care, which shall include dialysis care, intensive cardiac care, cancer treatment, mental illness, emergencymedical and trauma care etc.[228] In 2017, it launched a new project in order to eradicate TB in the Tribal population.

[226] National Health Mission (NHM) - PharmacyInfoline. https://pharmacyinfoline.com/national-health-mission-nhm/(last visited on 14th July 2022)

[227] National Health Mission, available at: https://nhm.gov.in/, (Visited on May 7, 2022).

[228] Ibid.

4.5.2 AMRIT Pharmacies

The word "AMRIT" stands for "Affordable Medicines and Reliable Implants for Treatment."[229] The key objective is to reduce out-of-pocket expenditure, specifically through pharmacies. This novel initiative has been set- up by the Ministry of Health and Family Welfare (MoHFW), Government of India, to access and avail all drugs, implants, surgical disposables at an affordable cost through a network of AMRIT Pharmacies across the country. It offers more than 5200 drugs, implants, surgical, disposables and other consumables at an average discount up to 60% of Maximum Retail Price (MRP). Nearly 156 AMRIT Pharmacies are established across India and Karnataka has only one outlet in Bangalore, which is established at the premises of Nimhans Hospital. Especially north Indian states like Assam has 24 outlets, Gujrat 57 outlets and thestands highest in India and Uttar Pradesh has more than 10 outlets of AMRIT Pharmacy. As of February 2019, the total maximum Retail price Value of these pharmacies was 1133.79 crore rupees and the total savings to the patients were 598.75 crore rupees and it has served 118.52 lakhs patients in total.[230] These pharmacies are much beneficial to the public to access the genericas well as life-saving branded drugs under one roof and it reduced the prescriptionbouncing. The patients are benefitted as they do not need to go for a private chemist who charges on MRP and in AMRIT pharmacies, it is economical and patients can save nearly 60% of their expenditure. If any free dispensing pharmacies run short supply of essential drugs, then they do purchase from the local approved vendors who charge a higher cost. If there are AMRIT pharmacies, these free dispensing pharmacies can buy from them at lower rates. This initiative reflects the strong commitment of the Indian Government to reducethe cost of treatment and drugs, which shall benefit the lakhs of patients. To reachthe maximum number of people in India, it shall establish at least in every taluk and make it easily accessible to every people, including those who live in rural parts of the country.

[229]HLL Life Care Limited, A Government of India Enterprise, *available at:* http://www.lifecarehll.com/page/render/reference/Amrit_Retail_Pharmacy_Stores_, (Last Visited on April 26th 2022).
[230] *ibid*

4.5.3 Pradhan Mantri Bhartiya Janaushadhi Pariyojana

This scheme has been launched in order to make accessible quality,affordable generic drugs by the people who are needy and poor through the Janaushadhi outlets. These outlets sell generic drugs and it saves 50-90% to the patients of their pocket expenditure. (The PMBJP initiatives and analysis has been done in Chapter V)

4.5.4 Ayushman Bharath

'Ayushman Bharat Pradhan Mantri Jan Arogya Yojana' (AB PM-JAY) isa flagship scheme of the National Health Policy of Government of India which proposes to offer free health coverage at the secondary and tertiary level to its bottom 40% poor and vulnerable population. This scheme was launched in September 2018 by the Ministry of Health and Family Welfare and to administerthe organization and it later established the authority called the National Health Authority. This scheme provides service for 50 crore people and is considered the world's largest government-sponsored health care program. The people withlow income are largely benefitted from this program. It adopts a different approach comprising of inter-related components. They are as follows:

a. Establishment of Health and Wellness Centres[231]

This was pertaining to establish 1,50,000 Health and Wellness Centres, which intends to bring healthcare closer to the houses of the people. They intend to provide Comprehensive Primary Health Care (CPHC), which shall cover maternal and child health services. It shall also cover non-communicable diseasesand the issue of free essential drugs and diagnostic services.

b. Pradhan Mantri Jan Arogya Yojana (PM-JAY)[232]

This is one of the major steps towards the achievement of providing Universal Health Coverage (UHC) and Sustainable Development Goal-3 (SDG3). It intends to provide

[231] National Health Authority, Ayushman Bharat Pradhan Mantri Jan Arogya Yojana.
[232] *Ibid*

Health Care Protection to poor and vulnerable families who are countering the financial risks which have arisen out of Catastrophic Health Episodes.

PM-JAY scheme intended to provide financial protection for the familieswho are poor, deprived and who come under the identified occupational categories as per the latest SECC (Socio-Economic Caste Census). The family can avail of benefits cover of Rs. 5,00,000/- per year on a floater basis. It shall cover all medical and hospitalization expenses and has defined 1,350 medical packages, which shall cover surgery, medical and day care treatments as well asmedicines, diagnostics and transport. The scheme shall include all the members of the family and there is no cap on family size and age. The scheme provided cashless and paperless at both public and empanelled private hospitals. It includesboth pre- and post-hospitalization expenses.Though this scheme provides excellent health care but facing challenges of relatively fewer doctors, more cases of infectious disease and less investmentin health care by the central government. Many government hospitals have joinedthis program, but a number of private hospitals yet to join to provide services under the scheme. The private hospital had given the report that it is not able to provide special services under the scheme to the government at a low price evenwith a government subsidy. The scheme also faced the challenges of fraudulent bills and the Authority had revoked the 171 hospitals empanelment and imposeda 4.6 crore rupees penalty. There are other 390 hospitals for which show-cause notice has been issued by the National Health Authority.

4.6 CONCLUSION

Every individual has Human Right to Health and it is the obligation on the part of the State to protect and provide good health to its citizens by providingeasy access to health care and also to access essential drugs that are in need. Access to essential medicines is a major determinant of health outcomes[233]. Though WHO, UDHR and other international instruments provide that it is an obligation on the part of the state to protect health and shall take steps with regardto it, there is no uniform international law governing with this regard. Indian Constitution has provided its citizens the Right to Health under the Right to Lifeand Liberty under Article 21. The Right to Health has been protected under Article 21 of the Constitution, but there is no separate provision

[233] Rituparna Maiti, Vikas Bhatia,Biswa Mohan Padhy, and Debasish Hota, *Essential Medicines: An Indian Perspective*,40(4), Indian J Community Med, 223,225(2015)

that enshrines the Right to health under the Constitution. But through various judicial decisions,it has been confirmed that the right to health is a fundamental right under the Indian Constitution. Thus, the Right to health being a fundamental right; it includes the right to access essential drugs as a right under it.

The word essential drug has not been defined under the Indian pharmacology, Drugs and Cosmetics Act, Drugs Control Act etc., but only the list of essential drugs is provided. There are no criteria to consider any drug as essential or not. Bulk drugs are not considered as essential but only ready to use drugs are considered as essential, but this has not been mentioned under the Act or Order. The quality of essential drugs are governed under the Drugs and Cosmetics Act, the prices are controlled under Drug Prices and Control Order and other policies adopted for the purpose of control of price but no criterion or strategy has been made to fix the prices of patented drugs to bring under price control. The DPCO controls the prices of all essential medicines by fixing ceiling prices, limiting the highest prices companies can charge. The National List of Essential Medicines (NLEM) is drawn up to include essential medicines that satisfy the priority health needs of the population. The list is made with considerations of safety, efficacy, disease prevalence and the comparative cost-effectiveness of medicines, and is updated periodically by an expert panel set up for this purpose under the aegis of the Ministry of Health and Family Welfare. This list forms the basis of price controls under the DPCO.

The Government of India has enforced several laws in order to provide its citizens with quality as well as affordable drugs. It has made efforts to bring drugs under the price cap but still not able to make a common price tag for a similar kind of drugs. Pharmaceutical companies should be brought on board to partner with the government to achieve the vision of health care access for all. [234]The policies and initiatives by the Government of India areappreciable and always aimed at providing poor and needy people quality affordable health care and access to quality affordable drugs. But still, the lacunasin the enforcement of policies and schemes made it difficult to access essential drugs on time and people are suffering due to the non-availability of quality affordable drugs.

[234]Akram Ahmad,Muhammad Umair Khan, and Isha Patel,*Drug pricing policies in one of the largest drug manufacturing nations in the world: Are affordability and access a cause for concern?,* 4(1) J Res Pharm Pract 1,2 (2015)

CHAPTER 5

CONCLUSION AND SUGGESTIONS

5.1 INTRODUCTION

Health is the greatest blessings of the human being. It is a state of complete harmony of the body, mind and spirit. The concept of health is not a new origin and it is rooted in antiquity. In ancient times more importance was given to the health and development of the individual. Before the existence of modern medicine (Allopathic Medicine), the people used to depend on traditional medicines which used to get in very nature such as Ayurveda, Unani, Siddha etc. Now, allopathic medicine is considered as priority medicine and emergency medicine over those traditional medicines. There are many primary health care hospitals, multi-specialty, super-specialty hospitals established by the state government, central government, private individual/sectors, public sectors etc., that have been providing service to the people. Thus, the motive is to provide, protect and ensure the public health and to make way for the development of society and the nation. The people spend more out of their pocket on the treatment of diseases and for medicines. The costs of some drugs are so high that it became difficult for low or middle-income people to afford drugs. Sometimes spending on health is more and leads them to take loans to buy medicines. The raises in the price of such medicines are due to a patent monopoly as well as the commercialization of patented drugs. The patent protection and commercialization of drugs are very much necessary to make a future investment in innovation and research.

If any individual if is unable to access and afford the drugs which are in need, then he may lose his life or may have physical or mental impairment. Every individual has every right to live peacefully in a society with dignity. Thus, if he does not have good health, then he may not lead a happy or dignified life in society. He may not able to work, progress and he may always be dependent on others for his existence.

The individual has the right to live a dignified life than a mere animal existence. Without good health, he may not think of good or dignified life. Thus, good health is the very foundation of a right to life and he has every right to access food, clothing,

shelter as well as health care. The person, if he is suffering from any disease, may be physical or mental, has every right to access the healthcare and drugs which are in need. Most of the time, he is unable to access the drugs which are in need because of non-availability, non-accessibility or non-affordability. Thus, he will be deprived of the basic rights of health and life, which is a very basic right of the individual. The State has an obligation to make avail and afford drugs for the individual in order to safeguard the health. The right to access to health has been considered a basic human right and the Indian Judiciary, in many cases, upholds the right to health as a fundamental right. In Paramananda Katara v. Union of India and Vincent v. Union of India, the has been clearly saying, Right to Life also includes the Right to Health. Human rights are basic rights that have been originated by the natural law doctrine. The right to access health is considered a basic human right. The right to access essential drugs is an inherent right of every individual and if such a right is hampered by any reason, then it will be a violation of the Right to Life of an individual. Most of the people in India and other developing countries are unable to access essential drugs because of their high cost. Every state has an obligation to protect the rights of its citizen and its obligation on the part of the state to provide good health for its citizens. The state must facilitate its citizens to access life-saving drugs at an affordable price or free of cost.

5.2 CONCLUSION

Through various case laws, the Apex court of India says that the right to health is an important aspect of fundamental right under Article 21 of the constitution of India. Though India is one of the countries having low drug process in the world, many people are still not in a position to access the essential drugs. The regulation of Drug Pricing in India is not efficient in ensuring access to essential drugs, a more structured and comprehensive legislation is required to tackle the problem.

By illustrating the concept and value of the right to health, as well as the importance of access to essential drugs, The right to health and medical care being a necessary concomitant of the right to live conferring to Article 21 of the Constitution of Indian, and the role of the judiciary in effectuating and safeguarding this precious right of the people the researcher proved the first part of hypothesis. existing legislations related to

drugs and access to drugs. It is very much necessary to regulate the quality of drugs and the price. Hence the Indian government has Then the research deals with enacted laws and policies regulating the manufacture, import, export, distribution, sale and price of the drugs. The relevant provisions of law and policies relating to the drugs. The essential list of drugs and drug pricing policy. In order to control the prices of drugs, India has implemented many laws, orders and policies like Drug Prices (Control) Order 1995, Drug Policy 1986, Pharmaceutical Policy 2002, National Pharmaceutical Pricing Policy 2012 etc. The Drug Policy 1986 was enacted in order to ensure an ample supply of quality, affordable life-saving drugs, to strengthen the quality control of the drug, encourage cost-effective production etc be responsible for monitoring standard practices in drug promotion and use. The Pharmaceutical Policy 2002 was adopted to ensure availability of quality drugs with reasonable price, cost-effective quality production, the export of drugs by reducing the trade barriers, strengthen the system of quality control, to encourage R&D and also to create incentive agenda to promote novel technologies and new drugs. The National Pharmaceutical Pricing Policy 2012 regulated the price of essential drugs, prices of formulations different than that of drugs covered under Drug Policy 1994. National Intellectual Property Rights Policy, 2016 has been formulated to foster innovation and creativity and also aimed at enhancing access to health care. The National Health Policy, 2017 made to provide drugs at an affordable price and also to protect the health of the public. So by the research, researcher proved the hypothesis that is, though India is one of the countries having low drug process in the world, many people are still not in a position to access the essential drugs. The regulation of Drug Pricing in India is not efficient in ensuring access to essential drugs, a more structured and comprehensive legislation is required to tackle the problem.

From the above-mentioned chapters, following conclusions can be drawn:

1. There are no efficient laws to monitor the price of essential drugs[235] .

The word essential drug has not been defined under the Indian pharmacology, Drugs and Cosmetics Act, Drugs Control Act etc., but only the list of essential drugs is

[235] See Chapter 3 of the Dissertation

provided. There are no criteria to consider any drug as essential or not. Bulk drugs are not considered as essential but only ready to use drugs are considered as essential, but this has not been mentioned under the Act or Order. The quality of essential drugs are governed under the Drugs and Cosmetics Act, the prices are controlled under Drug Prices and Control Order and other policies adopted for the purpose of control of price but no criterion or strategy has been made to fix the prices of patented essential drugs to bring under price control.

2. The non-affordability and non-accessibility of essential drugs are vitiating the Right to Health of an individual[236] .

Every individual has a right to access essential drugs and other drugs to protect and preserve good health. The Right to Health is a fundamental right that is enshrined under Article 21 (Right to Life) of the Indian Constitution and the state has an obligation to protect and preserve the health of the individual. There are many attempts made by the Indian Government to provide quality affordable drugs to the public and also plans and policies have been made to provide free drugs in primary, secondary and tertiary health care in order to protect the public health. The patented drugs pose high cost and there are few essential drugs that are unaffordable and made inaccessible by the needy and poor. There are generic essential affordable drugs available under different schemes of the government, but because of lack of knowledge and insufficient supply made inaccessible wherever it is in need. When an individual not able to access, afford or avail of the essential drugs on time, he may lose his life or may have a physical or mental impairment or lessen his life-expectancy and thus, the right to health has been curtailed.

3. The patients and the general public have lack of knowledge about essential generic drugs available in the market and at government established Janaushadhi Stores [237].

There is a necessity to create awareness among the public and patients relating to generic essential drugs as many of the people are not aware of generic drugs available at the market and under the Janaushadhi Scheme. The pharmaceutical sector is depreciatively significant to public health, societal equity, economic progress and

[236] See Chapter 2 of the Dissertation
[237] See Chapter 4 of the Dissertation

necessary for the security of the nation. Moreover, bringing new drugs to the market and giving them to the patients has been established to be a difficult, complex and expensive process. It has been observed that cost concerns are not solely limited to branded drugs. In many circumstances, the prices of generic drugs that are available for years are increasing substantially without any added health benefits for patients. This is a concern across the nation, but predominantly for customers on fixed incomes. Preferably, an active pharmaceutical system is essential to focus on prevention as well as on treatments and cures. It also required to motivate vigorous R&D on drugs that empower chief enhancements to human health. It quickly adapts to new scientific discoveries and adopts technologies, systems and practices. This is essential for the improvement of health care and to provide effective, affordable drugs to all patients, including the poor and disadvantaged.

4. The unintended consequences of drug price control policies led pharmaceutical companies to go out of the manufacturing of drugs because of the decrease profit margin[238] .

This has given way to substandard and spurious drugs to flood into the pharma market. As per the report by the United States Trade Representative that because of the lack of stringent quality regulations, there has been a trade-off between price and quality. It claims that nearly 20% of drugs produced in India are fake. It has been argued that the decrease in the profit margin has reduced investment in R&D. The quality manufacturers are deterred from investing in future pharma R&D. The quality manufacturers have been turned their face towards the manufacture of non-essential drugs or they stopped promoting essential drugs.

5. Accessibility, availability and affordability of life-saving drugs still remain a challenge in India [239].

Though India is considered as a medicinal hub and generic production house and drug price ceiling policy has been established for two decades. Still, out-of-pocket expenditure on healthcare remains high and many of them are deprived of access to essential drugs in India. It has been said that people of India pay more for drugs than

[238] ibid
[239] See Chapter 2 of the Dissertation

people in high-income countries. Hence, accessibility, availability and affordability of life-saving drugs still remain a challenge in India.

Thus, to overcome challenges of accessibility, availability and affordability of essential drugs and to protect the right to health of the individuals, the following suggestions are made

5.3 SUGGESTIONS

1. Promotion of healthy competition among manufacturers and also the encouragement of distribution of drugs

The price control is one of the mechanisms to provide quality affordable drugs, but other mechanisms like promoting competition among manufactures, strictly adhering to the quality of drugs, encourage procurement of bulk drugs for distribution through public institutions, increasing public expenses for healthcare, tackle the irregularities by promoting transparency that will bring healthier outcomes for India's pharmaceutical industry and are helpful in easy access and afford essential drugs.

2. State sponsorship to promote extensive and exhaustive research and price negotiations

• States should support and promote extensive and exhaustive research in developing life-saving drugs by providing research infrastructure at public cost. Sufficient funds and efficient support must be given to R&D to develop a new drug and the drugs which have been identified and developed by the R&D must consider as public goods. It must also directly provide incentives to researchers and scientists to encourage R&D. This will help to procure life-saving drugs at an affordable price for all.

• Government has to encourage the production of generic drugs by providing funds to the generic pharmaceutical companies and must include a more significant number of essential drugs in the list of generic drugs. The government must increase transparency and must do consolidated price negotiations with the pharma companies to obtain the supply of essential drugs.

3. Equity Pricing Policy

There should be an equity pricing policy for essential drugs. Equity pricing policies ensure the community and the individual that the price of a drug is fair, equitable and affordable even for poor people. This is based on the principle that the poor should pay less.

4. Price Control and Affordability of Drugs

• The existing price control mechanisms provided under the Drug Price Control Order, 2013 is not much successful; thus, there is a need to find better remedies by the government for the substantial manufacture of drugs and price control.

• The price capping of life-saving drugs and one drug one price policy will helpful to avoid unnecessary profits by the pharmaceutical manufacturers with the glorified price.

• Guaranteeing better transparency of fiscal flows and profit margins by the pharma companies may be helpful to fix the reasonable price for the drug.

5. Human Rights must be preferred over the commercial interest

• The human right must be preferred over the commercial interest and it is suggested to negotiate a new global agreement for the purpose of R&D. There is a necessity to look into the cost of R&D and how prices of drugs are charged. In practice, this means separating the value of drugs from the cost required for R&D. There must be increased transparency in order to check what really R&D costs and how drugs are priced. It means, according to international trade rules and free trade agreements provide governments the power to protect their people's right to access affordable drugs and presenting substantial sanctions against any country which attempts to weaken these rights. This means making more public money available for R&D, predominantly for drugs that are of little commercial interest.

• The affordability of essential drugs is difficult and a serious issue for the ordinary people who are living in developing and underdeveloped countries. Thus, the grant of compulsory licencing shall facilitate to regulate drug prices and it shall also ensure the public with an adequate supply of the drug in need. It also encourages the countries to help each other and bring them on a global platform. Therefore, if in case of need, the

compulsory licencing must be granted without hampering the innovation and R&D which is very much necessary for the complete evolution and progress of the country.

6. Promotion and Quality Control of Generic Drugs

• A criterion must be fixed for the production of generic drugs with regard to colour shape and combinations of drugs so that people can buy and use them without any doubt.

• As there are trust issues with regard to the use of generic drugs, a stringent law to certify the quality of generic drugs may solve the problem. The drug quality control committee must be reframed and a member from the judiciary must also be appointed.

7. Accelerate approvals to generic drugs and strict rules against the delayed entrance of generics

The generics and biosimilar drugs must be provided with accelerate approvals to enter into the market and must foster the competition to ensure the availability, accessibility and affordability of life-saving drugs. There must be strict rules to prevent manufacturers from paying the generic producers to restrict or to the delayed entrance of generics and biosimilars into the marketplace.

8. Health as a Priority

Public health must be given utmost priority and make people aware of the importance of health insurance and also modification in the insurance plans benefits to ease drug cost burdens to the patients.

9. Doctors to prescribe Generic Drugs

The doctors or physicians must be regularly updated with the information relating to drug cost and its efficacy to make them do a sound prescription of drugs to their patients. The government must make a policy regarding the compulsory prescription of generic drugs with brand name drugs by the doctors. The doctors should be encouraged by the government to use more generic drugs and make patients aware of the said scheme.

10. Awareness Program

• Most of the people in India are not having much knowledge about the generic drugs available at the market or at the government outlets. They are racing to buy costlier branded drugs when generics are available. The government must take initiations to educate the people through awareness programmes about the difference between branded and generic drugs and their active and inactive substances and also the effectiveness of generic drugs.

• Awareness programs must be conducted in rural and urban areas by the government about the different schemes available to provide affordable drugs.

11. Need for Constitutional Amendment

The Judiciary has made various decisions to protect the health of the public and also shaped the Right to health as a fundamental right under Article 21(Right to Health) of the Indian Constitution. But there is no separate Constitutional Article that protects and ensures access to health. Thus, it has been suggested to amend and include a new Article, i.e., Right to Health, by adding a new clause to Article 21 of the Indian Constitution. The success of providing good health to the public not only depends on the mere policies and programmes made by the government, but there must be a proper implementation, timely supervision and rectification of drawbacks are very much necessary.

If the above said suggestions are faithfully implemented, it facilitates a way forward to protect public health and also easy access, avail and afford the essential drugs.

BIBLIOGRAPHY

STATUTES AND LEGISLATIONS

- Competition Act, 2002
- Constitution of India ,1950
- Draft Pharmaceutical Policy ,2017
- Drug Policy, 1986
- Drug Price Control Order (DPCO),1979
- Drug Prices (Control) Order, 1995
- Drug (Prices Control Order) 2013
- Drugs and Cosmetics Act, 1940
- Drugs and Cosmetics Rules, 1945
- Indian Patents and Designs Act (Act II Of 1911)
- National Intellectual Property Rights Policy, 2016
- National Pharmaceutical Pricing Policy 2012
- Patents Act 1970
- Patents (Amendment) Act, 2005
- Pharmaceutical Policy, 2002
- Pharmacy Act,1948

CONVENTIONS, TREATIES AND DECLARATIONS

- African Charter on Human and People's Rights,1981
- Agreement on Trade Related Aspects of Intellectual Property Rights,1995
- American Declaration on Rights and Duties of Man,1948
- Charter of United Nations,1945
- Convention on the Elimination of All Forms of Discrimination Against Women,1979
- Convention on the Rights of Persons with Disabilities,2006
- Convention on the Rights of the Child,1989

- Declaration of Alma-Ata,1978
- European Social Charter,1961
- International Covenant on Civil and Political Rights (ICCPR),1966
- International Covenant on Economic, Social and Cultural Rights (ICESCR),1966
- International Convention on the Elimination of All Forms of Racial Discrimination
- Ottawa Charter for Health Promotion,1986
- Universal Declaration of Human Rights,1948

BOOKS

- SOUGATA TALUKDAR, RIGHT TO HEALTH IN INDIA – LAW, POLICY AND PRACTICE, [Sage Publication (2022)]
- YAEKO MITSUMORI, THE INDIAN PHARMACEUTICAL INDUSTRY-IMPACT OF CHANGES IN THE IPR REGIME, pp2-20 [Springer Singapore Pte.Ltd. (2018)]
- K.L. SHARMA, HEALING THE PHARMACY OF THE WORLD, [Notion press Pvt Ltd (1st Edi, 2021)]
- JOHN TOBIN, THE RIGHT TO HEALTH IN INTERNATIONAL LAW, [Oxford university press (1st Edi, 2012)]
- EMMANUEL KOLAWOLE OKE, PATENTS, HUMAN RIGHTS AND ACCESS T O MEDICINES ,[Cambridge University Press(2022)]
- DR.B.S.KUCHEKAR, PHARMACEUTICAL JURISPRUDENCE, [Nirali Prakashan Publishing Co. (13th Edi,2008)]
- MAINAK MAZUMDAR, PERFORMANCE OF PHARMACEUTICAL COMPANIES IN INDIA[Physica-Verlag HD (2012)]
- IRINA HARACOGLOU, COMPETITION LAW AND PATENTS: A FOLLOW-ON INNOVATION PERSPECTIVE IN THE BIOPHARMACEUTICAL INDUSTRY, [Edward Elgar Publishing Limited (1st Edi. 2008)]

ARTICLES

- Abu Saleh, *Pharmaceutical Patent and Right to Health: Seeking balance between IPRs and Human Rights* ,1 MLJ 17 (2015)
- Akram Ahmad,Muhammad Umair Khan, and Isha Patel,*Drug pricing policies in one of the largest drug manufacturing nations in the world: Are affordability and access a cause for concern*?, vol 4(1), J Res Pharm Pract. (2015)
- Ashutosh Kolte; Hoshiar Mal; Mugdha Fulambrikar; Aishwarya Jagtap, *Impact of price control on pharmaceutical sector with reference to India*,Vol 8(1), International Journal of Intelligent Enterprise (2021)
- Athar Imam Raza, *National Health Policy 2017: An Analysis*, available at:https://www.jagranjosh.com/articles/national-health-policy-2017-for-ias-exam-1490265221-1
- Atharva Sontakke,*Right to Health and Access to Patented Medicines Toward Constitutionalisation of IPR*,(2015), https://ww w.researchg ate.net/ publicat ion /308199112_Right_to_Health_nd_Access_to_Patented_Medicines_Toward_ Constitutionalisation_of_IPR
- Baharul Islam, *RIGHT TO HEALTH: A CONSTITUTIONAL MANDATE IN INDIA*, Vol 3(3) IJARIIE, pp 2627-2638 (2017)
- Bhagya MANOJ Sattigeri, *Counterfeit drugs in India: significance and impact on pharmacovigilance*, 3(9) Int J Res Med Sci., pp 2156-2160 (2015)
- Dinesh Kumar Meena, *Essential Medicines Research in India: Situation Analysis,*Vol 13(2), Journal of Young Pharmacists,pp82-86(2021)
- Dipika Bansal and Vilok K. Purohit, *Accessibility and use of essential medicines in health care: Current progress and challenges in India*, Vol 4(1), J Pharmacol Pharmacother, pp13-18 (2013)
- Dr Amit Patil, *Right to Health and Healthcare*, Vol 8(9), Indian Journal of Applied Research, pp141-142,(2020)
- Dr. Gargi Chakrabarti, *Interface of IPR And Competition Law: Impact On Access To Medicine*, ICLR, pp 87-103(2016)
- Dr. Soumitra Kumar Chatterjee, *Right to Health, Constitutional Safeguards and Role of Judiciary, Odisha Review*, Pp 85-89, (2016), https://magazines. odisha. gov.in/Orissareview/2016/April/engpdf/86-90.pdf

- Eleanor D. Kinney, *The International Human Right to Health: What does This Mean for Our Nation and World*? 34 Ind. L. Rev. 1457, (2001), https://mckinneylaw.iu.edu/ilr/pdf/vol34p1457.pdf
- Feroz Ali Khader, *The Law of Patents, with Special Focus on Pharmaceuticals in India*, 13Lexis Nexis, Nagpur (2009).
- Feroz Ali, Nexavar: The First Market-Initiated Compulsory Licence, 9 NUJS L Rev pp 295-323(2016)
- Forman L, *Rights and wrongs: what utility for the right to health in reforming trade rules on medicines*? Health and Human Rights Journal. Health Hum Rights,(2008), https://www.hhrjournal.org/2013/09/rights-and-wrongs-what-utility-for-the-right-to-health-in-reforming-trade-rules-on-medicines/
- Gautam Bhatia, *Delhi High Court rules on Article 21 and Access to Medicine,* (2014), https://indconlawphil.wordpress.com/2014/04/17/delhi-high-court-rules-on-article-21-and-access-to-medicine/
- Hana Onderkova.*Compulsory Licencing in India and changes brought to it by the TRIPS agreement*, (2021), https://intellectual-property-helpdesk.ec.europa.eu/news-events/news/compulsory-licensing-india-and-changes-brought-it-trips-agreement-2021-10-12_en
- Hans V. Hogerzeil, Melanie Samson, Jaume Vidal Casanovas, *Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable through the Courts*? Lancet 368, pp 305-11, (2006)
- Hassoun, N., 2015, *The Human Right to Health. Philosophy Compass*,Vol 10(4) , pp 275-283.
- Hilde Stevens and Isabelle Huys, *Innovative Approaches to Increase Access to Medicines in Developing Countries*, Vol 4 ,Front. Med ,pp 1-6 (2017)
- Jonathan.P.Caulkins &Peter Reuter, *How drug enforcement affects drug prices*,39CRIME&Just.213(2010)
- Kailash Satyarthi, *Why access to healthcare needs to be a fundamental right*, (2021),https://indianexpress.com/article/opinion/why-access-to-healthcare-needs-to-be-a-fundamental-right-7367734/
- Kaitlyn N. Dana, John B. Hert and Robert J. Weber,*Drug Pricing Transparency: The New Retail Revolution*,Vol 52(2), Hosp Pharm,pp 155-159,(2017)

- Kar SS, Pradhan HS, Mohanta GP,*Concept of essential medicines and rational use in public health*, Vol 35(1),Indian J Community Med,pp10-13, (2010)
- Katrina Perehudof, *Universal access to essential medicines as part of the right to health: a cross-national comparison of national laws, medicines policies, and health system indicators*, 13(1) Global Health Action ,pp 1-15 (2020)
- Kiran Kumari and Ajay Sharma, *Doha Declaration:Compulsory Licensing and Access to Drugs*,Vol.3(2), Amity Journal of Healthcare Management, pp 43-54 (2018)
- Manish Yadav and Sandip Sumbhate, *Critical Study of Competition Law with Reference to Patenting and Trade Secret in Pharmaceutical Products*, Vol 1, International Journal of Innovative and Informative Multidisciplinary Research, pp14-33 (2017)
- Maulik Chokshi, Rahul Mongia and Vasudha Watta, *Drug Quality and Safety Issues in India*, (2015), https://icrier.org/pdf/PolicyBrief_%202_health.pdf
- Mrs Mridula Sarmah, *A Study of Right to health under the Constitution of India*, International Journal of Humanities & Social Science Studies, pp85-90,(2019)
- Mukhopadhyay K, Singh R, *Essential medicine list 2011*, 5(1) Muller J Med Sci Res, (2014)
- Nazim Akbar,*Access to Medicines as an element of Right to Health: With special reference to Pharmaceutical Patents in India*, Vol 10(1), DLR, (2018)
- Nilesh Zacharias and Sandeep Farias, *India: Patents And The Indian Pharmaceutical Industry*, (2019),https://www.mondaq.com/india/patent /865888/ patents-and-the-indian-pharmaceutical-industry
- Nisha K Jose,*Right to health as human right*, ISBN: 987-3-659-76922, (2017), https://www.researchgate.net/publication/319291598_Right_to_health_as_human _right
- Nupur Chowdhury,Pallavi Joshi ,Arpita Patnaik and Beena Saraswathy, *Administrative Structure and Functions of Drug Regulatory Authorities in India*, Indian Council For Research on International Economic relations,(2015), https:// icrier.org/pdf/ Working _Paper 309.pdf
- Omprakash V. Nandimath, *Consent and medical treatment: The legal paradigm in India,*Vol 25(3), Indian J Urol,pp343-347, (2009

- Priyanka V. Patel,*Drug Regulation in India: Swot Analysis*,Vol 3(3), International Journal of Drug Regulatory Affairs,pp21-27, (2018)
- Rajesh Kumar,*Right to health: Challenges and Opportunities*,Vol 40(4), Indian J Community Med,pp218-222,(2015)
- Renganathan R, Vijayabanu C, Srinivasakumar V& Vijay Anand V, *Pharmaceutical Pricing Policy And Control: Indian Perspective*, 9(6) Asian Journal of Pharmaceutical and clinical research,pp 305-308 (2016)
- Rhyea Malik, *Striking a Balance between Patent Rights and Access to Essential Medicines through the Use of Compulsory Licenses - Comparative Study of Indian and Malaysian Patent Laws*, 42 JMCL 27 pp 27-45 (2015).
- Ritika Sharma, *Pharmaceutical Patents and Their Impact on Indian Pharmaceutical Industry*, 2 INT'l J.L. MGMT. & HUMAN. Pp 400-413 (2019).
- Rituparna Maiti, Vikas Bhatia,Biswa Mohan Padhy, and Debasish Hota, *Essential Medicines: An Indian Perspective*,Vol 40(4), Indian J Community Med, pp223-232,(2015)
- Riya Jain, *Article 21: Understanding The Right to Life and Personal Liberty from Case Laws, (*2015), https://www.lawctopus.com/academike/article-21-of-the-constitution-of-india-right-to-life-and-personal-liberty/
- Saeed Ahmadiani and Shekoufeh Nikfar, *Challenges of access to medicine and the responsibility of pharmaceutical companies a legal perspective*, DARU Journal of Pharmaceutical Sciences,pp13-24, (2016)
- Sakthivel Selvaraj,*How Effective IsIndia's Drug Price Control Regime*?, (2007),https://cdn1.sph.harvard.edu/wpcontent/uploads/sites/114/2012/10/RP256.pdf
- Sandeep Narula,*Current Drug Pricing Status in India*, (2015), https://www.researchgate.net/publication/327181272_Current_Drug_Pricing_Status_in_India
- Sangeeta Sharma and Ranjit Roy Chaudhury, *Improving Availability and Accessibility of Medicines: A Tool for Increasing Healthcare Coverage*, Vol 7, iMedPub Journals,pp 1-9 (2015)
- Shree Agnihotri and Sumathi Chandrashekaran, *Drug Regulation In India: The Working And Performance Of CDSCO And SDRAs*, (2019), https://thakur-

foundation.org/TFF%20State%20Drug%20Regulatory%20Authorities%20Capability%20Assessment%20Report.pdf

- Singh, Prachi; Ravi, Shamika & Dam, David,*Medicines in India: Accessibility, Affordability and Quality*,(2020),https://www.brookings.edu/wp-content/uploads/2020/03/Medicines-in-India_for-web-1-1.pdf
- StephenP.Marks,*Access to essential medicines as a component of the Right to Health*,(2008),https://cdn1.sph.harvard.edu/wpcontent/uploads/sites/580/2012/10/marks_access_to_essential_medecines-2009.pdf
- Sunil Chopra, *Constitutional and Legal Protection of right to Health in the Perspective of Governance in India*,(2018)
- Timothy Bazzle, *Pharmacy of the Developing World: Reconciling Intellectual PropertyRights in India with the Right to Health: TRIPS, India's Patent System and Essential Medicines*, 42 GEO. J. INT'l L. pp 785- 815 (2011).
- Uday Shankar and Nidhi Mehrotra, Patent Regime and Drug Pricing Regulations: *An Intertwining Thread in Determining Accessibility and Affordability of Essential Medicines in India*, 12 RMLNLUJ pp29-45(2020)
- Vagish Yadav, *Rare Diseases in India: Analysis of Laws and Policies*,(2020), https://www.legalbites.in/rare-diseases-in-india-laws-and-policies
- Venkatanarayana Motkuri and Rudra Narayan Mishra, *Pharmaceutical Market and Drug Price Policy in India*, Vol 25,Review of Development and Change ,pp 30-53 (2020)

ONLINE SOURCES

- Access to Medicines and Human Rights, https://www .hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/ (last visited on 28th July 2022)
- Access to medicines and the right to health, https://www.ohchr.org/en/special-procedures/sr-health/access-medicines-and-right-health(last visited on 22nd July 2022)
- Access to medicines, https://en.wikipedia.org/wiki/Access_to_medicines (last visited on 22nd July 2022)
- Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social And Cultural Rights “Protocol of San Salvador, http://www.oas.org/juridico/english/treaties/a-52.html.(last visited on 10th July 2022

- Availability and Price Management of Drugs and Pharmaceuticals. http://164.100.24.208/ls/CommitteeR/chemicals/7rep.pdf(last visited on 14th July 2022)
- Central Drugs Laboratory (Kasauli), https://cdsco.gov.in/ opencms/opencms/en /Departments /Lab/CDL_Kasauli/(last visited on 14th July 2022)
- Central Drugs Standard Control Organization, https:// cdsco.gov.in/ opencms/ opencms/en/Home/(last visited on 14th July 2022)
- Centre for Environmental Health Activities, https://applications.emro. who.int/docs/who_em_ceha_55_e_en.pdf (last visited on 14th July 2022)
- Constitution of India and Environmental Concern, https://lawpage.in/ environment/article/constitution-and-environmental-concern (last visited on 14th July 2022)
- Dealing with compulsory licensing in India, https://www. Worldtrademarkrevi ew. com/dealing-compulsory-licensing-india,last visited on 14th July 2022)
- Drug Pricing Policy in India, https://byjusexamprep.com/drug-pricing-policy-in-india-i(last visited 26th April 2022)
- Essential Drug Concept and Rational Use of Drugs, https://www.researchgate .net /publication/207423715_Essential_Drug_Concept_and_Rational_Use_of_Drugs (last visited 26th April 2022)
- HLL Life Care Limited, A Government of India Enterprise, available at: htt p:/ / www..lifecarehll.com/page/render/reference/Amrit_Retail_Pharmacy_Stores_, (Last Visited on April 26th 2022).
- http://supremecourtofindia.nic.in/speeches/speeches_2008/right_to_health_-_bhopal_14-(Last Visited on April 26th 2022).
- Human Rights and Jurisprudence: Right to Life / Livelihood Archives, https://www.hurights.or.jp/english/human_rights_and_jurisprudence/right-to-lifelivelihood/(last visited on 14th July 2022)
- Human Rights and Responsibilities Health & Social Care Essay Questions , https://assignmenttask.com/answers/human-rights-and-responsibilities-health-social-care-essay-questions-and-answers/(last visited on 14th July 2022)
- Impact of Competition Law on Pharma Industry, available at http://w ww . nishithdesai.com/fileadmin/user_upload/pdfs/Impact_of_Competition_Law_on_Pharma_Industry .pdf (last visited on 21st July 2022)

- Impact of Mediation on Health & Social Welfare – Indian Context. https://www.arbitrationindia.com/pdf/mediation_health.pdf(last visited on 8th July 2022)
- India's price control policy has destroyed drug manufacturers. This is how they can be saved,https://theprint.in/opinion/indias-price-control-policy-has-destroyed-manufacturers-this-is-how-they-can-be-saved/338095/(last visited 26th April 2022)
- In The High Court of Delhi at New Delhi - globalhealthrights.org. https://www.globalhealthrights.org/wp-content/uploads/2015/04/Mohd-Ahmed-v.-Union-of-India-2014.pdf((last visited on 20th July 2022)
- Just because someone is poor, the State cannot allow him to die Delhi .... http://www.legalservicesindia.com/article/1653/Just-because-someone-is-poor,-the-State-cannot-allow-him-to-die-Delhi-HC-landmark-Judgment.html(last visited on 20th July 2022)
- K.G. Balakrishnan, National seminar on the 'Human right to health' Organized by the MadhyaPradesh State Human Rights Commission (At Bhopal), September 14, 2008,https://scitechuman.files.wordpress.com/2015/10/right_to_health_-_bhopal_14-9-081.pdf(last visited on 22nd July 2022)
- Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights, https://www.escr-net. org/docs /i/425445 (last visited on 20th July 2022)
- Managing medicine selection - msh.org. https://msh.org/wp-content/uploads/2013/04/mds3-ch16-selection-mar2012.pdf(last visited on 14th July 2022)
- Michael R Rech, Essential drugs: Economics and politics in international health, 1987 , https://cdn1.sph.harvard.edu/wp-content/uploa ds/sites/480/2 013/01 / essential _ drugs.pdf (last visited on 28th May 2022)
- National Health Mission, available at: https://nhm.gov.in/, (last visited on May 7, 2022).
- National Health Mission (NHM) -PharmacyInfoline.https://pharmacyinfoline.com national-health-mission-nhm/(last visited on 24th July 2022)
- National Health Policy, 2017 available at: https://vik aspedia.in /health/nr hm/ national-health-policies/national- health-policy-2017 (last visited on 2nd July, 2022)
- NPPA fixes the ceiling price of medicines. https://www.teamleaseregtech.com/

updates/article/18296/nppa-fixes-the-ceiling-price-of-medicines/(last visited on 14th July 2022)

- Obligations and exceptions, https: //www .wto.or g/English /tratop_e/t rips_e/fact sheet_ph arm 02_e.htm(last visited on 24th July 2022)
- OHCHR and World Health Organization, The Right to Health, Fact Sheet No. 31, http://www.ohchr.org/Documents/Publications/Factsheet31.pdf.,(last visited on 20th July 2022
- Olga Tellis v. Bombay Municipal Corporation, https://www.elaw.org/content/ india-olga-tellis-v-bombay-municipal-corporation-19850710-right-life-and-livelihood-homeless(last visited on 24th July 2022)
- Personal Dignity: Tracing The Role of Indian Judiciary in its Interpretation,https://www.legalserviceindia.com/article/l74-Personal-Dignity. Html (last visited on 22nd July 2022)
- Pharmaceutical Policy 2002,Department of Pharmaceuticals, https:// pharmaceuticals.gov.in/policy/pharmaceutical-policy-2002(last visited on 10h July 2022)
- Pharmaceutical Policy 2002 | Department of Pharmaceuticals. https://pharmaceuticals.gov.in/policy/pharmaceutical-policy-2002(last visited on 14th June 2022)
- Research and Reviews: Journal of Zoological Sciences, available at: https:// www.rroij.com/openaccess/prolonged-effects-of-an-antialzheimers-drug-galantamine-hydrobromide-on-morphometric-andbehavioural-aspects-of-albino-mice-1-6.pdf (last visited on 16th April 2022)
- Right to Health Facilities, Goods and Services - Icelandic Human Rights,https://www.humanrights.is/en/human-rights-education-project/comparative-analysis-of-selected-case-law-achpr-iachr-echr-hrc/the-right-to-health/right-to-health-facilities-goods-and-services(last visited on 14th July 2022)
- Right to Health – WMA – The World Medical Association, https:/ /www .wma. net/what-we- do/human-rights/right-to-health/, (Last visited on April 16th ,2022).
- Span of Control - National Pharmaceutical Pricing Authority. https://www.nppaindia.nic.in/en/drug-policies/modification-in-drug-policy-1986/span-of-control/(last visited on 14th July 2022)

- The Right To Health – Uneasy Silence - Live Law. https://www.livelaw.in/right-to-health-uneasy-silence/(last visited on 12th June 2022)
- TRIPs and Pharmaceuticals: Implications for India, http://www.cuts-india.org/ 1997- 8.htm#Pharmaceutical %20Industry%20in(last visted on 14th July 2022)
- UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 14, U.N. Doc. E/C.12/2000/4, https://www .refworld.org/p dfid/453 8838d0.pdf(last visited on 20th July 2022)
- United Nations, Universal Declaration of Human Rights, available at:http:// www. un.org /en/universaldeclaration-human-rights/ (last visited on 16th April 2022)
- University of Minnesota Human Rights Library. http://hrlibrary.umn.edu/ monitoring/adminchap14.html(last visited on 22nd July 2022)
- What did the Court say in the case of Hakim Sheik? https://www.vedantu. com/question-answer/did-the-court-say-in-the-case-of-hakim-sheik-class-12-social-science-cbse-5fc67926d58f2b581a13dcd4(last visited on 4th August 2022
- World Health Organization. Advancing the Right to Health: The Vital Role of Law. World Health Organization, 2017. JSTOR, http://www.jstor.org/stable/resrep39155. (last accessed 24th July 2022.)
- WHO called to return to the Declaration of Alma-Ata, International conference on primary health care, available at: https://www.who.int/teams/social-determinants-of-health/declaration-of-alma-ata, (last visited on April 22nd 2022)
- WHO, Declaration of Alma-Ata, International Conference on primary health care, Alma-Ata, USSR, 6–12 September, 1978, http:// www.searo .who.int/Link Files/ Health_Systems_declaration_ almaata.pdf.(last visited on 20th July 2022)
- WHO, "Equitable Access to Essential Medicines: A Framework for Collective Action" in WHO Policy Perspectives on Medicines Bulletin(2004), http://apps .who.int/medicinedocs/pdf/s4962e/s4962e.pdf, 2. (last visited on 20th July 2022)
- World Health Organization, Who.int, https:// www.who.int/ topics/essentialedicin es/en (last visited on 26th April 2022)
- World Medical Association, Medical Ethics Manual, The World Medical Ass oc iation , Inc9-08.pdf. (last visited on 8th July 2022)

APPENDIX

THE NATIONAL UNIVERSITY OF ADVANCED LEGAL STUDIES
Kalamassery, Kochi – 683503, Kerala, India

CERTIFICATE ON PLAGIARISM CHECK

1.	Name of the Candidate	Akshaya. R.S
2.	Title of Thesis/Dissertation	ACCESS TO ESSENTIAL DRUGS AND DRUG PRICING POLICY IN INDIA: A CRITICAL STUDY
3.	Name of the Supervisor	Dr. Liji Samuel
4.	Similar Content (%) Identified	8%
5.	Acceptable Maximum Limit (%)	10 %
6.	Software Used	Grammarly
7.	Date of Verification	29-07-2022

Checked by (Name, Designation & Signature) :

Name and Signature of the Candidate :
Akshaya. R.S

Name & Signature of the Supervisor :
Dr. Liji Samuel