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INDIA'S DESIDERATUM FOR A COMPREHENSIVE LEGISLATION TO DEAL WITH PUBLIC HEALTH EMERGENCY BASED ON INTERNATIONAL REGULATIONS AND COMPARATIVE LEGAL RESPONSES AMONG DEVELOPED AND DEVELOPING NATIONS

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Date: 11.10.2021

Place: Ernakulam

DECLARATION

I declare that this Dissertation titled "**INDIA'S DESIDERATUM FOR A COMPREHENSIVE LEGISLATION TO DEAL WITH PUBLIC HEALTH EMERGENCY BASED ON INTERNATIONAL REGULATIONS AND COMPARATIVE LEGAL RESPONSES AMONG DEVELOPED AND DEVELOPING NATIONS**" 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**, Assistant Professor and is an original, bona fide and legitimate work. It has been pursued for academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this University or any other University.

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LETTER OF APPROVAL

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ABBREVIATIONS

AIR	ALL INDIA REPORTER
AJPH	AMERICAL JOURNAL OF PUBLIC HEALTH
ALL ER	ALL ENGLAND LAW REPORT
APHA	ASSAM PUBLIC HEALTH ACT
BMJ	BRITISH MEDICAL JOURNAL
BMW	BIOMEDICAL WASTE MANAGEMENT
CA	CIVIL APPEAL
CA	CORONA VIRUS ACT
CAA	CIVIL CONTINGENCIES ACT
CBHI	CENTRAL BUREAU OF HEALTH INTELLIGENCE
CDC	CENTRE FOR DISEASE CONTROL AND PREVENTION
CDSCO	CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CE(RR)A	CLINICAL ESTABLISHEMNTS (REGISTRATION AND REGULATION) ACT
CEDAW	CONVENTION ON THE ELIMINATION OF ALL FORMS OF DISCRIMINATION AGAINST WOMEN
CERC	CONSUMER EDUCATION AND RESEARCH CENTRE
COVID-19	CORONA VIRUS DISEASE- 2019
CRPC	CODE OF CRIMINAL PROCEDURE
DCA	DRUGS AND COSMETICS ACT
DPSP	DIRECTIVE PRINCIPLES OF THE STATE POLICY

DREAA	DISASTER RELIEF AND EMERGENCY ASSISTANCE ACT
DSCSA	DRUG SUPPLY CHAIN SECURITY ACT
EC	EUROPEAN COMMUNITY
EDA	EPIDEMIC DISEASES ACT
EMR	EXCLUSIVE MARKETING RIGHTS
ERL	EMERGENCY RESPONSE LAW
ESA	ESSENTIAL COMMODITIES ACT
EU	EUROPEAN UNION
F.3D	FEDERAL REPORTER
FECA	FEDERAL EMPLOYEES' COMPENSATION ACT
GOI	GOVERNEMENT OF INDIA
GPHA	GUJARAT PUBLIC HEALTH ACT
HC	HIGH COURT
HIV/AIDS	HUMAN IMMUNODEFICIENCY VIRUS AND ACQUIRED IMMUNE DEFICIENCY SYNDROME
HIV/AIDSA	HUMAN IMMUNODEFICIENCY VIRUS AND ACQUIRED IMMUNE DEFICIENCY SYNDROME (PREVENTION AND CONTROL) ACT
ICCPR	INTERNATIONAL COVENENANT ON CIVIL AND POLITCAL RIGHTS
ICESCR	INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS
ICH-GCP	INTERNATIONAL COMMITTEE ON HARMONIZATION OF GOOD CLINICAL PRACTICES

IDSP	INTEGRATED DISEASE SURVEILLANCE PROGRAMME
IHR	INTERNATIONAL HEALTH REGULATIONS
IPC	INDIAN PENAL CODE
IPR	INTELLECTUAL PROPERTY RIGHTS
MHA	MENTAL HEALTH ACT
MOHFW	MINISTRY OF HEALTH AND FAMILY WELFARE
MSPHA	MODEL STATE PUBLIC HEALTH ACT
NCBI	NATIONAL CENTRE FOR BIOTECHNOLOGY I NFORMATION
NCDC	NATIONAL CENTRE FOR DISEASE CONTROL
NDMA	NATIONAL DISASTER MANAGEMENT AUTHORITY
NDMA, 2005	NATIONAL DISASTER MANAGEMENT ACT, 2005
NE	NORTH EASTERN REPORTER
NHS	NATIONAL HEALTH SERVICE
OHCHR	OFFICE OF COMMISSIONER FOR HUMAN RIGHTS
PAHPA	PANDEMIC AND ALL-HAZARDS PREPAREDNESS ACT
PHA	PUBLIC HEALTH (CONTROL OF DISEASES) ACT
PHE	PUBLIC HEALTH EMERGENCY
PHSA	PUBLIC HEALTH SERVICE ACT
SC	SUPREME COURT
SCC	SUPREME COURT CASES
SCR	SUPREME COURT REPORTER

TRIPS	TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS
UDHR	UNIVERSAL DECLARATION OF HUMAN RIGHTS
UN	UNITED NATIONS
UNGA	UNITED NATIONS GENERAL ASSEMBLY
UOI	UNION OF INDIA
VPA	VOLUNTEER PROTECTION ACT
WHO	WORLD HEALTH ORGANIZATION
WLR	WEEKLY LAW REPORTS
WMA	WORLD MEDICAL ASSOCIATION
WP	WRIT PETITION

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CHAPTER 1

INTRODUCTION

Public health emergency[1] is an occurrence or imminent threat of an extraordinary event which includes illness or health condition, caused by bioterrorism or chemical incident, epidemic or pandemic diseases or a novel and highly fatal infectious agent or biological toxin that constitute a public health risk to a significant number of human facilities or incidents or permanent or long-term disability. The health risks caused by PHE give rise to legal issues such as protection human rights during PHE, emphasizing on right to health, prevention, and control of spread infectious or communicable diseases, management of health care establishments, regulation of clinical trials, and ensuring availability of vaccines and essential medicines at affordable and reasonable price.

The study aims at identifying the lacunae in legislative responses in India towards public health emergency. There are State legislations, in Orissa, Gujarat, that identifies and defines the concept of Public Health Emergency. However, India does not have a uniform central legislation that deals with this area. Not only there is no legislation to deal with Public Health Emergency, but India does also not even have a proper and comprehensive public health legislation. There is Clinical Establishments Act, Epidemic Diseases Act, and Drugs and Cosmetics Act, that deals with public health related matters, however, these legislations are limited to registration of Clinical Establishments, or are operative only during outbreak of epidemics and are limited to clinical trials and manufacture and distribution of Drugs, respectively. India is in ample need of an adequate public health legislation to deal with instances such as COVID-19 pandemic, Bhopal Gas Leakage, or Bombay Terrorist attack which has caused numerous casualties, which cannot be met by ordinary clinical practices. There is a high demand for demarcating the role of State in health preparedness, creating awareness among people, management and distribution of resources, adoption of post-emergency measures, etc. The study is based on identifying the

[1] Hereinafter referred to as PHE.

gaps in Indian law while examining whether India has adequately implemented International Regulations, and based on comparative analysis with China, USA, and UK. Based on conclusions reached, a conceptual framework for a model law to deal with public health emergency will be recommended.

1.1 SCOPE AND SIGNIFIANCE OF STUDY

The COVID-19 pandemic situation has exposed the incapability of Health laws in India. The public health risks due to outbreak of diseases, natural calamities, industrial accidents or any other biological, chemical, or radioactive disasters have a devastating effect on the socio-economic conditions as well as the health and wellbeing of people. India in the past 73 years have witnessed numerous industrial accidents, outbreak of diseases and natural calamities, which required emergency health care provisions. By the virtue of duties of state under Part IV of the Constitution of India, there are several laws applicable to medical practice and hospitals in India. It includes, Clinical Establishments (Registration and Regulation) Act, 2010, The Epidemic Diseases Act, 1955 and 2020 Amendment Ordinance, The Mental Health Care Act, 2017. However, these legislations are silent about the regulation of health care services during public health emergency. For instance, government of India placed its reliance on Epidemic Diseases Act, 1897, National Disaster Management Act, 2005, Essential Commodities Act, and sections 269, 270 and 271 of Indian Penal Code for the prevention and control of COVID-19 Pandemic. The government of India under the provisions of Disaster Management Act, imposed a nation-wide lockdown from March 2020. The lockdown has imposed restrictions on the civil liberties of citizens. However, the state action had suffered from several ambiguities in respect of matters including right to movement of citizens, the extend of action of required to maintain public order and health, violence against health care personnel, denial of treatment to patients tested positive.

A public health emergency may occur for the reasons of disease, natural calamity and chemical, radioactive or any other industrial accidents. The major challenges in this regard are prevention and control, well trained and prepared health workforce, pharmaceutical and laboratory facilities, psychological support services, surge capacity, and provisions for allocation of resources at the right time in right quantities. In India, the present legislations

do not have any provisions to deal with these problems. The case *Court on its own motion v Union of India*[2], reflects the problems of lack of special legislation to deal with public health emergencies. In this case the Bombay High Court relying on the decision in *Paramananda Katre v Union of India*[3]has ordered that non-availability of ICU, Ventilators or any other medical equipment should not be a reason to deny admission to hospital and it is the duty of the state to make all such infrastructural and medical facilities available to save the life of people who are affected or likely to be affected by Coronavirus. The court in this also observed that, "*the doctors and para-medical staff to rise on the occasion of severity and shall discharge their duties and obligations with promptitude."* The issues and concerned in this case show the problems due to absence of a specific legislation.

1.2 RESEARCH PROBLEM

The primary challenges before the health care system during a public health emergency, protection of healthcare workforce, ensuring the quality of healthcare, access to healthcare, collection and management of primary health data, regulation on drug price and public health surveillance. Currently, in India there are no specific legislations that deal with public health emergencies. The present legislations do not recognize public health emergency nor provide any provisions for regulations public health sector during such events. There is need for a new legislation that identifies the concept of public health emergency, the issues faced by the health care sector, and the role and responsibilities of state in ensuring the same.

1.3 OBJECTIVES OF THE STUDY

1. To identify the nature and concept of public health emergency
2. To identify the lacunae in the present public health laws in India to deal with public health emergency.
3. To conduct a comparative study between developed and developing nations to find out the best suitable legal framework for India.

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[2][Suo Motu Public Interest Litigation No.4 of 2020]
[3][1989(4) SCC 286].

4. To recommend a conceptual framework for improving the quality of healthcare systems during public health emergencies.

1.4 RESEARCH QUESTIONS

1. Whether the public health laws in India capable of dealing with public health emergency?

2. Whether the present Public Health Laws in India are in conformity with International Standards in dealing with public health emergency?

3. Whether it is necessary to enact a comprehensive legislation in India to deal with public health emergency?

4. Whether a comparative study on legislative responses of nations such as China, USA, and UK, would be beneficial and applicable in India, based on its socio-economic and demographic factors?

5. Whether there is a need for declaring emergency under Article 365 of the Indian Constitution?

6. Whether State has the power to determine the mechanism to be adopted by the healthcare personnel in the event of PHE?

7. Whether there is a need to make a definitive demarcation between the three levels of governments, i.e., Central, State and Local Governments, during PHE?

8. Whether it is justifiable to invoke Penal Laws to prevent and mitigate PHE?

9. Whether there is a need to include regulations on telemedicine practices, which is a distinct area in public health law, as a part of PHE regulations?

10. Whether it is required to address mental health issues and rights of persons with mental illness in law relating to PHE ?

1.5 HYPOTHESIS OF THE STUDY

The absence of a single comprehensive public health legislation in India points out the lacunae in ensuring right to health during a Public Health Emergency. The present legislations governing public health law in India are inadequate to meet the challenges and requirements posed by public health emergency. There is a need for new legislation to deal with Public Health Emergency that helps to improve the quality of services provided by the public health institutions, by clearly demarcating the role of State. A PHE, though a state of emergency, does not demand invoking of emergency under Article 365, and application of stringent penal law for its prevention and mitigation.

1.6 METHODOLOGY OF THE STUDY

Doctrinal research or non-empirical research methodology will be used in the dissertation. The primary sources include, the legislations governing public health law and the relevant guidelines issued by the Government of India and Judicial Precedents.

1.7 LITERATURE REVIEW

The research is based on primary sources including International Covenant on Economic, Social and Cultural Rights, International Health Regulations, 2005, American Constitution, Constitution of India, various legislations including, Response Law of the People's Republic of China, Model State Public Health Act, 2003, Model State Emergency Health Act, 2001, UK Civil Contingencies Act, Epidemics Diseases Act, Disaster Management Act, Clinical Establishments (Registration and Regulation) Act, 2010, Drugs and Cosmetics Act, and case laws. The research has also used secondary resources like books, commentaries for the purpose of understanding the contemporary legal position. The research is widely dependent on electronic resources like online databases such as JSTOR, PubMed, etc. for gathering resources.

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- **Henk Th, Disaster, Vulnerability and Human Rights, Disasters: Core Concepts and Ethical Theories, (Springer, 2018):** The book deals with principle of vulnerability during disasters in context of protecting the human rights, including right to health. It contemplates the sufferers of disasters as bearers of rights rather than as victims.
- **Weidling P, Villiez A, Loewanue A, Farron N, Thevictms of unethical human experiments and coerced research under National Socialism:** The study on law relating to protection of rights of human participants in clinical trials are based on the article "the victims of unethical human experiments and coerced research under National Socialism". The article deals with evaluation of victims of Nazi research, types of experiments and research. It gives the results of a comprehensive evidence-based evaluation of the different categories of victims.
- **Sharma BH, Challenges, and opportunities in solid waste management during and post covid-19 scenario, RCR, 162, 2020:** The article deals with management of biomedical waste a raising concern during Pandemic. It addresses the urgency of the situation and need for legal provisions to appropriately dispose off the biomedical waste.
- **Gummel A, *Modelling Strategies for controlling SARS Outbreak,* 271, PBS, 2223-2232, (2017):** The Emergency Response law in China is based on the outbreak of SARS viral disease in late 2002. The article presents the challenges that China has faced in early 2000s due to outbreak of the contagious disease which has led to adoption of an efficient legal mechanism to deal with Public Health Emergencies in future.

- **Ratan Lal &Dhiraj Lal, Code of Criminal Procedure, (Lexis Nexis, 2013):** The book gives detailed analysis of application of Criminal law to public health emergencies are based on certain provisions of Indian Penal Code.
- **MP Jain, Constitutional Law, (Lexis Nexis):** The book deals with federal nature of Indian polity as well as gives a detailed analysis of emergency provisions under Constitution of India.

1.8 CHAPTERIZATION

Chapter-1: Introduction: The introductory chapter gives a basic framework within which the research is conducted. It denotes the objectives of the study, the research problem, research question and hypothesis to be tested. It deals with literature review. And it also gives a brief idea about the contents of subsequent chapters.

Chapter-2: Right to health and public health emergency: Chapter 2 aims at identifying the essential elements in a Public Health Emergency, the legal challenges posed by Public Health Emergency in the light of right to health as given under international and domestic legal instruments. The chapter begins with an introduction to the concept of right to health upon which law relating public health emergency places reliance. Under the concept of right to health International Instruments including International Covenant on Economic, Social and Cultural Rights, Declaration of Alma-Ata adopted by the International Conference on Primary Health Care in 1978, The Convention on the Elimination of all forms of Discrimination against Women as well as the concept of right to health under the Constitution of India. The chapter also identifies the components of right health. Based on the detailed analysis of concept of right to health, the challenges before the State to ensure people's fundamental right during a PHE is identified and discussed.

Chapter-3: International legal instruments on prevention and mitigation of public health emergency: The chapter covers four areas. At first it deals with role of World Health Organization, second part deals with the legal duties of State parties to implement International Health Regulations, in its third part, it deals with international instruments regulating clinical trials and finally it deals with international instruments for management of healthcare waste. The aim of the chapter is to analyze the International legal framework is to understand the lacunae in the present Indian legal system governing the public health

provisioning, in special reference to PHE. The implementation of such international regulations in India are discussed in Chapter 5 and 6.

Chapter-4: Comparative analysis of legal responses to public health emergency in China, United States of America and United Kingdom: This chapter discusses the legislative response to PHE in three different countries. These countries are taken for study due to similarities in the governmental, economic, and demographic situations. Comparative analysis of India with these countries would help to frame a conceptual framework for India to deal with PHE and to find out lacunae in Indian legal framework concerning PHE.

Chapter-5: General Overview of Legal Response to Public Health Emergency in India: Chapter 5 focuses on implementation of IHR and other WHO guidelines and principles in India. It gives an overall insight into the present legal framework for prevention and mitigation of PHE in India.

Chapter 6: Critical Evaluation of Applicability of Public Health Legislations in India During A PHE. India does not have a central legislation to deal with PHE. However, it has several Public Health Law Legislations, such as Clinical Establishments Act, Drugs and Cosmetics Act, etc. This chapter examines whether the existing legislations are sufficient to deal with a PHE.

Chapter-7: Conclusion: The final chapter marks the conclusions reached based on research and recommends a conceptual framework for improving the quality of healthcare systems during public health emergencies.

CHAPTER 2

RIGHT TO HEALTH AND PUBLIC HEALTH EMERGENCY

2.1 INTRODUCTION

Health Care provisioning is more than mere treatment and cure. It includes several activities such as control of diseases, reduction in mortality rate through generation and utilization of knowledge, where the system is equipped to provide urgent and good quality services. It helps to enhance the mind and body of people. Guarantee and assurance of public health is one of the primary functions of every State. It is closely linked with human rights. The concept of public health promotes and protects the health of people and communities where they live, learn, work and play[4].

A Public Health Emergency[5] may occur for the reasons of disease, natural calamity or chemical, biological, radioactive accidents or hazards or any industrial accidents. It is detrimental to the maintenance of public health. There is no comprehensive definition of a public health emergency. The State and its population face several challenges during a public health emergency. It includes prevention and control, the requirement of a well-trained and prepared health workforce, the need for pharmaceutical and laboratory facilities, psychological support services, surge capacity, and provisions for allocating resources at the right time in the right quantities. The health consequences during a public health emergency hereinafter, PHE, are severe. During a PHE, the State must ensure the rights to access to health are enforced.

Chapter II aims at mapping the essential elements in a PHE, the legal challenges posed by PHE in the light of right to health as given under international and domestic legal instruments.

2.2 RIGHT TO HEALTH

Right to health is a multi-faceted and inclusive right. It is the availability and accessibility of means to ensure the highest attainable physical and mental health standard. It means all

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[4] American Public Health Association, https://www.apha.org/what-is-public-health, (last visited May 15th 2021).
[5] Hereinafter referred to as PHE.

services and facilities must be available in acceptable quality and equally accessible to all. The underlying determinants of the right to health are related to other human rights, such as education, equality, non-discrimination, right to work, right to participation, and right to life and liberty. All human rights are universal, indivisible, and interdependent and interrelated[6].

Public health is defined as "*the art and science of preventing disease, prolonging life and promoting health through organized efforts of society*[7]". Here the overall vision of the State is to promote greater health and well-being in a sustainable way, while strengthening integrated public health services and reducing inequalities[8]. It is achieved through a right based approach.

The human rights-based approach is a conceptual framework for the process of human development. It recognizes a human right and imposes a corresponding duty upon the State to enforce such right. The right-based approach to health is visible in several international and domestic instruments. The establishment of healthcare through the human rights route is the best way to fulfil the obligations mandated by international law and domestic constitutional provisions. However, the country situations are very different, and hence there should not be a global core content; it needs to be country-specific[9]. There are three aspects of the nature of health as a human right[10]. First, the indivisibility of civil and political rights and socio-economic rights, second, active agency by those vulnerable to human rights violations, and lastly, the role of human rights in establishing accountability for protections and freedom.

According to World Health Organization, health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity[11]. Right to health

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[6] UN General Assembly, Article 5, *Vienna Declaration and Programme of Action,* The world conference on Human rights, (1969), United Nations

[7] WORLD HEALTH ORGANIZATION, https://www.euro.who.int/en/health-topics/Health-systems/public-health-services/public-health-services, (last visited May 15th 2021).

[8] *Id* at 3.

[9] Ravi Duggal, *Operationalizing Right to Healthcare in India,* The ICFAI Journal of Healthcare Law, 2004,13-42.

[10] Lesli London, *What is human rights approach to health and why does it matter?*HHRJ, 10, 2008.

[11] International Health Conference (2002), Constitution of World Health Organization, 1946, *Bulletin of World Health Organization,* World Health Organization

was first explicitly mentioned in the Constitution of World Health Organization[12]. Article 1 of the Constitution says that the objective of the World Health Organization shall be the attainment by all peoples of the highest possible level of health.

2.2.1 International Instruments on Right to Health

Universal Declaration of Human Rights doesn't explicitly provide for right to health but recognizes health as a part of an adequate standard of living. Article 25 of the UDHR says that everyone has the right to a standard of living adequate for the health and well- being of himself and of him 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[13].

The International Covenant on Economic, Social, And Cultural Rights[14] under Article 12 says that every state party to the Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The General Comment 14 to Article 12 of the covenant interprets the human right of health. It differentiated between right to health and right to be *healthy*. The right to health contains both freedoms and entitlements. It is often perplexed with right of being healthy[15]. Right to healthy life is related and achieved through adequate nutrition adequate nutrition and healthy environment, socio-economic and biological conditions of an individual[16]. Right to health on the other hand is the availability and accessibility of means to ensure highest attainable standard of physical and mental health. It means all services and facilities must be available in acceptable quality and equally accessible to all. The general comment specifies that the notion of "highest attainable standard of health" under Article 12 is based on the balance between individual's biological and socio-economic preconditions and State's available resources.

[12] WHO Const. art 1
[13] UDHR. art 25
[14] ICESCR. art 12
[15] UN Office of the High Commissioner for Human Rights (OHCHR), *Fact Sheet No. 31, The Right to Health*, June 2008, No. 31, World Health Organization
[16] *Id.*

The general comment has recognized four essential elements of right to health, *vis-à-vis*, availability, accessibility, acceptability, and quality[17].

The element of availability requires sufficient availability of functioning public health and healthcare facilities, goods and services, programmes. It is inclusive of several other factors such as safe and potable drinking water, adequate sanitation facilities, hospitals, clinics, trained medical and professional personnel, and essential drugs[18].

The accessibility of health care is based on four overlapping dimensions. First, the principle of non-discrimination. The health care facilities shall be accessible to everyone without any discrimination. It shall be within safe physical reach for all sections of the population, especially vulnerable or marginalized groups, such as ethnic minorities and indigenous populations, women, children, adolescents, older persons, persons with disabilities, and persons with HIV/AIDS. There should be economic accessibility along with physical accessibility. The health facilities must be affordable to all. And the last aspect of information accessibility. It covers the right to seek, receive, and impart information and ideas concerning health issues[19].

The third element of the right to health is acceptability. It means that all the facilities shall be respectful of medical ethics. It shall be culturally appropriate and designed to respect confidentiality[20].

Lastly, the quality of health facilities and related goods and services to be of good quality. It must be scientifically and medically appropriate[21].

The General Comment clarifies the duties of state parties and suggest approaches to implementation of such provisions. The general comment has recommended General Legal Obligations, Specific Legal Obligations, International Obligations and Core Obligations of the State parties under Article 12. The Covenant allows the progressive realization of the human right taking into consideration the resources available to a nation. The concept of

[17]ICESCR, General Comment 14 to Article 12, Paragraph 12.
[18] ICESCR, General Comment 14 to Article 12, Paragraph 12(a).
[19] ICESCR, General Comment 14 to Article 12, Paragraph 12(b).
[20] ICESCR, General Comment 14 to Article 12, Paragraph 12(c).
[21] ICESCR, General Comment 14 to Article 12, Paragraph 12(d).

progressive realization describes the core aspects of State's obligations in respect of Economic, Social, and Cultural Rights. The progressive realization clause is inserted with the intention that in certain nations due non availability of adequate resources immediate implementation of the provisions may not be possible, in such situations, the Covenant allows attainments of the human right over a period. However, it doesn't mean that such member states do not have any obligations in this regard. It simply means that they shall ensure continuous progress on the implementation of such rights and shall take deliberate steps targeting its attainment. As per General Comment 14, progressive realization means that States parties have a specific and continuing obligation to move as expeditiously and effectively as possible towards the full realization. It contains steps to be taken by State parties to achieve the realization of this right to include provision for the reduction of the stillbirth-rate and infant mortality and for the healthy development of the child, improvement of all aspects of environmental and industrial hygiene, prevention, treatment and control of epidemic, endemic, occupational, and other diseases, and the creation of conditions which would assure to all medical service and medical attention in the event of sickness.

The Declaration of Alma-Ata adopted by the International Conference on Primary Health Care in 1978, is a milestone in the history right to health care and its administration and governance. It recognized right to health as a fundamental right. It imposed obligations on the government as well as international organizations. In its preamble it expressed need for urgent action by all governments, all health and development workers, and the world community to protect and promote the health of all the people of the world. Paragraph 1 of the Declaration reaffirms that health is a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity. The attainment of highest possible level of fundamental human right to health has been recognized as the most important social goal. The declaration has also pointed out the gross inequality in health status of people, particularly between developed and developing nations, and also within the countries. The Declaration thus, emphasized on the principle of non-discrimination, economic and physical accessibility. The declaration also stressed on the role of primary health care and endorsed certain guidelines. Accordingly, it should be based on the

application of the relevant results of social, biomedical and health services research and public health experience.

The Convention on the Elimination of all forms of Discrimination against Women talks about protection of right to health. It talks about access to specific educational information to ensure health[22] and well-being of families, protection of right to health[23] and safety in working conditions, including the safeguarding of the function of reproduction. Article 12 of CEDAW specifically speaks about access to healthcare services to eliminate discrimination. Article 14 talks about access to healthcare facilities of rural women.

As the former United Nations Special Rapporteur on the Right to Health Paul Hunt, observed, the key next step is to foster an understanding "that the right to the highest attainable standard of health is not just a rhetorical device, but a tool that can save lives and reduce suffering, especially among the most disadvantaged." The most powerful tool to achieve this is a concept of accountability that, rather than seeking to blame or punish, seeks to sets standards and to discover what works and what can be improved[24].

2.2.2 Constitutional perspective of right to health

Several Constitutions around the globe has recognized right to health as a fundamental right. Some of them have also recognized the duties imposed upon the State. Article 56 of Constitution of Democratic People's Republic of Korea explicitly provides right to healthcare. It says that the State shall take measures to consolidate and develop the system of universal free medical service. The Constitution of the Republic of Maldives provides a positive right to health. Article 23 of the Constitution provides for realization of good standards of health care, both physical and mental within the limits of its ability and resources. It is recognized as a part of Economic and social rights. Similarly, Article 44 of the Constitution of Uruguay also recognize right to healthcare. On the other hands under some constitutions, like that of India, has recognized as a duty of State.

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[22]CEDAW, art 10
[23]CEDAW, art 11
[24] https://unu.edu/publications/articles/health-and-human-security-in-emergencies.html

In India, the preamble to the Constitution, says that it tries to secure social, economic, and political justice. Right to health is brought under the perspective of social justice.

The Constitution of India does not explicitly provide for right to health as a fundamental right under Part III. The Directive Principles of the State Policy under Part IV of the Constitution imposes an obligation on the State to take adequate steps to ensure health of its people. The provisions of Part IV that specifically talks about right to health are, articles 47, 39 and 41. Article 47 provides for the duty of State to raise the level of nutrition and the standard of living and to 'improve public health'[25]. Under Article 39, guarantee of the health and strength of workers, men and women, children[26] is a state obligation. Under Article 41 state has the duty to ensure public assistance[27] in cases of sickness and disablement.

A crucial feature of DPSP is that they are unenforceable or non-justiciable. It means that unlike Fundamental rights under Part III, the provisions of part IV are not enforceable by any courts. For instance, a person can move the Supreme Court or High Court for the enforcement of a fundamental right, however, for the enforcement of DPSP it is not possible. It has been advocated that they are not law, much less constitutional law and, therefore, their non-observance by the State does not entail any legal consequences[28]. The increasing recognition of social and economic rights in the international sphere has weakened the notion that DPSP are unenforceable[29]. The importance of DPSP was recognized in the case, *Unni Krishnan, J.P*v *State of AP*[30], when the court relied upon Articles 41 and 45 of Part IV to determine the right to education.

Regarding the right to health, some judicial interventions have brought it under the scope of Article 21 of the Indian Constitution, diluting the concept of "unenforceability". Regarding right to health, some judicial interventions have brought it under the scope of

[25]INDIA CONST. art. 47
[26]INDIA CONST. art. 39
[27]INDIA CONST. art. 41
[28] V N Shukla and MP Singh, VN Shukla's Constitution of India, 367, Eastern Book Company, 2013.
[29]*Id. at 371.*
[30]AIR 1993 SC 2178

Article 21 of the Indian Constitution. Right to life is considered one of the fundamental rights, and health is one of the vital indicators reflecting quality of human life[31].

Referring to the judgment in *Munn* v *Illinios*[32], court in *Kharak Singh* v *State of Uttar Pradesh*[33], observed that:

> "*right to life is something more than mere animal existence. The inhibition against its deprivation extends to all those limbs and faculties by which life is enjoyed. The provision equally prohibits the mutilation of the body by the amputation of an arm or leg, or the putting out of an eye, or the destruction of any other organ of the body through which the soul communicates with the outer world.*"

The decision in *Francis Coralie* v *Administrator*[34], expanded the concept of right to life. In this case court observed that:

> "*the right to life enshrined under Article 21 cannot be restricted to mere animal existence, it means something more than just physical survival.*"

Following the decision in *Kharak Singh* v *State of Uttar Pradesh*[35], SC in *PUCL*v *UOI*[36] observed the State's obligation to follow International Laws and regulations while ensuring the fundamental right under Article 21. Later in *C.E.S.C Ltd* v *Subhash Chandra Bose*[37], SC read right to health under Article 21 in accordance with international law, by requiring the application of Article 7(b) of ICESCR and Article 25 of UDHR. The court observed that, "the term 'health' implies more than absence of sickness". It broadly discussed the operational efficacy of Human Rights and the constitutional rights, including right to medical aid and health. The court went further to say that Article 39 (e) of the Constitution enjoins the State to direct its policies to secure the health and strength of workers. It springs from the right to life guaranteed under Article 21.

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[31] National Human Rights Commission, https://www.ihrc.in/wp-content/uploads/2018/06/Womens.pdf, last visited on August 21st 2021.
[32] 94 US 113.
[33] AIR 1963 SC 1295.
[34] AIR 1984 SC 746.
[35] Id.
[36] AIR 1997 SC 568.
[37] AIR 1992 SC 573.

In *State of HP* v *Umed Ram Sharma*[38], 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.

The concept of right to health was a directive principle, which couldn't be enforced by the Courts, however, through various decision it was brought under the concept of right to life under Article 21 widening its ambit and scope, giving it the recognition of a fundamental right.

In *Paramananda Katre* v *Union of India*[39], in context of medico-legal cases, court emphasized that under Article 21 of the Constitution of India, the State has an obligation to preserve life.

2.2.3 Components of Right to health

The first and primary component of right to health is to ensure the availability and access to adequate health care facilities. There are several aspects to right to access to health care. It includes availability of medical equipments, facilities for transportation, adequate health care personnel prepared and ready to meet with large influx of patients, affordability of treatment and medicines, equal access to health care facilities based on principle of non-discrimination, and right to safe and quality care.

In *Consumer Education and Research Centre* v *Union of India*[40],the health consequences of occupational hazards and diseases were discussed. In this case, the concept right to health was brought under the ambit of right to life under Article 21. SC took this decision based on Article 1 of UDHR that it asserts human sensitivity and moral responsibility of every state that all human beings are born free and equal in dignity and rights. It reinforces the faith in the notions of dignity and worth of human beings as envisaged in DPSP. The jurisprudence of personhood or philosophy is covered by Article 21 of the Indian Constitution. SC observed that denial of right to health denudes the livelihood of one person. Thus, in this case, SC held that right to health and medical care is a fundamental right under Article 21 read with Articles 39(c), 41, and 43 of the Indian Constitution. Here, it is hard to overlook the fact that the development of health care system in its present form

[38](1986) 2 SCC 68
[39]AIR 1989 SC 2039.
[40]AIR 1995 SC 922.

began when the health consequences of workmen were taken into consideration. By the end of 19th century, the health care system began to evolve reflecting concerns about health of workers and soldiers[41]. Germany in 1883 offered universal health coverage to include low-income workers. The health care system in Germany is based on the Bismarck Model. It provides insurance system is which is financed jointly by employers and employees through payroll taxes, known as "sickness funds"[42]. Under part IV of the Indian Constitution, the health of workmen is given special consideration. After the decision in *MC Mehta* v *Union of India*[43] , made in wake of Bhopal Gas Tragedy, the Union Parliament inserted a new chapter in the Factories Act, 1948. Presently, the law relating to hazardous processes in factories are dealt under Chapter IV-A of the Act. However, the Act provides for provisions to ensure that the hazardous processes does not end up causing occupational accidents, the State remains silent about the regulation on health care provisioning in instances of occupational and chemical hazards causing public health emergency. In *NALSA* v *Union of India*[44], equal access to health care was brought under the ambit of fundamental rights.

The second component is right to emergency medical care. In *Paschim Banga Khet Mazdoorsamity* v *State of WB*[45], the SC has directed the state to ensure the Constitutional duty of government-owned hospitals to provide timely emergency treatment. The obligation of government was brought under the ambit of right to life under Article 21. The SC made certain directions in this case to ensure proper medical facilities are available for dealing with emergency cases. They are as follows:

I. Availability of immediate primary treatment at Primary Health Centres to stabilize the condition of the affected person;
II. Upgradation of hospitals at District and Sub-Division level to deal with severe cases;

[41] *Supra* note 33 at 11
[42] T.R. REID, *Four Basic Models of Health Care,* 26, The Change Agent, 2009, https://changeagent.nelrc.org/wp-content/uploads/2018/05/Four-Basic-Models-of-Health-Care.pdf
[43] AIR 1987 SC 965.
[44] WP 604 of 2013
[45] AIR 1996 SC (4) 37

III. Provisions for specialist treatments at District and Sub- Division Level to meet the growing needs;
IV. Establishment of a centralized communication system so that the patient can be sent to such hospitals where there are beds available;
V. Proper arrangement of ambulance for transportation of patients if required;
VI. The ambulance shall be adequately equipped, along with necessary medical personal;
VII. The Health Centers, hospitals and medical personnel involved shall be prepared to deal with larger number of patients needing emergency treatments.

In *LabonyaMoyee Chandra* v *State of WB*[46], the role of state in implementing the directions of supreme court given in *Paschim Banga Khet Mazdoorsamity* v *State of WB*.[47] Similarly, in *Ram LubhayyaBhaga*v *State of Punjab*[48], the role and responsibility of State to ensure right to health was upheld.

The right to health as already mentioned is inclusive of quality health care services. According to WHO quality of care is the extent to which health care services provided to individuals and patient populations improve desired health outcomes. In order to achieve this health care must be safe, effective, timely, efficient, equitable and people-centered. It means that the health care shall be of minimum risks and harm to the consumers based on scientific and evidence-based knowledge. One of the most important elements of quality of care is that the delivery of health care services shall be equal to all and shall not differ in quality according to personal characteristics such as gender, race, ethnicity, geographical location or socio-economic status. It shall also take into consideration the needs, and preferences of individuals that avail the services and their culture.

There are judicial decisions where the affordability of medical treatment and government's role in it has been brought under the purview of right to health. In *Kikloskar Bros Ltd* v *ESI Corpn*[49], it was observed that in a welfare state it is the primary duty of Government to provide adequate medical facilities for the people. The Government discharges this

[46] AIR 1998 CAL 494
[47] *Supra* note at 37.
[48] 1998 1 SCR 1120.
[49] (1996) 2 SCC 682.

obligation by running hospitals and health centres that provides medical to person seeking to avail of those facilities. The SC further added right to health care at affordable prices, to the concept of right to health, holding it as a universally recognized right. In *Lt.Col. K S Gopinath* v *Union of India*[50], the Supreme Court has directed the Union of India to consider and formulate criteria for ensuring essential drugs not to fall out of the price control. The decision was based on the notion that drug price control comes under the ambit of right to health. Therefore, it is the State's responsibility to regulate and control the drug price and balance between intellectual property rights and interest of the general public.

In India under the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana, a Central Government initiative has taken steps to ensure free access to health care for economically weaker sections of the population. It includes free diagnosis, treatment, medicines and pre-hospitalization expenses to people below the poverty line.

In *Shashank Deo Sudhi* v *Union of India*[51], affordability of medical treatments in backdrop of COVID-19 pandemic has been discussed. Several applications were made to Supreme Court of India seeking directions to ensure the treatment of COVID-19 infected patients free of cost in all hospitals. The SC has considered the point of view of laboratories with regard to charging of fee as prescribed by ICMR and conducting free test of COVID-19. It was submitted that the fee charged by laboratories were found to cover the expenses incurred by the laboratories, otherwise they would suffer financial restraints. The SC has made clarifications in this regard through its orders. The SC clarified that the PM-JAY already covers the economically weaker sections of the society to avail free access to medical services and held that the private laboratories may charge the payment for testing of COVID-19 from persons who are able to make it. It also directed the Government of India to issue necessary guidelines for reimbursement of cost-free testing conducted by the Private Laboratories.

In *Re: the proper treatment of COVID-19 patients and dignified handling of dead bodies in the Hospital, etc*[52], right to affordable treatment was brought under the ambit of right to

[50]LAWS(KAR)-2002-11-64
[51]WP (Civil) No. 10816 of 2020.
[52]Sou Motu Writ Petition (CIVIL) No.7 of 2020.

health in context of COVID-19 pandemic. In this case Court also looked into the safety measures taken by the hospitals. SC emphasized that the hospitals shall take ensure that the lives of the patients are safe and free from accidents and deaths noticing some incidents of fire in COVID hospitals.

Right to information in health is another essential component of right to health. In order to promote and ensure transparency and accountability, the person availing the services shall be allowed to access the information including medical records. The right to patient to access their medical records have been brought for discussion before the court.

The next component of right to health is right to privacy. According to Black's Law Dictionary, privacy means "*right to be let alone. It is the right of a person to live without unwanted publicity"*. Article 12 of UDHR says that no one shall be subjected to arbitrary interference with his privacy. Article 17 of ICCPR provides for right to privacy.

In India through a series of judicial decisions right to privacy was brought under the purview of Article 21, giving it the status of a fundamental right[53]. In context of patients' rights, it is essential to protect their privacy and maintain confidentiality. In *Mr.X* v *Hospital Z*[54], a patient was diagnosed to be HIV positive. This information was disclosed to the fiancée of the patient by the Doctor. The first issue was the conflict between right to privacy of the patient and fundamental right to live without threat to life or health. The Court in this situation held that the right to be informed overrides the appellant's right to privacy. The second issue was determination of duty to maintain secrecy in doctor-patient relationship. Court held that it is not absolute. Court concluded that the Hippocratic Oath taken by medical practitioners, which becomes a part of professional ethics is not enforceable in the Court of law because it lacks statutory force. In *Kush Kalra* v *Union of*

[53] In *MP Sharma* v *Satish Chandra*, (AIR 1954 SC 300), and *Kharak Singh* v *State of UP,* (AIR 1963 SC 1925), it was held that right to privacy is not a fundamental right. In *Govind* v *State of MP* (AIR 1975 SC 1378), SC took a different turn. It was observed that the Constitution of India does not explicitly provides for right to privacy, however, by expanding the scope of Article 21, it can be given the status of a fundamental right. In *Naz Foundation* v *Government of NCT* (WP(C) No.7455/2001) , while dealing with consensual homosexual relationships, court upheld *right to privacy to protect a private space in which man may become and remain himself.* Finally, in *KS Puttuswamy* v *Union of India* (WP (C) No. 494 of 2012) , it was settled that right to privacy comes under the scope of Article 21.

[54] CA 4641 of 1998.

India[55], in context of right to privacy, SC put an end to affixing posters outside the homes of patients having COVID-19. It is an important decision in context of PHE for the protection of privacy and data concerning the affected person.

2.3 CONCEPT OF PUBLIC HEALTH EMERGENCY

A PHE is defined as much by their health consequences as by their causes and precipitating events[56]. A situation becomes emergent when its health consequences have the potential to overwhelm routine community capabilities to address them[57]. The definition is inclined towards the whole scale, timing or unpredictability that threatens to overwhelm the routine capabilities and with all-hazards approach to preparedness[58]. The emergence of deadly virus, pathogens, bacterial and other communicable infections were expected and feared by public health community due to the fluctuating life patterns of human beings across the world. Outbreak of communicable diseases had been an international concern at several points in the history. It dates back to medieval times, at the outbreak of Bubonic Plague, which had resurfaced several times through history[59].

According to WHO, a public health emergency is defined as "*an occurrence or imminent threat of an illness or health condition, caused by bio-terrorism, epidemic or pandemic diseases or a novel and highly fatal infectious agent or biological toxin that poses a substantial risk of a significant number of human facilities or incidents or permanent or long-term disability. It is further states that the declaration of a state of public health emergency permits the governor to suspend state regulations, change the functions of state*

[55]WP(C) No 1213 of 2020.

[56] AUF DER HEIDE, DISASTER RESPONSE: PRINCIPLES OF PREPAREDNESS AND COORDINATION, (Mosby 1989).

[57] LINDELL MK, PERRY RW, BEHAVIORAL FOUNDATIONS OF COMMUNITY EMERGENCY PLANNING, (Hemisphere Publishing Corp).

[58] Christopher N, Lurie N, Wasserman J, Zakowski S, *Conceptualizing and defining Public Health Emergency Preparedness,* AJPH, 2007, 9-11.

[59] Seven J, *The Black Death: The timeline of Gruesome Pandemic,* (last visited March 15th 2021, 9:20PM), https://www.history.com/news/black-death-timeline

agencies"[60]. WHO in this regard has opined that due to the increase in production and use of chemicals, the health sector shall widen its conventional roles and responsibilities to address the public health and medical issues associated with the use of chemical and their effect on health.

Article 1 of International Health Regulations, 2005, defines a public health emergency of international concern as *an "extraordinary event which is determined as provided in these regulations; to constitute a public health risk to other States through the international spread of diseases and to potentially require a coordinated international response*". It further defines "public health risk" as a "*likelihood of an event that may affect adversely the health of human populations with an emphasis on one which may spread internationally or may present a serious and direct danger"*[61].

There is no uniform definition for public health emergency. From the above observations a more inclusive definition can be formulated. A public health emergency is a situation where there is an occurrence or imminent threat of an infectious or a communicable a disease, including pandemics and epidemics, or a chemical incident including radio-active disasters or biological accidents, damaging the health and well-being of the affected populations, or the requirement of emergency medical care arising out of natural calamities, resultantly compelling the appropriate government to take immediate measures to provide health care facilities to affected population which is different from the ordinary public health measures.

To understand the concept of PHE in its completeness it is essential to identify the meaning of the terms used in the above definition. They are as follows.

- Communicable diseases are illness caused by viruses or bacteria that people spread to one another through contact with contaminated surfaces, bodily fluids, blood products, insect bites or through the air[62]. HIV, Hepatitis A, B and C, Measles, Salmonella, etc. are examples of communicable diseases[63]. A Communicable or

[60] WORLD HEALTH ORGANIZATION, https://www.who.int/hac/about/definitions/en/, (last visited March 15th 2021).
[61] IHR, Article 1.
[62] NCBI, https://www.ncbi.nlm.nih.gov/books/NBK470303/,(last visited May 15 2021).
[63] *Id* at 6.

infectious disease is an illness due to the transmission of a specific infectious agent or its toxic products from an infected person, animal, or inanimate source to a susceptible host, either directly or indirectly[64].

- An epidemic is "*the occurrence of more cases of disease, injury or other health conditions than expected in a given area or among a specific group of persons during a particular period*"[65].
- A pandemic occurs over a wide geographic area such as multiple countries or continents and affect a significant portion of population. There will be widespread growth or extend of the disease[66]. According to WHO, a pandemic is the world wise spread of a new disease. Pandemic is often defined as *"an epidemic occurring worldwide or over a very wide area, crossing international boundaries and usually affecting a large number of people*"[67]. In January 2020, WHO has declared COVID-19 as a Public Health Emergency of International concern[68]. Later in March 2020 COVID-19 was declared as global pandemic by WHO[69]. According to WHO, Coronavirus disease or COVID-19 is an infectious disease caused by a newly discovered coronavirus, causing mild to moderate respiratory illness and recover without special treatment[70]. The Spanish flu of 1918 have had lasted for almost two years[71]. Earlier, the 2009 H1N1 Swine Flu had been considered as a

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[64] MIQUEL PORTA, 2008, A DICTIONARY OF EPIDEMIOLOGY, (Oxford university Press, Oxford, 2014).
[65] CENTERS FOR DISEASE CONTROL PREVENTION, https://www.oxfordreference.com/view/10.1093/acref/9780199976720.001.0001/acref-9780199976720-e-1373 https://www.cdc.gov/csels/dsepd/ss1978/glossary.html#:~:text=epidemic%20the%20occurrence%20of%20more,way%20(see%20also%20outbreak). (last visited April 6th 2021).
[66] MERRIAM WEBSTER, https://www.merriam-webster.com/dictionary/pandemic#:~:text=1%20%3A%20occurring%20over%20a%20wide,and%20claimed%20millions%20of%20lives, (last visited April 6th 2021).
[67] PORTA M, A DICTIONARY OF EPIDEMIOLOGY, (Oxford University Press, 2014).
[68] WORLD HEALTH ORGANIZATION, https://www.who.int/publications/m/item/covid-19-public-health-emergency-of-international-concern-(pheic)-global-research-and-innovation-forum, (last visited March 15th 2021).
[69] *Id.* at 11.
[70] WORLD HEALTH ORGANIZATION, https://www.who.int/health-topics/coronavirus,), (last visited April 6th 2021).
[71] CENTERS FOR DISEASE CONTROL PREVENTION, https://www.cdc.gov/flu/pandemic-resources/1918-pandemic-h1n1.html, (last visited March 15th 2021).

global pandemic[72]. Various forms of cholera have also been revived several times and been a global threat at different times[73].

- A chemical incident is the uncontrolled release of a toxic substance, potentially resulting in harm to public health and the environment[74]. Chemical incidents can occur as a result of natural events, or as a result of accident or intentional events[75]. It might refer to anthropogenic or technological events, including explosion at a factory that stores or uses chemical, contamination of the food or water supply with a chemical, oil spill, a leak from a storage unit during transportation, deliberate release of chemicals in conflict or terrorism, and outbreak of disease that is associated with a chemical exposure[76]. Chemical incidents arising from natural sources include volcanoes, earthquakes, and forest fires[77].
- A biological incident is likely to take on of the following forms: Rapid epidemic spread of an infectious disease within or spreading from its normal geographic boundaries; accidental escape of a pathogenic disease-causing organism from a laboratory, deliberate release as part of terrorist or other malicious activity[78]. Examples include outbreak of smallpox in Birmingham in 1980, and 2001 Anthrax Attacks in USA[79].
- Bioterrorism is the intentional release or threat of release of biological agents, such as viruses, bacteria, fungi, or their toxins, in order to cause disease or death among human population or food crops and livestock to terrorize a civilian population or manipulate the government[80].

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[72]CENTERS FOR DISEASE CONTROL PREVENTION, https://www.cdc.gov/h1n1flu/who/ , (last visited March 15th 2021).
[73]WORLD HEALTH ORGANIZATION, https://www.who.int/news-room/fact-sheets/detail/cholera, last visited March 15th 2021).
[74] WORLD HEALTH ORGANIZATION, https://www.who.int/health-topics/chemical-incidents#tab=tab_1, (last visited April 6th 2021).
[75] *Id* at 12.
[76] *Id* at 12.
[77] *Id* at 12.
[78] Hunt P, Greaves I, *Oxford Manual of Major Incident Management, 2-27, 2017,* OXFORD MEDICINE ONLINE, https://oxfordmedicine.com/view/10.1093/med/9780199238088.001.0001/med-9780199238088-chapter-9, (last visited April 6th 2021).
[79] *Id* at 16.
[80] CENTERS FOR DISEASE CONTROL PREVENTION, http://www.bt.cdc.gov/bioterrorism/overview.asp, (last visited April 6th 2021).

- Health as already mentioned is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity[81].
- Well-being includes physical, economic, social. Developmental, emotional and psychological well-being along with life satisfaction[82].
- Affected persons include the populations and the community members who seek assistance[83].
- Emergency medical care is a specialty medical service concerned with the care and the treatment of acutely ill or injured patients who need immediate medical attention[84].
- Natural disasters are sudden and terrible event in nature such as hurricane, tornado or flood that usually results in serious damage and many deaths[85].
- Appropriate Government means the Central and State government of a Nation[86].
- Health-care facilities are hospitals, primary health-care centres, isolation camps, burn patient units, feeding centres and others. In emergency situations, health-care facilities are often faced with an exceptionally high number of patients, some of whom may require specific medical care. For instance, treatment of chemical poisonings[87].

2.4. CHALLENGES POSED BY PUBLIC HEALTH EMERGENCY

The challenges faced by Appropriate Governments during a PHE can be categorized into six. They are protection of human rights during PHE, emphasizing on right to health, prevention, and control of spread infectious or communicable diseases, management of

[81] International Health Conference (2002), Constitution of World Health Organization, 1946, *Bulletin of World Health Organization,* World Health Organization
[82] [82] CENTERS FOR DISEASE CONTROL PREVENTION, https://www.cdc.gov/hrqol/wellbeing.htm, (last visited May 6th 2021).
[83] The concept is understood on the basis of definition of Affected persons given by International Organization for Migrants, https://www.iom.int/sites/default/files/our_work/DOE/humanitarian_emergencies/AAP/two-pagebriefonaap.pdf, (last visited May 16th 2021).
[84] Based on the definition of emergency medicine by Merriam Webster, https://www.merriam-webster.com/dictionary/emergency%20medicine, (last visited May 16th 2021).
[85] Merriam Webster, https://www.merriam-webster.com/dictionary/natural%20disaster , (last visited May 16th 2021).
[86] Based on Section 2(a) of Industrial Disputes Act, 1947, https://indiankanoon.org/doc/1737494/, , (last visited May 16th 2021).
[87] WORLD HEALTH ORGANIZATION https://www.who.int/environmental_health_emergencies/services/en/, (last visited March 15th 2021).

health care establishments, regulation of clinical trials, and ensuring availability of vaccines and essential medicines at affordable and reasonable price.

2.4.1 Protection of Human Rights

Protection of Human rights is a key component of disaster management[88]. The human rights that shall be given priority during a PHE includes *vis-à-vis* right to life and duty to protect life[89], right to non-discrimination, and right to health and access to health care[90] and its various dimensions[91].

2.4.2 Prevention and Control of disease and toxic agents

The State when informed that there is a potential or an imminent threat of illness or communicable or infectious disease, shall take measures to prevent its occurrence in the country, by ensuring isolation and quarantine facilities. It is the duty of the State to prevent the occurrence of such disease by gathering information and conducting public health surveillance (hereinafter referred to as PHS). A public health surveillance is the ongoing, systematic collection, analysis, and interpretation of health-related date essential to the planning, implementation, and evaluation of public health practice[92]. It helps in detecting the health events, collection and consolidation of pertinent data, investigation and confirmation of cases or outbreaks, feedback of information to those providing the data, feed-forwarding to central levels and reporting data to the next administrative level[93]. Once there is an outbreak of such disease, the government shall continue with the PHS and shall take steps to prevent uncontrollable spread of the disease or illness. The maintenance of PHS will be beneficial at the events of natural calamities and chemical disasters as well, to prevent spread of illness at relief camps, etc. In the event of ongoing COVID-19 pandemic

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[88] HENK TEN HAVE, Disaster, *Vulnerability and Human Rights*, DISASTERS: CORE CONCEPTS AND ETHICAL THEORIES, 157-174, (Springer, 2018).
[89] UNITED NATIONS, https://www.un.org/victimsofterrorism/sites/www.un.org.victimsofterrorism/files/un_-_human_rights_and_covid_april_2020.pdf, (last visited May 18th 2021).
[90] Id at 35.
[91] The concept of right to health has already been discussed at pages 1-14
[92] WORLD HEALTH ORGANIZATION, https://www.who.int/immunization/monitoring_surveillance/burden/vpd/en/ , (last visited May 18th 2021).
[93] Id at 28.

one of the major obstacles is the re-emergence and relapse of the disease[94]. The most important methods were social distancing, use of masks, proper sanitization[95]. It has also issued guidelines on surveillance, preparedness, essential health services, including clinical and laboratory services, country level monitoring, healthcare of healthcare workforce, essential resource planning and guidelines with respect of travelling.

2.4.3. Management of Health-Care Facilities

The management of health-care facilities have to be viewed in two aspects. The State plays two important roles here, vis-à-vis, a provider and a regulator. It is the duty upon the State to ensure quality health care services to its citizens. The inadequacy in public health system leads people to approach the private health sector, here state becomes compelled to make laws for regulating the existing system. In this regard the duties and obligations of state include formulation of legal provisions to regulate clinical establishments, giving importance to emergency medicine, isolation wards, quarantine facilities, and other infrastructural provisions; preparing the health care workers to deal with unforeseen situations such as pandemic, natural calamities and chemical disasters; management of medical records, protection of patients' rights, ensuring the mental health of affected population, regulating the telemedicine practices, and management of biomedical wastes.

2.4.4 Regulation of health care workforce

At the same stance as protection of patients' rights lie, the rights of healthcare workforce should also be noted. There shall sufficient labour laws protecting the interests of the health workers, which ranges from medical to para medical professionals. The State is obliged to take steps to prevent violence against health care workers, while discharging their duties. The wages, working hours, reimbursement in matters of leave due to exposure disease or toxic chemical or biological agents, etc. shall also be given sufficient consideration.

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[94] Infectious diseases and Epidemiology, https://clinmedjournals.org/articles/jide/journal-of-infectious-diseases-and-epidemiology-jide-6-138.php?jid=jide , (last visited May 18th 2021).

[95] WORLD HEALTH ORGANIZATION, https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public, (last visited April 8th 2021).

In this regard the concept of medical negligence comes into play which helps to establish the liability of medical professionals. In *Bolam* v *Friern Hospital Management Committee*[96], the test for determination of standard of care owed by a medical professional was established. It is often known as the Bolam Test. The medical professional will not be in breach of their duty of care if they have acted in a manner which was in accordance with practices accepted as proper by a responsible body of other medical professionals with expertise in those particular areas. The Bolam Test has often been adopted in several Indian decisions. In *Whitehouse* v *Jordan*[97], determination of error of judgement depends on the nature of error. It is one that would not have been made by a reasonably competent professional man professing to have the standard and type of skill and acting with ordinary care, then it is not negligent. In *Whitehouse* v *Jordan*[98], determination of error of judgement depends on the nature of error. It is one that would not have been made by a reasonably competent professional man professing to have the standard and type of skill and acting with ordinary care, then it is not negligent.

The decision in *Indian Medical Association* v *VP Shantha*[99], is primarily known for bringing 'service' rendered by medical practitioner and proceedings against the 'deficiency in service' by such medical practitioner before a forum under the Consumer Protection Act, 1986. SC observed that in order to determine medical negligence, sufficient consideration shall be given to expert opinion. Earlier in *Laxman Balakrishna Joshi* v *TrimbakBapu Godbole*[100], it was observed that a doctor owes a duty of care in deciding whether to undertake the case, determining the form of treatment and administration of such treatment. A breach of any of these duties renders it negligent. He or she shall also exercise a reasonable degree of care while administering such treatment.

In *Poonam Verma* v *Ashwin Patel*[101], a registered homeopathic practitioner prescribed allopathic medicine to a patient, was held to negligent and liable to compensate for the

[96] [1957] 1 WLR 583.
[97] [1981] 1 ALL ER 267.
[98] [1981] 1 ALL ER 267.
[99](1995) 6 SCC 651
[100] 1969 (1) SCR 206.
[101]AIR 1996 SC 2111.

death of such patient. In *AchutraoHaribhau Khodwa* v *State of Maharashtra*[102], it was held that negligence cannot be attributed to a doctor so long as he is performing his duties to the best of his ability with due care and caution. In, *M/S Spring Meadows Hospital* v *Hariol Ahluwalia*[103], SC held that an error of judgement alone is not necessarily negligence. In *State of Haryana* v *Santra*[104]approved the Bolam test and held that only the breach of certain duties owed by a doctor in his professional capacity will become negligence.

In *Jacob Matthew* v *State of Punjab*[105], offence under Section 304A of Indian Penal Code was registered against the appellants, who were doctors. The deceased was suffering from cancer in an advanced stage and was required to be kept at home and given proper nursing, food, and care. The appellants admitted him as an in-patient due to the influence of the sons of the deceased. Though the patient was treated with utmost care and caution and given all the required medical assistance by the doctors and para-medical staff, he finally yielded to death on hospital bed. Here, the liability in cases of medical negligence was discussed. The Court observed that generally the negligence shall be gross or of a very high degree and further added that a simple lack of care, an error of judgment or an accident, is not proof of negligence on the part of a medical professional. The Supreme Court concluded that a professional may be held liable for negligence in the following instances:

I. He or she does not possess the requisite skills
II. He or she did not exercise his possessed skills with reasonable competence in the given case
III. The standard to be applied whether the person has been negligent or not would be that of an ordinary competent person exercising ordinary skill in that profession, as it is not possible for every professional to possess the highest level of expertise or skills in that branch
IV. A failure to use special or extraordinary precautions or existence of alternative methods is not a standard for judging the alleged negligence.

[102] (1996) 2 SCC 634.
[103] (1998) 4 SCC 39
[104] (2000) 5 SCC 182.
[105]AIR 2005 SC 3180.

V. prosecute a medical professional for negligence it must be shown that the accused did something or failed to do something which in the given facts and circumstances no medical professional in his ordinary senses and prudence would have done or failed to do.

Proper legal regulations on medical negligence will give legal immunity to medical and paramedical Practioners when the matter is taken before a Court. Also creating awareness among people regarding the same would also curb the violence against health care workforce.

2.4.4. Regulation on clinical trials

The clinical trials involving and affecting human beings through time has raised several controversial issues. The Nuremberg Trial, Dachau Hypothermia Study, the experiments of twins conducted by Joseph Mengele, have evidenced the encroachment of human rights, and thereby reflecting the need for legal regulations in this regard. Particularly, in the events of outbreak of infectious diseases, it is necessary to ensure the clinical trials are not corrupted by any mal practices. The key issues in clinical trials include data collection considerations; observance of ethical principles; training, communication and management of the trial team and leadership, protecting the interests of the participants[106]. In this regard the State shall make laws in conformity with the international standards taking into consideration the situation in hand.

2.4.5. Availability of pharmaceutical products at affordable and reasonable price

As already discussed, access to health care is integrated with the notion of availability of medicines at affordable and reasonable price. It is one of the basic rights of patients. However, the intellectual property rights granted to pharmaceutical products have often faced criticism that it results in increase in drug price and negates the access to healthcare. It mainly affects the low-income and middle-income class. For this reason, the strict implementation of the TRIPS Agreement had been widely criticized particularly by India and Brazil as it led to conflict between health and welfare of society and the economic

[106] Francs Shiely, Managing Clinical Trials during COVID-19: experience from a clinical research facilitiy, https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-020-05004-8, (last visited April 8th 2021).

rights of the individual patent holders. This issue was overcome by the Doha Declaration which gave a pro-health interpretation to TRIPS Agreement[107]. In this regard it is the duty of State to ensure that the essential medicines will be available to general public during the event of a PHE. The conflict between the Intellectual property rights and interests of general public shall be balanced during such situations.

2.5 CONCLUSION

The right to health has been recognized by several international and domestic legal instruments as well enforced by judiciary. It is a settled law that right to health comes under scope and ambit of right to live. At every point in health care services including public health emergency it is the duty of the state to ensure right to health and its components have been recognized and enforced. This could be achieved by the help of enacting a new legislation containing the provisions to deal with and regulate the functioning of hospitals and other clinical establishments, identifying their duty and defining the quality of care.

Most of the regulations, in India are inclined towards disaster management, prevention of spread of disease or infection and distress relief. There are only a few legal provisions regarding ensuring sufficient health care facilities and provisions during PHE, which are sine qua non to prevention and management of PHE. In such instances it is necessary to regulate the availability of essential medicines, including vaccines, drug prices, clinical and laboratory availability and provide adequate financial support for preparation and response to clinical establishments. The state shall pay special attention to the needs of affected persons requiring medical care which includes, emergency medical care to affected persons, medical care to persons with chronic illness, sexual and reproductive health services, mental health and psychological care, and prevention of infectious diseases during natural calamities and industrial accidents.

Currently, the primary objective of a State in the event of a PHE, are focused on prevention and curing of the disease. Here the question is whether the Nation States were prepared to

[107] Nadia Natasha Seeratan, *The negative impact of intellectual property patent rights on developing countries: An examination of the Indian Pharmaceutical Industry*, 3 SCHOLAR 339 (2001).

face such a situation and capable enough to address the health rights of its individuals, as if in a normal situation? On 14th April 2021, there were 679,003 COVID-19 cases were reported in 24 hours globally[108].. In a technologically advanced epoch, even a year after emergence, identification, and declaration as a pandemic, and taking several steps to tackle it, COVID-19 cases were found to be increasing. It shows the inadequacy of legislative measures in ensuring preparedness on part of health care system to address such situations. The nation states have taken measures for the prevention of diseases, however failed to address the issue whether the health care system in respective countries are efficient to deal with a pandemic.

[108] WORLD HEALTH ORGANIZATION, https://covid19.who.int/table, (last visited April 14 2021).

CHAPTER 3

INTERNATIONAL LEGAL INSTRUMENTS ON PREVENTION AND MITIGATION OF PUBLIC HEALTH EMERGENCY

3.1 INTRODUCTION

Chapter 3 deals with the legal framework at international level that deals with prevention and control of public health emergency. It deals with Examination of International Legal Framework governing global health in PHE situations. The chapter analyzes the role of World Health Organization, the guidelines issued by World Health Organization and the provisions of International Health Regulations, an instrument of International Law which is binding on WHO Members. The aim to analyze the International legal framework is to understand the lacunae in the present Indian legal system governing the public health provisioning, in special reference to PHE. An analysis of International Law in this area, helps to examine whether the Indian Laws follow the same.

The concept of right to health at international level has already been discussed in chapter 2. This chapter conducts a critical examination of the international legal instruments on prevention and mitigation of public health emergency. The public health emergency as identified by the international instruments is not limited to epidemic prone diseases alone but also extends to biological, chemical and nuclear hazards, including the chemical or nuclear contamination of the environment, and contaminated food and pharmaceuticals[109].

This chapter gives an insight into an overview of international position, based on role of WHO and implementation of International Health Regulations, 2005.

This chapter is divided into four parts. The first part deals with the determination and termination of PHE. The role of WHO and other international bodies to provide aid and assistance. It mainly prescribes the mechanism by which a PHE must be approached, beginning with obtaining verification from the concerned party. The second part deals with legal obligations of the member states to set up national focal points, encourage and maintain health surveillance, their obligation to notify WHO on events constituting PHE, duties of information sharing, health response and compliance with temporary recommendations of WHO. In the third part, the chapter deals with protection of rights of human participants involved in clinical trials to develop drugs and vaccines during public health emergency. It analyzes the previous violations of human rights of research

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[109] *Infra* at 20.

participants, based on which the contemporary legal position is discussed. And the fourth part deals with management of health care waste, which is an inevitable aspect particularly during pandemics, epidemics, and radioactive disasters.

The implementation of international legal provisions in India will be discussed specifically in Chapter 5 that deals with "general overview of legal response to PHE in India". The critical analysis conducted in this chapter would also help to identify and fill in the lacunae in Indian legal position dealing with PHE.

3.2 AN OVERVIEW OF PREVENTION AND MITIGATION OF PUBLIC HEALTH EMERGENCY AT INTERNATIONAL LEVEL

The pandemics and natural and man-made disasters have devastating effect on public health. World Health Organization, which is a specialized agency of United Nations, having its own Constitution, separate member states, governing bodies, executive heads and secretariats. It conducts a Programme of importance for the United Nations in a particular field, in case of WHO, it is health, under general review of the General Assembly and the Economic and Social Council[110]. World Health Organization's primary objective is to direct and coordinate authority on public health to promote highest possible level of health[111]. The World Health Organization Report titled "Advancing *the Right to Health: the vital role of law*", specifically deals with Public Health Emergencies[112]. The report observes that an effective system for prevention and control of PHE could be achieved through legal instruments, when supported by effective health governance systems[113]. The health governance system should be based on coordinated and intersectional action, evidence-based laws, regulatory capacity, and through judicial intervention[114]. WHO provides guidance and leadership in matters critical to health and engages in partnership where joint action is required. It works with countries to increase and sustain access to prevention, treatment, and care. It set priorities and strategies for conducting and coordinating health responses. It stimulates the generation and dissemination of valuable knowledge shaping the research agenda.

The report discusses the fundamental principles and objectives of the Regulations and its importance in the event of PHE. The report further provides for National Public Health Emergency

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[110]KC JOSHI, INTERNATIONAL LAW AND HUMAN RIGHTS, 381-390, Eastern Book Company, (2019).
[111]WORLD HEALTH ORGANIZATION,https://www.who.int/about.
[112]WORLD HEALTH ORGANIZATION, *Advancing the right to health: the vital role of law,* 165-180, (2017) http://www.who.int/healthsystems/topics/health-law/health_law-report/en.
[113]Gostin L, *Advancing the right to health: the vital role of law,* 107(11), AJPH,1755-1756, (2017).
[114]*Id* at 1755.

Plans. The report suggest that the State Parties shall prepare and regularly review a national emergency plan, during ordinary times. The National Emergency plan helps to establish a clear command structure for decision-making and for activating and coordinating resources during PHE. It shall address the officials, agencies and relevant advisory bodies, such as national emergency councils and standing committees advising in specialist areas being in operation during a PHE. It shall describe the roles and powers of officials performing key operational or executive roles during an emergency. It includes the health minister, chief health officer, director of human biosecurity. Under the National Public Health Emergency Plan the authorities shall have the powers to expand the health care or disaster management workforce by co-opting personnel from other agencies and jurisdictions under a unified command structure; seizure of property to establish emergency response, ensure the availability and rapid distribution of pharmaceuticals and supplies; conduct surveillance, mandate vaccinations, treatment, isolation or quarantine of infected or potentially infected individuals. It shall ensure stockpiling of essential pharmaceuticals and medical supplies. The plan shall consider logistics while distributing essential supplies to areas of greatest need following a PHE. The report provides for the management and regulations of premises, facilities and supplies during a PHE. The areas affected or contaminated with infectious diseases during a PHE shall immediately be closed off to general public. The authorities in operation during PHE shall have the power to compel evacuation and closure of such premises. They shall be authorized to enter any premise, including private property for disposal of infectious waste or contaminated material. The report also identifies the scarcity of healthcare workforce during a PHE and provide recommendations to overcome this issue. The Public Health Legislation shall encourage assistance by health professionals during PHE or grant temporary practice licenses to medical professionals and nurses who are inactive, retired, or licensed in other countries or jurisdictions, or allow health professionals to perform functions beyond their licensed scope of practice. The report also provides for immunity of health care workforce from civil suits during PHE, based on United States Model State Public Health Act. It is recommended that the emergency plan during a PHE shall be in accordance with human rights protection provided in International Health Regulations, 2005 and as per the domestic laws. Finally, the report suggests that all these aspects shall be defined in a legislation[115].

The report provides that there shall be proper observance of International Health Regulations, 2005. Under Article 21 of the Constitution of WHO, the World Health Assembly has the authority to adopt regulations to prevent international spread of diseases. Maintenance and promotion of health

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[115] WORLD HEALTH ORGANIZATION, *supra* note at 14.

and safety of people is one of the most important priorities WHO. There are different measures taken to prevent the spread of communicable diseases, beginning from the International Sanitary Conference in 1851[116]. This 19th Century public health diplomacy placed certain obligations on the participating states to give information about outbreaks in their states. The 1951 International Sanitary Conference was replaced and renamed in 1969 as International Health Regulations[117]. The underlying principle of International Health Regulations is to ensure maximum security against the international spread of diseases with a minimum interference with world traffic[118]. This document was limited to the management of cholera, plague, and yellow fever. It imposed requirements of health and vaccination certificate for travellers. The growth and development international travel and trade has led to the emergence or re-emergence of international disease threats and other public health risks, thus, in the Forty-eighth World Health Assembly in 1995 substantial revision of the Regulations adopted in 1969 was demanded[119]. After extensive preliminary works and investigations on revision of IHR, the 58th World Health Assembly adopted the International Health Regulations[120], 2005 on 23rd May 2005, which came into force on 15th June 2007[121]. The purpose and scope of the IHR are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade[122].Presently, the International Legal Instrument governing the PHE is IHR,2005[123]. It is one of the six leadership priorities of the WHO Programme of work, the purpose of which is to promote health and well-being[124].

3.3 DEFINITIONS OF TERMS ASSOCIATED WITH PUBLIC HEALTH EMERGENCYUNDER INTERNATIONAL HEALTH REGULATIONS, 2005.

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[116] Cumming H, *The International Sanitary Conference,* 16(10), AJPH, 975-980, https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.16.10.975-a.

[117]WORLD HEALTH ORGANIZATION, https://www.who.int/ihr/about/FAQ2009.pdf.

[118]WORLD HEALTH ORGANIZATION, *Bulletin of World Health Organization, International Law and Communicable Diseases, https://www.who.int/bulletin/archives/80%2812%29946.pdf*.

[119]WORLD HEALTH ORGANIZATION ,48th WORLD HEALTH ASSEMBLY, http://apps.who.int/iris/bitstream/handle/10665/178296/WHA48_1995-REC-1_eng.pdf?sequence=1, last visited on August 21st 2021.

[120] Hereinafter referred to IHR

[121]WORLD HEALTH ORGANIZATION, https://www.who.int/csr/ihr/WHA58-en.pdf.

[122]IHR, Article 2.

[123] Hereinafter referred to IHR.

[124] Smith WA, Osman S, Public Health Emergencies of International Concern: A historic overview, 27(8), JTM, (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7798963/.

IHR, 2005 defines the terms that are relevant to PHE under Article 1[125]. Proper consideration to the definitions helps to avoid ambiguity and understand the provisions for prevention and control. They are as follows.

- **Affected:** *persons, baggage, cargo, containers, conveyances, goods, postal parcels or human remains that are infected or contaminated, or carry sources of infection or contamination, so as to constitute a public health risk;*
- **Affected area:** *a geographical location specifically for which health measures have been recommended by WHO under these Regulations;*
- **Contamination:** *the presence of an infectious or toxic agent or matter on a human or animal body surface, in or on a product prepared for consumption or on other inanimate objects, including conveyances, that may constitute a public health risk;*
- **Ill person:** *an individual suffering from or affected with a physical ailment that may pose a public health risk;*
- **International traffic:** *the movement of persons, baggage, cargo, containers, conveyances, goods or postal parcels across an international border, including international trade;*
- **International voyage:** *in the case of a conveyance, a voyage between points of entry in the territories of more than one State, or a voyage between points of entry in the territory or territories of the same State if the conveyance has contacts with the territory of any other State on its voyage but only as regards those contacts; in the case of a traveller, a voyage involving entry into the territory of a State other than the territory of the State in which that traveller commences the voyage;*
- **Isolation:** *separation of ill or contaminated persons or affected baggage, containers, conveyances, goods or postal parcels from others in such a manner as to prevent the spread of infection or contamination;*
- **National IHR Focal Point:** *the national centre, designated by each State Party, which shall be accessible at all times for communications with WHO IHR Contact Points under these Regulations;*
- **Public Health Emergency of International Concern:** *an extraordinary event which is determined as provided in these regulations; to constitute a public health risk to other States through the international spread of diseases and to potentially require a coordinated international response*;

[125] IHR, Article 1.

- **Public health risk:** *likelihood of an event that may affect adversely the health of human populations with an emphasis on one which may spread internationally or may present a serious and direct danger.* The concept of a "public health emergency of international concern" is not limited to epidemic prone diseases[126]. It also extends to biological, chemical and nuclear hazards, including the chemical or nuclear contamination of the environment, and contaminated food and pharmaceuticals[127].
- **Quarantine:** *the restriction of activities and/or separation from others of suspect persons who are not ill or of suspect baggage, containers, conveyances or goods in such a manner as to prevent the possible spread of infection or contamination;*
- **Surveillance:** *the systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary;*
- **Traveller:** *a natural person undertaking an international voyage.*

Proper definitions given to the terms associated with public health emergency helps to avoid ambiguities during such vulnerable times. Definitions ensures sustenance to classification of entities within the legal categories and warrant the enforcement of legal consequences[128]. Thus, it helps to determine the nature of public health emergency which in turns helps the governments to take appropriate measures.

3.4 ROLE OF WORLD HEALTH ORGANIZATION UNDER INTERNATIONAL HEALTH REGULATIONS, 2005.

IHR, 2005 deals with the role of WHO in prevention and control of PHE. It talks about duty towards the State party in whose territory an event of PHE has occurred its obligation as well towards other state parties. The functions of WHO is carried out through the Director-General, who determines the event, issues guidelines, aids and offer to collaborate and on the proposal made by the concerned State party declared the termination of such event.

3.4.1 Determination of Public Health Emergency of International Concern:

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[126]WORLD HEALTH ORGANIZATION, *supra* note at 14.

[127] REVISED WHO GUIDANCE FOR THE USE OF ANNEX 2 OF THE INTERNATIONAL HEALTH REGULATIONS (2005), https://www.who.int/ihr/revised.annex2.guidance.pdf, last visited on August 21st 2021.

[128] Macagno F, *Definitions in Law,* BSLA, 2010, 199-217, https://www.researchgate.net/publication/256008191_Definitions_in_Law, visited on August 24th 2021.

The mechanism for determination of Public Health Emergency of International Concern is given under Article 12 of IHR. It is determined by the Director-General of World Health Organization, based on the information received, from the State Party within whose territory an event is occurring. In such event, the Director-General shall consult with the State Party in whose territory the event arises regarding the preliminary determination. If the Director-general and the State Party agree regarding the determination, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the Committee known as Emergency Committee established under Article 48 on appropriate temporary recommendations. If the Director-General and the State Party in whose territory the event arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination shall be made in accordance with the procedure set forth in Article 49. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider the following factors:

- information provided by the State Party,
- the decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern contained in Annex 2 to IHR,
- the advice of the Emergency Committee,
- scientific principles as well as the available scientific evidence and other relevant information; and
- an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic.

If the Director-General, following consultations with the State Party within whose territory the public health emergency of international concern has occurred, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49.

The procedure for determination is given under Article 49. Accordingly, the Director-General shall convene meetings of the Emergency Committee by selecting a number of experts from among those referred to in paragraph 2 of Article 48, based on the fields of expertise and experience most relevant to the specific event that is occurring. The Director-General shall provide the Emergency Committee with the agenda and any relevant information concerning the event, including information provided by the States Parties, as well as any temporary recommendation that the Director-General proposes for issuance. The Emergency Committee shall elect its Chairperson and prepare following each meeting a brief summary report of its proceedings and deliberations,

including any advice on recommendations. The Director-General shall invite the State Party in whose territory the event arises to present its views to the Emergency Committee. To that effect, the Director-General shall notify to it the dates and the agenda of the meeting of the Emergency Committee with as much advance notice as necessary. The State Party concerned, however, may not seek a postponement of the meeting of the Emergency Committee for the purpose of presenting its views thereto. The views of the Emergency Committee shall be forwarded to the Director-General for consideration. The Director-General shall make the final determination on these matters. The Director-General shall communicate to States Parties the determination and the termination of a public health emergency of international concern, any health measure taken by the State Party concerned, any temporary recommendation, and the modification, extension and termination of such recommendations, together with the views of the Emergency Committee.

For the purpose of this Article, "meetings" of the Emergency Committee may include teleconferences, videoconferences or electronic communications[129].

3.4.2 Issuance of Temporary Recommendations

Article 15 provides for issuance of temporary recommendations by Director-General as per the procedure under Article 49 after the determination of public health emergency of international concern under Article 12. Under Article 49 the Director-General shall inform conveyance operators through States Parties and the relevant international agencies of such temporary recommendations, including their modification, extension or termination. The Director General shall subsequently make such information and recommendations available to the general public.

Temporary recommendations may include health measures to be implemented by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.

3.4.3 Assistance by WHO in the form of guidelines

The WHO after consultation with Member States, shall publish guidelines to support States Parties in the development of public health response capacities. On request by a State Party, WHO shall collaborate in the response to public health risks and other events by providing technical guidance and assistance. It shall also assess the effectiveness of the control measures and the severity of the

[129] IHR, Article 12, para.1

international risk in place. It includes the mobilization of international teams of experts for on-site assistance, when necessary. WHO shall provide information supporting such an offer when requested by the State party[130].

On 25th March 2020, WHO had issued a set of interim guidelines titled: "COVID-19: Operational guidance for maintaining essential health services during an outbreak[131]" with aim to ensure immediate actions that countries should consider at national, regional, and local level to reorganize and maintain access to essential quality health services for all[132]. The Covid-19 Guidelines have 6 sections dealing with the following issues:

i. Establish simplified purpose-designed governance and coordination mechanisms to complement response protocols;
ii. Identify context-relevant essential service;
iii. Optimize service delivery settings and platforms;
iv. Establish effective patient flow at all levels;
v. Rapidly re-distribute health workforce capacity;
vi. Identify mechanisms to maintain availability of essential medications, equipment and supplies.

Under Section 1 WHO recommends countries to establish simplified purpose-designed governance and coordination mechanisms to complement response protocols. It includes setting up of triggers or thresholds that activate a phased reallocation of routine comprehensive service capacity towards essential services, through the specific mechanisms identified below. The countries shall also assess and monitor ongoing delivery of essential health services to identify gaps and potential need to dynamically remap referral pathways.

The selection of priorities under Section 2 will be guided by health system context and the local burden of disease. Nevertheless, the primary objectives should be oriented to prevention of communicable disease, averting maternal and child morbidity and mortality, preventing acute exacerbations of chronic conditions by maintaining established treatment regimens, and managing emergency conditions that require time-sensitive intervention. The countries may limit or restrict

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130 IHR, Article 13.
131 Hereinafter referred to as Covid-19 Guidelines.
132 WORLD HEALTH ORGANIZATION, *COVID-19: operational guidance for maintaining essential health services during an outbreak: interim guidance*, World Health Organization, (2020), https://apps.who.int/iris/handle/10665/331561,(last visited on July 7, 2021).

the routine health promotion visits and encourage delivery of vaccinations and antenatal care. The High-priority categories of essential services under Section 2 include the following:

- Essential prevention for communicable diseases, particularly vaccination,
- Services related to reproductive health, including care during pregnancy and childbirth,
- Care of vulnerable populations, such as young infants and older adults,
- Provision of medications and supplies for the ongoing management of chronic diseases, including mental health conditions,
- Continuity of critical inpatient therapies,
- Management of emergency health conditions and common acute presentations that require time-sensitive intervention,
- Auxiliary services, such as basic diagnostic imaging, laboratory services, and blood bank services.

The essential services may be country-specific based on WHO guidance and tools. They countries shall also identify routine and elective services that can be delayed or relocated to non-affected areas. The countries are also encouraged to maintain a report for progressive phased reduction of services.

Section 3 provides for modification of the settings where specific essential services are delivered. Such modifications are made because the existing service locations may be unavailable as they have been designated for the exclusive care of people affected by COVID-19 or for carrying out the routine health service delivery in respect of COVID-19. Section 4 encourages screening and mechanism for isolation of patients tested COVID positive.

Section 5 deals with healthcare workforce. The COVID-19 guidelines address the issues such as shortage, maldistribution, and misalignment between population health needs and health worker competencies. The countries may establish mechanism to identify additional health workforce capacity and shall maximize occupational health and staff safety measure. The countries shall take measures to allocate finances for timely payment of salaries, overtime, sick leave, and incentives or hazard pay, including for temporary workers.

As per Section 6 the Covid-19 guidelines, the countries shall develop priority resource lists. It should be executed in coordination with the overall outbreak response. Suppliers and pharmacies both public and private shall be networked to allow dynamic inventory assessment and coordinated re-distribution. The countries may also create a platform for reporting inventory and stockouts, and for coordination of re-distribution of supplies.

The provisions under COVID-19 guidelines are executed in accordance to Operational Planning Guidelines to support Country Preparedness and Response[133]. It consists of eight pillars that outlines the public health measures that need to be taken to support countries to prepare for and respond to COVID-19. It includes Country-level coordination, planning, and monitoring; risk communication and community engagement; surveillance, rapid response teams, and case investigation; points of entry; national laboratories; infection prevention and control; case management; and provisions for operational support and logistics.

3.4.4 Obtain verification from State parties with respect to public health risks

WHO shall assess the reports from such sources other than notifications or consultations according to established epidemiological principles. After assessment, WHO shall communicate information on the event to the State Party in whose territory the event is allegedly occurring. Before taking any action based on such reports, WHO shall consult with and attempt to obtain verification from the State Party in whose territory the event is allegedly occurring in accordance with the procedure set forth in Article 10[134]. After obtaining verification under Article 10[135], WHO shall offer to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. WHO is obliged to furnish the State Party with sufficient information supporting such offer[136]. In case the State Party does not accept the offer of collaboration, WHO may, when justified by the magnitude of the public health risk, share with other States Parties the information available to it, whilst encouraging the State Party to accept the offer of collaboration by WHO, considering the views of the State Party concerned[137].

3.4.5 Provision of information by WHO

WHO shall send public health information which it has received under Articles 5 to 10 to all States Parties and relevant intergovernmental organizations. It is to enable States Parties to respond to a public health risk and to help other State Parties to prevent the occurrence of similar incidents[138]. The information received is used for verification, assessment and assistance purposes under IHR.

[133] WORLD HEALTH ORGANIZATION Operational Planning Guidelines to support Country Preparedness and Response, World Health Organization, (2020https://www.who.int/docs/default-source/coronaviruse/covid-19-sprp-unct-guidelines.pdf,(last visited on July 7, 2021).
[134] IHR, Article 9.
[135] IHR, Article 10 para 1.
[136] IHR, Article 10 para 3.
[137] IHR, Article 10 para 4.
[138] IHR, Article 11.

WHO shall not make this information generally available to other States Parties, unless otherwise agreed with the concerned States Parties or if the event is determined to constitute a public health emergency of international concern in accordance with Article 12 or information evidencing the international spread of the infection or contamination has been confirmed by WHO in accordance with established epidemiological principles or control measures against the international spread are unlikely to succeed because of the nature of the contamination, disease agent, vector or reservoir or the State Party lacks sufficient operational capacity to carry out necessary measures to prevent further spread of disease or the nature and scope of the international movement of travellers, baggage, cargo, containers, conveyances, goods or postal parcels that may be affected by the infection or contamination requires the immediate application of international control measures[139]. Such information shall be made available to the general public if the other information has already been communicated with the public or if there is a need for the dissemination of authoritative and independent information.

3.4.6 Termination of Public Health Emergency of International Concern.

The procedure for termination of a public health emergency of international concern is given in Article 49. States Parties in whose territories the event has occurred may propose to the Director-General the termination of a public health emergency of international concern and/or the temporary recommendations and may make a presentation to that effect to the Emergency Committee. Establishment of Emergency Committee Article 48. Based on the proposal after carrying out sufficient investigation, it will be terminated. It results in termination of such recommendations, together with the views of the Emergency Committee.

3.5 LEGAL OBLIGATIONS OF THE STATE PARTIES UNDER INTERNATIONAL HEALTH REGULATIONS, 2005.

The regulations provide for the core legal obligations imposed upon the State parties in the event of determination and declaration of a public health emergency of International Concern. The legal obligations include establishment of responsible authorities, dissemination of information and public health response. There are general obligations and obligations to PHE or specific obligations. They are as follows.

3.5.1 Establishment of National Focal Point

[139] IHR, Article 11 para 2.

Each State Party shall designate or establish a National IHR Focal Point and the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations. National IHR Focal Points shall be accessible at all times for communications with the IHR Contact Points designated by WHO. The WHO IHR Contact Points send urgent communications concerning the implementation of IHR with Articles 6 to 12, to the National IHR Focal Point of the States Parties concerned. There are two-fold function to National IHR Focal Points. First, sending urgent communications concerning the implementation of these Regulations to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, under Articles 6 to 12. Secondly, disseminating information to, and consolidating input from, relevant sectors of the administration of the State Party concerned. It includes those responsible for surveillance and reporting, points of entry, public health services, clinics and hospitals and other government departments[140].

3.5.2 Surveillance

Each State Party shall develop, strengthen, and maintain, as soon as possible but no later than five years from the entry into force of the Regulations for that State Party, the capacity to detect, assess, notify, and report events in accordance with these Regulations based on Annex 1 of IHR, 2005. Accordingly, each State party shall develop and maintain capabilities to detect, assess and report disease events at local, intermediate, and national levels[141]. The state parties are primarily responsible for providing resources needed to develop their health surveillance capacities.

3.5.3 Obligation to notify WHO on events constituting public health emergency of international concern

Each State Party shall notify WHO, by the most efficient means of communication available, by way of the National IHR Focal Point, and within 24 hours of assessment of public health information, of all events which may constitute a public health emergency of international concern within its territory in accordance with the decision instrument, as well as any health measure implemented in response to those events. If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA), WHO shall immediately notify the IAEA. It shall be followed by timely, accurate and sufficiently detailed public health information available to it on the notified event. It shall include case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the

[140] IHR, Article 4.
[141] IHR, Article 5.1.

disease and the health measures employed; and report, the difficulties faced and support needed in responding to the potential public health emergency of international concern[142].Under Article 9 States Parties shall, as far as practicable, inform WHO within 24 hours of receipt of evidence of a public health risk identified outside their territory that may cause international disease spread, as manifested by exported or imported; human cases, vectors which carry infection or contamination, goods that are contaminated[143]. WHO based on the information after obtaining verification from concerned State Party shall take immediate action in this regard. In such situations the concerned State Party shall verify and provide within 24 hours: an initial reply to, or acknowledgement of, the request from WHO, available public health information on the status of events referred to in WHO's request; and information to WHO in the context of an assessment under Article 6, including other relevant information[144].

3.5.4 Obligation of Information-sharing

If a State Party has evidence of an unexpected or unusual public health event within its territory, irrespective of origin or source, which may constitute a public health emergency of international concern, it shall provide to WHO all relevant public health information. In such a case, the provisions of Article 6 shall apply in full.

3.5.5 Obligation of Public Health Response

Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern. When requested by WHO, States Parties should provide, to the extent possible, support to WHO-coordinated response activities and shall provide appropriate guidance and assistance to other State Parties affected or threatened by the public health emergency of international concern[145].

3.5.6 Obligation to comply with the temporary recommendations:

The State Parties have an obligation to observe and comply with the directions and recommendations of Director-General in the event of public health emergency of international concern[146].

[142] IHR, Article 6.
[143] IHR, Article 9 para 2.
[144] IHR, Article 10 para 2.
[145] IHR, Article 13.
[146] IHR, Article 15.

Therefore, it is found that the WHO provides guidance and leadership in matters critical to health and engages in partnership where joint action is required. It works with countries to increase and sustain access to prevention, treatment, and care. It set priorities and strategies for conducting and coordinating health responses. It stimulates the generation and dissemination of valuable knowledge shaping the research agenda. The member states will adopt different strategies to tackle the PHE based on International and Domestic laws.

3.6 PROTECTION OF RIGHTS OF HUMAN PARTICIPANTS INVOLVED IN CLINICAL TRIALS TO DEVELOP DRUGS AND VACCINES DURING PHE

Human beings have always been skeptical about clinical trials due to the previous experiences as it was mostly used in military[147]. In *USA* v *Karl Brandt et al*[148] the doctors and administrators were prosecuted for their involvement in unethical and inhumane clinical trials on human beings. The core principles of ethics in clinical trials are autonomy, beneficence, non-maleficence and justice. These principles were formulated by the philosophers Beauchamp and Childress in 1979[149].Autonomy describes the right of an adult to make an informed decision about the procedure they undergo. In *Schloendorff* v *Society of New York Hospital*[150], in the judgement delivered by Justice Cardozo, it was observed that "every adult who is of sound mind has the right to determine what shall be done with his body". It is an essential element in the decision-making process of an individual's health. In *Abduallhi*v *Pfizer*[151], popularly known as the Kano Trovafloxacin trial litigation case children from Kano, a city in Nigeria were made the participants of a clinical trial without their knowledge and consent of their parents. In this case, the trial was conducted overlooking the fact the drug was earlier denied permission to be used in Children. The Kano trial also had the issue of lack of proper communication where the documents furnished to the parents were in English, a language they did not understand. Due to insufficient communication from the investigators, the children were not able to make an intellectual and legitimate decision. The principle of beneficence simply means; "the medical procedure shall be conducted in a manner not prejudicial to the participant". Otherwise, the physician shall perform their duties in a manner

[147] Shuster E, American Physicians at Nuremberg Trial, AJPH, 47-52, (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5719680/, visited on 15th August 2021.
[148] Case I, November 21, 1946-August 20, 1947,https://www.archives.gov/files/research/captured-german-records/microfilm/m887.pdf, visited on 15th August 2021.
[149] Principles of Biomedical Ethics, https://jme.bmj.com/content/28/5/332.2, last visited on 15th August 2021.
[150] 105 NE 92.
[151] 562 F.3d 163.

beneficial to the patients[152]. It is based on the central theme of utilitarianism. Beneficence is the obligation to provide benefits and to balance benefits against risks. The physician shall only act in the best interests of the patients. Utilitarianism**,** a derivative of consequentialism depends on on the notion that it is that is results of actions, laws and policies determines whether certain acts or omissions are right or wrong[153]. The basic aim is to ensure greatest good for the greatest number. It is applied in the field of medicine based on protecting the best interests of the patients. The principle of non-maleficence stands on the notion that do no harm. It is based on the principle of *primum non nocere*, which means "*do no harm*". The physician doesn't have an obligation to benefit the patient but has a duty not to cause harm[154]. It states that the physician shall not do anything harmful to the patient or shall not impose any unnecessary or unacceptable burden upon the patient. The principle of justice aims to promote fair and equitable treatment of individuals. It is an inalienable and imprescriptible right inherent in every human being by virtue of their personality. The duty-based approach in Deontology proposed by WD Ross obligates duty of justice in a physician[155]. It also includes fair distribution of resources. The physicians shall have respect for patients' rights and for morally acceptable laws. It is also seen that the human right to health is available to everyone irrespective of gender, race, caste, place of birth, religion, income. There is historical evidence where poor and vulnerable classes are subjected to clinical trials[156]. Nazi Human experimentation which later underwent the Nuremberg trials is an example of this. Here the experimentation was conducted on prisoners of war, Jews, children etc.[157]. The Kano Trovafloxacin Trial is a modern example[158]. When participants of such categories are taken for study, the investigator shall substantiate the same with scientific validity.

3.6.1 Meaning of Clinical Trials and Phases of Clinical trials

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[152] WMA.com, https://www.wma.net/policies-post/wma-international-code-of-medical-ethics/, (last visited May 22nd 2021).

[153] Stanford Encyclopedia of Philosophy, https://plato.stanford.edu/entries/consequentialism/, (last visited May 22nd 2021).

[154] MN.State.Education, http://web.mnstate.edu/gracyk/courses/phil%20115/Four_Basic_principles.htm, (last visited May 22nd 2021).

[155] Stanford Encyclopedia, https://plato.stanford.edu/entries/william-david-ross/, (last visited May 22nd 2021).

[156] *Supra* at 37.

[157] Weidling P, Villiez A, Loewanue A, Farron N, *Thevictms of unethical human experiments and coerced research under National Socialism, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4822534/*, last visited on August 17th 2021.

[158] International Center for investigative reporting, Nigeria, https://www.icirnigeria.org/pfizer-kano-trial-24-years-after-some-victims-not-compensated-and-still-cant-live-normal-lives/, last visited on August 17th 2021.

Clinical trials are the mode of research which evaluates the effectiveness of drug being developed based on human health outcomes. World Health Organization defines clinical trials as follows[159]:

> *"Clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes. People volunteer to take part in clinical trials to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioral treatments and preventive care."*

Accordingly, Clinical trials are carefully designed, reviewed and completed, and need to be approved before they can start. People of all ages can take part in clinical trials, including children[160]. Phase I studies usually test new drugs for the first time in a small group of people to evaluate a safe dosage range and identify side effects[161].Phase II studies test treatments that have been found to be safe in phase I but now need a larger group of human subjects to monitor for any adverse effects. Phase III studies are conducted on larger populations and in different regions and countries and are often the step right before a new treatment is approved. Phase IV studies take place after country approval and there is a need for further testing in a wide population over a longer timeframe[162].Clinical trials are the primary way to assess the effects of a new drug or medical intervention inhumans and find out if it is effective and safe on them[163].

3.6.2 Human right to free consent in medical and scientific experimentation.

The above-mentioned ethical principles are incorporated in several human rights documents including International Covenant on civil and political rights (ICCPR). Under Article 7 of ICCPR, no one shall be subjected without his free consent to medical or scientific experimentation[164]. The Council of Europe Convention on Human Rights and Biomedicine[165] is the first legal instrument that particularly dealt with biomedical advancements to address the rights and interests of participants in a human rights-based approach. It preserves the right to live with dignity[166]. It ensures the right to respect for

[159] WORLD HEALTH ORGANIZATION, https://www.who.int/health-topics/clinical-trials#tab=tab_1, visited on August 17th, 2021.
[160] *Id.*
[161] *Id.*
[162] *Id.*
[163] US Department of Health and Human Services, https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies, last visited on August 21st 2021.
[164] ICCPR, Article 7.
[165] Hereinafter referred to as Oviedo Convention.
[166] Oviedo Convention, Article 1.

private life in relation to information about his or her health[167].The additional protocol to the convention recognizes informed consent[168], and safety measures[169]. The safety measures include minimization of risk and burden[170], assessment of health status[171], and non-interference with necessary clinical interventions[172]. Likewise in the Convention the additional protocol too addresses the issue of privacy and confidentiality. Any information of a personal nature collected during biomedical research shall be considered as confidential and treated according to the rules relating to the protection of private life[173]. Also, the research participants shall be entitled to know any information collected on their health in conformity with the provisions of Article 10 of the Convention[174].

3.6.3 Duties of physicians

The Nuremberg Code was a resultant of the judgement on Nuremberg Trials involving war Crimes[175] The Code has established 10 standards a physician shall comply with while conducting experiments on human beings. They are:

- Voluntary consent of the subject,
- The experiment shall yield to fruitful results,
- It shall be based on results of experiments on animals,
- Shall avoid all unnecessary physical and mental sufferings and injury,
- No experiment shall be conducted knowing it would result in death,
- Degree of risk shall not exceed the potential outcome,
- Proper preparations shall be taken to avoid death and injuries,
- The experiment shall be conducted only by scientifically qualified persons,
- The subjects shall have the option of withdrawal during the conduct of trial, and

[167]Oviedo Convention, Article 10.
[168]Additional Protocol, Oviedo Convention, Article 14.
[169]Additional Protocol, Oviedo Convention, Article 21 to 23.
[170]Additional Protocol, Oviedo Convention, Article 21.
[171]Additional Protocol, Oviedo Convention, Article 22.
[172]Additional Protocol, Oviedo Convention, Article 23.
[173]Additional Protocol, Oviedo Convention, Article 25.
[174]Additional Protocol, Oviedo Convention, Article 26.
[175] The British Medical Journal, https://media.tghn.org/medialibrary/2011/04/BMJ_No_7070_Volume_313_The_Nuremberg_Code.pdf, visited on August 20th 2021.

- The investigator shall be prepared to terminate the experiment, if he or she has sufficient cause to believe that it is likely to end in death, injuries, etc.

Another important instrument is the Belmont Report, prepared by the National Commission for the protection of human subjects of biomedical and behavioral research. It prescribes clear boundaries between research and practice. It provides for basic ethical principles which refers to those general judgments that serve as a basic justification for the many ethical prescriptions and evaluations of human actions[176]. It propounds the core principles of respect for persons, beneficence, and justice[177]. It also talks about informed consent[178]. Informed consent under the report stands for respect for persons to the degree that they are capable be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied. It also gives guideline son application of justice for selection of research participants[179]. Accordingly, they shall be selected on basis of principles of beneficence in risk benefit assessment[180], the principle of justice giving rise to moral requirements to ensure fair procedures and outcomes in the selection of research subjects[181].

The Helsinki Declaration developed by the World Medical Association provides for the duty of the physician to promote and safeguard the health as well as to respect the rights and interests of the participants[182]. It provides for the right to self-determination which forms part of autonomy[183]. It says that vulnerable groups shall be given special consideration and be protected from exploitation[184]. It also gives importance to informed consent[185].

3.6.4. Ethical Guidelines and good practices in clinical trails

International Ethical Guidelines for Health-Related research involving Humans prepared by the Council for International Organizations of Medical Sciences with the World Health Organization provides for fundamental justification for undertaking research that shall

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[176] Belmont Report, Part B.
[177] *Id.*
[178] Belmont Report, Part C, Paragraph 1.
[179] *Id.*
[180] Belmont Report, Part C, Paragraph 2.
[181] Belmont Report, Part C, Paragraph 3.
[182] Helsinki Declaration, Preamble.
[183] Helsinki Declaration, Paragraph 9.
[184] Helsinki Declaration, Paragraph 19.
[185] Helsinki Declaration, Paragraph 25.

have scientific and social values. It shall be carried out in a way protecting human rights, and respect, protect and shall be fair to all participants[186]. It says that there shall be equitable distribution of benefits and burdens in selection of participants[187]. There shall be effective intervention by the participants enforcing choice of control in clinical trials[188]. In addition, the ICH Guidelines for Good Clinical Practices provides for informed consent[189], safety and wellbeing of trial subjects[190]. It is applicable in the EU, Japan and the United States. And there is EC Ethical Considerations for clinical trials conducted in Children that provides for Legal Representation for minors[191], informed consent[192], measures of risks and benefits[193], avoidance of pain and sufferings[194], assent from children[195], and provides for insurance schemes for their protection[196].

3.7 HEALTH CARE WASTE MANAGEMENT

Management of health care waste is an important issue having effect on environment and public health in general[197]. It includes all wastes generated by medical activities. When it comes to pandemic, such as COVID-19 due to its contagious nature, such health waste shall be appropriately disposed off with adequate care and caution in a way preventing further spread[198]. The WHO Guidelines on Health care Waste management talks about radio-active wastes[199], human anatomical waste[200], pharmaceutical waste[201], etc. Radioactive waste includes liquids, gases and solids contaminated with radionuclides whose ionizing radiations have genotoxic effects. Human anatomical waste comprises non-infectious human body parts, organs and tissues and blood bags. Pharmaceutical waste embraces a multitude of active ingredients and types of preparations. The spectrum ranges from teas through heavy metal containing disinfectants to highly specific

[186] WHO Guidelines, Guideline 1.
[187] WHO Guidelines, Guideline 2.
[188] WHO Guidelines, Guideline 5.
[189] ICH Guidelines, Paragraph 4.8.
[190] ICH Guidelines, Paragraph 1.
[191] EC Guidelines, Paragraph 5.
[192] EC Guidelines, Paragraph 6.
[193] EC Guidelines, Paragraph 11 and 12.
[194] EC Guidelines, Paragraph 10.
[195] EC Guidelines, Paragraph 7.
[196] EC Guidelines, Paragraph 22.
[197] WHO Guidelines on Health Care Waste Management, Paragraph 1.3.
[198] Sharma BH, *Challenges and opportunities in solid waste management during and post covid-19 scenario,* RCR, 162, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7362850/, last visited on August 20th 2021.
[199] WHO Guidelines on Health Care Waste Management, Paragraph 1.3.
[200] *Id.*
[201] *Id.*

medicines. Waste management therefore requires the use of a differentiated approach. This category of waste comprises expired pharmaceuticals or pharmaceuticals that are unusable for other reasons[202].

The WHO guidelines recommend that the health care waste shall appropriately managed through a well identified stream from their point of generation until their final disposal. It is comprised of various steps, starting from generation, segregation, collection and on-site transportation, on-site storage, offsite transportation, to treatment and disposal of the health care waste[203]. Before the generation of waste, the clinical establishments shall investigate whether they can reduce the amount of waste produced and their mechanism for its collection, storage, treatment and disposal.

3.8 CONCLUSION

In this chapter, the various aspects and legal provisions governing public health emergency has been discusses. Three major issues are basically dealt in this chapter. The first one is purely related to role and responsibilities of state in ensuring right to health in the events of PHE. A detailed examination of WHO instruments show that an effective system for prevention and control of PHE could be achieved through legal instruments that are to be adopted by the member states. World Health Organization Report titled "Advancing *the Right to Health: the vital role of law*"[204] gives an insight into the concept of public health emergency, where it states that adequate coordination and intersectional action are the primary requirements to be satisfied by the State to provide health care services to affected persons. It gives support and assistance to affected states in the form of guidelines. And in case of a PHE, it also specifies the conditions for declaration of emergency as well as its termination. WHO repeatedly recommends for adoption of emergency plan during a PHE in accordance with human rights protection provided in International Health Regulations, 2005 and as per the domestic laws. The UN agency stresses on the enactment of a uniform legislation to ensure appropriate health care action during PHE.

The second aspect deals with clinical trials and development of vaccination and other drugs. There are no specific international instrument dealing with this area, however, it is based upon the existing instruments such as Nuremberg Code, Phases of Clinical trials as recognized by WHO, Belmont Report, International Ethical Guidelines etc. The guidelines and international instruments in this regard are based on the basic medical ethical principles *vis-à-vis*, autonomy, beneficence, non-

[202] *Id.*
[203] WHO Guidelines on Health Care Waste Management, Paragraph 1.4.
[204] WORLD HEALTH ORGANIZATION, Supra, at 3.

maleficence, and justice. The ethical principles are established in order to protect the lives of human participants in clinical trials and to prevent inhumane practices.

The third part of the Chapter deals with management of health care waste. The WHO guidelines provide for management of day-to-day health care wastes as well as other hazardous wastes including radioactive waste. Thus, the WHO guidelines on management of Health Care Waste are also crucial to a study relating to PHE.

The analysis thus, helps in examining whether the present Indian Legal framework follows the international standards. The different strategies adopted and executed by the above-mentioned nations show the inadequacy in Indian Laws. The International and the comparative analysis show that India should adopt a more proactive strategy to combat public health emergencies, which could be achieved through enacting a comprehensive legislation to deal with the above-mentioned situations. A detailed examination of extend of application of the above-mentioned provisions in India will dealt separately in this consequent chapters.

CHAPTER 4

COMPARATIVE ANALYSIS OF LEGAL RESPONSES TO PUBLIC HEALTH EMERGENCY IN CHINA, UNITED STATES OF AMERICA AND UNITED KINGDOM

4.1 INTRODUCTION

Domestic Public Health Emergency responses and plans is country specific. Different countries have different approached based on economic and scientific factors. For example, in the current COVID-19 pandemic situation, many countries, including India mandated social distancing, use of masks, proper sanitization and lockdown[205]. There are countries having an emergency plan to meet with public health crisis, including pandemic, natural and human-made disasters, which is absent in India.

This chapter deals with Comparative Analysis. Three countries are opted for comparative analysis, vis-à-vis, USA, UK and China due to similarities in the governmental, economic and demographic situations. USA is taken to sketch a comparative analysis based on federal structure of the government in the event of emergency. United Kingdom is taken due to its proven efficacy of public health laws and its similarity in governmental structure with India. China is taken for analysis due to cultural and demographic similarities. According to World Bank, the population of China in the year 2020 is 1,4202,112.00 and India's population is 1,38,004.39[206]. China has succeeded in containing the COVID-19 pandemic based on previous experiences[207]. The legal framework in the selected nations is not compared amongst themselves, but they are examined, in order to reach a comprehensive and comparative conclusion pointing out the reformation that could be made in Indian law.

4.2 LEGAL FRAMEWORK GOVERNING PUBLIC HEALTH DURING A PUBLIC HEALTH EMERGENCY IN CHINA

[205] Human Rights Watch, https://www.hrw.org/news/2020/03/19/human-rights-dimensions-covid-19-response, (last visited on July 7, 2021).

[206] The World Bank, https://data.worldbank.org/indicator/SP.POP.TOTL?locations=IN, last visited on August 3rd, 2020).

[207] *Infra* at 16.

China relies on to Emergency Response Law of the People's Republic of China, adopted on August 20, 2007, to deal with Public Health Emergency[208]. It could be taken as a model law for improving or framing provisions governing public health emergency in India.

A PHE give rises to many challenges due to its unpredictability. Thus, the states shall keep in mind two major goals. First, to adopt an effective mechanism to prevent the occurrence of any public health emergency. It be achieved through conducting studies, collecting information, and maintaining a sound surveillance system. Second, the state shall undergo sufficient preparedness before the occurrence of emergency, so that, when it occurs, the state would not have to unconversant with the situation. It could be achieved through proper training among the concerned departments and creating awareness among the people. The Chinese Law has succeeded in achieving both the goals. The Emergency Response Law in accordance with the Constitution of People's Republic of China have had taken sufficient measures to deal with public health emergency. The emergency experiences and practical lessons of the past 10 years have caused China's laws and regulations related to health emergencies to become self-contained[209].

The law provides for the construction of a sound emergency mechanism. The Emergency Response law has provided for well-defined powers and functions for each level of government and departments involved in the emergency. The clear demarcation among the State bodies ensures efficient administrative functioning during the occurrence of an emergency. The law has mapped the powers and functions of the local governments so that the facilities would far reach the people at grass root level.

The Constitution of People's Republic of China under Article 21 promotes public health activities of mass character, all to protect the people's health[210]. Accordingly, the State shall develop medical and health services, promoting modern medicine and traditional Chinese medicine[211]. Right to health has been recognized as part of General Principles of the Constitution. Under Article 45, citizens of People's Republic of China have the right to material assistance from the state and society when they are old, ill, or disabled[212]. To ensure the same, the state develops the social insurance, social relief, and medical and health services that are required to enable citizens to enjoy

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[208]China.org.cn, http://www.china.org.cn/china/LegislationsForm2001-2010/2011-02/11/content_21899265.html, (last visited on July 7, 2021).

[209] Lian Y, *Epidemic prevention station to Chinese Center for disease control and prevention,* CAJ, 30-33, (2018).

[210]Constitution of People's Republic of China, Article 21, clause 1.

[211]Constitution of People's Republic of China, Article 45, clause 1.

[212]Constitution of People's Republic of China, Article 45, clause 1.

this right[213]. The National People's Congress establishes a Public Health Committee[214].The State Council has the power to adopt administrative measures, enact administrative rules and regulations, and issue decisions and orders in accordance with the Constitution and the statutes to direct and administer affairs of public health[215]. The Constitution also addresses the powers of local governments. Local people's governments at and above the county level, within the limits of their authority as prescribed by law, conduct the administrative work concerning public health[216]. The committees on Grass Roots Level established by residents and villages provide for administration of matters including public health[217]. Article 80 prescribes the power of the President to proclaim entering of the state of emergency.

The novel coronavirus was first identified in by Wuhan Municipal Health Commission in China on 31st December 2019[218]. Based on the WHO reports, on 14th day of June 2021, there are only 288 new cases with 26 deaths and culminative total number of cases from time of outbreak is 116,103[219]. China is the biggest populous country in the world, with 1.44 billion population, yet the nation has succeeded in containing the COVID-19 pandemic. India stands second most populous country with 1.39 billion[220]. The culminative total cases of COVID-19 in India as of 14th day of June 2021 is 29439989 with 370,384 deaths, whereas the culminative total of deaths in China is only 5257. China was able to deal with the 2019 pandemic due to its previous experiences[221]. China has been prone to outbreak of infectious diseases as well as health hazards due to natural and man-made disasters several times[222].

4.2.1 Applicability of Emergency Law during Public Health Emergency

As aforementioned, Emergency Response Law is the applicable law during a public health emergency. There are 70 articles in the Emergency Response Law divided into 6 chapters. The aim and purpose of Emergency Response Law is preventing and reducing the occurrence of emergencies; controlling, mitigating and eliminating the serious social harm

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[213]Constitution of People's Republic of China, Article 45, clause 2
[214]Constitution of People's Republic of China, Article 70, clause 2
[215]Constitution of People's Republic of China, Article 89, clause 7.
[216]Constitution of People's Republic of China, Article 107.
[217]Constitution of People's Republic of China, Article 111.
[218] World Health Organization, https://www.who.int/news/item/27-04-2020-who-timeline---covid-19,, (last visited on July 7, 2021).
[219] United Nations, https://www.un.org/en/global-issues/population, (last visited on July 7, 2021).
[220]*Id.*
[221]Gummel A, *Modelling Strategies for controlling SARS Outbreak,* 271, PBS, 2223-2232, (2017).
[222] Zhong Shuang, *Progress and Challenges in Disaster Health Management in China*, 7, GHA, 3-10.

caused by emergencies, regulating the activities in response to emergencies, protecting the lives and property of the people and maintaining national security, public security, environmental safety and public order[223]. It mainly deals with, prevention of emergency, preparation for response to emergency, monitoring and early warnings of emergency, handling of emergency, rescue and relief during emergency, and post emergency measures such as rehabilitation and reconstruction[224]. Article 3 defines the term "emergency". It includes natural disasters, calamitous accidents, public health accidents and public security incidents, which occur abruptly and cause or may potentially cause serious social harm[225]. The public health accidents, along with other forms of emergencies are divided into four grades. They are especially serious, serious, relatively serious and common[226]. It is based on the degree of social harm and extent of repercussions.

4.2.2 Role of State during PHE

The State plays an important role during an emergency. During serious emergencies, the State establishes a risk assessment system. It helps to assess the potential emergencies and reduce the chance of their occurrence and mitigate their repercussions to the maximum extent[227]. Awareness is created among all the citizens regarding public security and risk prevention. It is achieved by the establishment of an effective social mobilization mechanism. It helps to increase the ability of the entire society to avoid risks and offer assistance[228]. The decisions made by the State is communicated with the public on a timely manner[229]. It shall carry out cooperation and exchange with the governments of other countries and international organizations to prevent emergency. In case of occurrence of emergency, it shall take actions for monitoring, early warnings, handling, rescue and relied on and post emergency measures[230]. The role of local government should also be noticed in this regard. Under Articles 7 to 9 provides for the functions of local government

[223] Emergency Response Law, Article 1.
[224] Emergency Response Law, Article 2.
[225] Emergency Response Law, Article 3.
[226] *Id* at 60.
[227] Emergency Response Law, Article 5.
[228] Emergency Response Law, Article 6.
[229] Emergency Response Law, Article 10.
[230] Emergency Response Law, Article 15.

during an emergency. The people's governments at the county level shall be responsible for the dealing with emergencies taking place within their own administrative areas. When two or more administrative areas are involved in an emergency, the matter will be taken to the next higher level[231]. On occurrence of emergency, the people's government at county level shall take immediate measures to keep the situation under control, handling, and provide for rescue and relief. If it is found that the local government cannot keep the situation under control it shall report the same immediately to the next higher level[232]. Article 7 says that if the administrative regulations provide that the situation requires involvement of State Council, in such situations, the people's government at county level shall cooperate in a proactive manner and provide necessary support. The State Council under the leadership of Premier, shall conduct a study and take decisions to develop a response to especially serious emergencies. It shall also establish a national command for emergency response[233]. The local governments shall establish a command for emergency response. Such command comprises of principal leading persons of the said local government, leaders of concerned departments, and other relevant leaders of units of Chinese People's Liberation Army and of the People's Armed Police Force. Such Command for emergency response exercise unified leadership and coordinate the efforts of relevant departments[234]. According to Article 9 the State Council and the local people's governments at or above the county level shall be the leading administrative organs for emergency response.

4.2.3 Responsibilities of Armed Forces in the events of PHE

The Emergency Response Law addresses the role and functions performed by Army, Armed Police Force and the militia during an emergency. Under Article 14, the Chinese People's Liberation Army, the Chinese People's Armed Police Force and the militia shall participate in emergency rescue, relief and handling. It shall be in accordance with the provisions of Emergency Response Law and of the other relevant laws, administrative regulations and military regulations, as well as the orders issued by the State Council and the Central Military Commission. They shall, in a

[231] Emergency Response Law, Article 7.
[232] *Id* at 66.
[233] Emergency Response Law, Article 8.
[234] *Id* at 68.

planned way, organize and conduct special training for emergency rescue[235]. The integration of army and other military forces by virtue of the Emergency Response Law helps to improve emergency management because the army and militia have advantages including intrinsic infrastructure, well-trained personnel, modern equipments, better communication facilities and improved transportation system[236].

4.2.4 Healthcare preparedness as an emergency response

The Emergency Response Law provides for preparedness of State to meet with emergency. Under Article 17 the State establishes a precautionary system for emergency response. The State council, and relevant departments of State councils shall be responsible for its functioning. They make departmental precautionary plans. They make timely modifications according to changing needs and demands. The procedure for such modification is formulated by the State Council[237]. There shall be both urban and rural planning to meet the need for prevention and handling of emergency[238]. It is the duty of the local government to check and register sources of danger within their administrative area which may give rise to emergencies. They shall assess the risk, regularly inspect and monitor such sources and areas, and order the units concerned to take safety and prevention measures. Such dangerous situations, areas and its sources based on its degree of harm will be communicated with the general public in a timely manner. It prescribes a sound training system for control of emergencies[239]. It shall provide regular training to the staff members of the people's governments and of their relevant departments who are charged with the duty to handle emergencies. As a part of creating awareness among general public, the knowledge on emergency response is included in the teaching curriculums of schools, to help them foster their awareness of importance of safety and acquire the ability of self-rescue and mutual rescue[240]. The notable feature of the law is provisions for the surveillance system. China has a broader all-hazard approach, including, for example, chemical incidents[241]. An effective surveillance system is an integral part of every health system. It helps to detect undesired health effects in each population, with the primary aim to eliminate the source of the problem[242].

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[235] Emergency Response Law, Article 28.
[236] Zhong S, *Progress and Challenges of disaster health management in China: A scoping review,* 7(1) GHA,
[237] Emergency Response Law, Article 17.
[238] Emergency Response Law, Article 18.
[239] Emergency Response Law, Article 25.
[240] Emergency Response Law, Article 30.
[241] Vleing WL, *Comparing National Infectious disease surveillance systems: China and the Netherlands,* 17(1), BMCPH, (2017).
[242] Lele D, *Occupational Health Surveillance,* 22, IJOEM, 117-120, (2018).

4.2.5 Provisions for management of material resources during PHE

There are provisions for the management of material resources. It provides for mobilization of resources to facilitate rescue and relief missions[243]. The State establishes of a sound guarantee system for material reserves as part of emergency response[244]. It improves the system of control, production, reservation, allocation and urgent distribution of the important materials for emergency response. The people's government has the power to expropriate enterprises that produce or supply daily necessities and materials for emergency rescue to organize production and ensure supply, and require the organizations that provide medical services, transportation and other public services to do so[245]. China has also succeeded in establishing an effective systemization for management and distribution of resources during emergency. It is a material basis for improving the ability to respond to PHE. It guarantees comprehensive level of emergency management and helps to respond more effectively to future public health risks[246].

4.2.6 Communication system and Information dissemination for monitoring the events during PHE

The emergency response law provides mechanism for collection and communication of information among different levels of government. The State Council shall establish a unified national information system for emergencies[247]. People's governments at or above the county level and their relevant departments and the specialized institutions shall collect information on emergencies through a variety of channels[248]. They shall also establish a full-time or part-time information reporter system in the resident's committees, the villagers' committees and the units concerned. Article 38 also imposes a duty on the citizens, legal persons and other organizations that get information on emergencies. They

[243] Emergency Response Law, Article 26 and 45.
[244] Emergency Response Law, Article 30.
[245] Emergency Response Law, Article 52.
[246] Cao Y, *Status and Challenges of Public Health Emergency Management in China related to COVID-19,*FPH, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7273973/.
[247] Emergency Response Law, Article 37.
[248] Emergency Response Law, Article 38.

shall immediately report to the local people's governments, the relevant competent departments or the designated specialized institutions.

To ensure monitoring of an emergency, the State shall establish a sound emergency monitoring system[249]. It is the duty of local governments to maintain the basic information database, improve the monitoring networks, divide the regions for monitoring, determine the sites and define the items for monitoring, provide the necessary equipment and facilities, and assign full-time or part-time workers, in order to monitor potential emergencies. To prevent and control emergencies, the State stablishes a sound early warning system for emergencies[250].

4.2.7 Specific provisions to deal with PHE after its occurrence

The Emergency law contains specific provisions to deal with an emergency after its occurrence. The State on occurrence of an emergency shall immediately organize the relevant departments, deploy the emergency rescue teams and people from different sectors of the society, and take measures for handling the emergency[251]. The measures to be taken by the people's government on occurrence of an emergency are as follows[252]:

- organizing the rescue and treatment of victims, dispersing and evacuating persons exposed to danger and having them properly resettled or taking other measures to help them,
- promptly keeping the source of danger under control, clearly marking the endangered areas, blockading the endangered places, demarcating the security areas, exercising traffic control, and taking other control measures,
- facilitating transportation, communications, water supply, drainage, power supply, gas supply and heat supply,

[249] Emergency Response Law, Article 41.
[250] Emergency Response Law, Article 42.
[251] Emergency Response Law, Article 48.
[252] Emergency Response Law, Article 49.

- providing the victims with shelters and daily necessities, and giving them first aid, and
- providing sanitation and anti-epidemic measures and other safeguard measures to affected people,
- prohibiting or restricting the use of the relevant equipment and facilities, closing or restricting the use of related places, suspending the activities which draw a high density of people or the production or business activities which may lead to increased scale of damage, and taking other protective measures,
- bringing into use the fiscal reserve funds set aside and the emergency rescue materials reserved by the people's government and, appropriation of such materials,
- organizing citizens to participate in emergency rescue and handling, and requiring the ones with given specialties to provide services,
- guaranteeing the supply of food, drinking water, fuels and other basic daily necessities,
- in accordance with law, imposing severe punishment on persons who disrupt market order by hoarding and cornering, forcing up prices, making and selling counterfeit goods, etc., to stabilize market prices and maintain market order,
- in accordance with law, imposing severe punishment on persons who disrupt public order by looting, and interfering with and sabotaging emergency handling, etc., to maintain public security; and
- taking necessary measures for preventing the occurrence of secondary and derivative incidents.

4.2.8 Duties and responsibilities of Citizens

Article 57 imposes duties of citizens during emergency. Citizens in the place where an emergency occurs shall follow the direction and arrangements of the people's government, residents' committees, villagers' committees or the units to which they belong, cooperate with the people's government in implementing the measures it adopts for handling the emergency, proactively participate in emergency rescue and help maintain social order[253].

4.2.9 Post-Emergency Measures

One of the most important part of the Emergency Law is management of post-emergency situation. It is essential prevent recurrence or re-emergence of the public health risk. After the threat of and the damage caused by an emergency is brought under control or eliminated, the people's government shall terminate the implementation of the measures for handling the emergency[254]. They shall take or continue to implement the necessary measures to prevent the occurrence of the secondary or derivative incidents of such emergency. The government shall then assess the losses caused by the emergency and organize rapid restoration of production, normal life and work and social order in the affected areas and make rehabilitation and reconstruction plans[255]. The State Council shall, according to the losses suffered by the area affected by an emergency, formulate preferential policies to support the development of the related industries in the said area[256].

4.2.10 Role and responsibilities of local government

Chapter VI of Emergency Response law deals with legal liability of the local government[257], related units[258], individuals[259], in case of violation of provisions of the emergency response law. On failure of performance of statutory duties by the local government, the superior administrative organ shall make orders to rectify such failure[260]. Thus, the local bodies have the statutory duty to take preventive measures, submission of report, give alarm for an emergency or take measures for the period of early warning, share the funds and materials allotted and perform the functions under

[253] Emergency Response Law, Article 57.
[254] Emergency Response Law, Article 58.
[255] Emergency Response Law, Article 58.
[256] Emergency Response Law, Article 61.
[257] Emergency Response Law, Article 63.
[258] Emergency Response Law, Article 65.
[259] Emergency Response Law, Article 66.
[260] Emergency Response Law, Article 66.

unified leadership and command[261]. Article 68 states that anyone who violates the provisions of this Law, which constitutes a crime, shall be investigated for criminal responsibility according to law.

Thus, it can be said that the comprehensive legislation in China for emergency response, though not a pure public health legislation has played a pivotal role is containing the COVID-19 pandemic and the provisions show that the nation is prepared to tackle any form of public health emergencies in the future.

4.3 LEGAL FRAMEWORK GOVERNING PUBLIC HEALTH DURING A PUBLIC HEALTH EMERGENCY IN UNITED STATES OF AMERICA

United States of America has a pure federal structure[262]. It comprises of dual polity or dual form of government. The form of govt existing in the US is always taken as the reference for comparing to find whether a country is truly federal or not. In *Re Distribution of Essential Supplies and Services During Pandemic*[263], the Federal nature of Indian Polity was taken into consideration while criticizing the current vaccine policy, which lead to the procurement of vaccine by Centres for distribution for States[264]. An examination of Legal Framework in USA purports to understand the powers and functions of Union and its States during a PHE.

Like India, the right to health is not expressly mentioned in the US Constitution. However, the Supreme Court decisions in *Roe* v *Wade*[265] and *Cruzen* v *Missouri Department of Health*[266] suggests that the concept of right to health is implicit in US Constitution. In the first case, the court recognized the constitutionally protected right to choose whether to terminate a pregnancy. Supreme Court in *Cruzen*[267] held that there is a constitutional right to refuse medical treatment that sustains life. Both decisions involve a right to bodily integrity that may logically be extended to a person seeking health care services[268]. Though not recognized as a constitutional right, Congress has enacted numerous legislations for the protection of health people. It is based on authority of

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[261] *Id.*
[262] US Constitution, Article 1
[263] WP(C) no. 3 of 2021
[264]Live law, https://www.livelaw.in/top-stories/centre-to-procure-vaccines-for-states-free-vaccines-for-18-44-years-says-pm-modi-175355,(last visited on July 7, 2021).
[265] 410 US 113(1973).
[266] 497 US 261 (1990).
[267]*Id.*
[268] Swendiman, K, *Healthcare Constitutional Rights and Legislative Powers,* CRS, 2-16, (2012).

Congress to enact legislation under Article 1 of the Constitution, giving right to health a constitutional footing[269].

In USA, there are several legislations that deal with public health and PHE. Public Health Services Act is one of the most important legislation[270]. The public health services are mostly carried out through the public health agency, the center for disease control and prevention[271].

4.2.1 Impact of *Jacobson*[272] Decision on Police powers of State to impose restrictions during PHE

The factual background of this case is based on outbreak of smallpox during 1901 and 1903 in United States. The case checks validity of a resolution passed by Board of Health in Cambridge compelling all residents of the town to be vaccinated for smallpox under the US Constitution. This resolution was challenged by the petitioner. The petitioner has refused to get vaccinated as result criminal complaint was proceeded against him. In this case the petitioner argued that such a resolution is opposed to the spirit of Constitution and violative of XIV Amendment[273]. Section of the XIV Amendment states that:

> *"All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No state shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any state deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws."*

The case raised questions about the power of state government to protect the public's health and protection of personal liberty under Constitution. In this case, court has upheld the powers of Health Department of Cambridge. During COVID-19 pandemic, the application of police powers of State has been widely seen[274]. In USA, police power means the authority conferred upon the

[269] *Id* at 6.
[270] The Public Health Services Act was amended through the Pandemic and All-Hazards Preparedness Act and Pandemic Readiness and Preparation Act.
[271] Public Health Emergency, https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx,(last visited on July 7, 2021).
[272] *Jacobson* v *Massachusetts*,197 US 11.
[273] US CONST. Section 1, XIV Amendment.
[274] In Australia on declaration of emergency most states have imposed restrictions on civil liberties of the people and increased police powers of States., Human Rights Law Center, https://www.hrlc.org.au/factsheets/2020/8/11/explainer-increased-police-powers-and-covid-19, visited on August 16th 2021.

states by the X amendment to the US Constitution. Such power is delegated by the states to their political subdivisions to enact measures to preserve and protect the safety, health and welfare and morals of the community[275]. Likewise in India too, the penal provisions have been imposed to restrict the spread of COVID-19 pandemic by virtue of Epidemic Diseases Act[276]. and Disaster Management Act[277]. In *Jacobson*[278] it was observed that the settled principle is that the police power of a state must be held to embrace the reasonable regulations established directly by legislative enactment to protect the public health and public safety. The mode and way the results are attained are within the discretion of the State subject to concerned Federal powers and it shall not contravene the provisions of the Constitution of United States. Court observed that an adult must not be compulsorily vaccinated if it would seriously impair his health or probably cause his death. In such circumstances having reasonable certainty compulsory vaccination shall not be imposed. However, in the case in hand, there is no such circumstance. The petitioner is in perfect state of health and fit for vaccination. Thus, Court held that the compulsory vaccination imposed by the department of health is not unconstitutional. The contemporary legal position regarding compulsory vaccination is that a law that authorizes mandatory vaccination during a public health emergency in matters of an epidemic of lethal disease, the non-compliance punishable by a monetary penalty, would not be unconstitutional under the test of "rationality review". However, it is subject to the condition that the vaccines shall be approved by Federal Drugs Agency as safe and effective[279].

4.2.1 Provisions for declaration and termination of public health emergency under Public Health Services Act

The Act encourages to cooperate and render assistance to other public authorities, for the conduct of research, experiments, investigations, demonstrations and studies, relating to cause, diagnosis, treatment, control and prevention of physical and mental diseases[280]. The Act under Section 319 has recognized "Public Health Emergency". It includes outbreaks of infectious disease or bioterrorist attacks, or those public health emergencies otherwise exist. The appropriate actions

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[275] Cornell Law School, Legal Information Center, https://www.law.cornell.edu/wex/police_powers#:~:text=The%20Tenth%20Amendment%20to%20the,and%20powers%20%E2%80%9Cpolice%20power%E2%80%9D.&text=The%20government%20may%20properly%20exercise,regulate%20land%20use%20as%20well., visited on August 16th 2021.
[276] India, EDA, Section 3.
[277] India, NDMA, Sections 51-60.
[278] *Jacobson* v *Massachusetts*,197 US 11.
[279] Mariner WK, Annas GJ, Glantz LH, *Jacobson v Massachusetts: it's not your great great-grandfather's public health law,* AJPH, 581-890, (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1449224/, visited on August 16th 2021.
[280]PHSA, Section 313.

taken against PHE, includes, provisions for grants, awards for expenses, entering contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder. The duration of such declaration is 90 days. Therefore, a PHE terminates on expiry of 90 days or when the Secretary declares that the emergency no longer exists, whichever occurs first[281].

Another legislation that recognizes public health emergency is the Drug Supply Chain Security Act, 2013[282]. When a public health emergency is declared by the Secretary under Section 319 of the Public Health Services Act, there is an unavoidable demand to ensure effective and affordable distribution of drugs under emergency conditions. Under the relevant provisions, PHE is considered as an emergency medical reason[283].

4.2.2 Preparedness and surveillance mechanism

The primary issue is the preparedness and surveillance mechanism before the occurrence of a PHE. The Pandemic and All-Hazards Preparedness Act[284], to meet with this challenge, aims at establishment of national All-hazards preparedness and response planning[285]. It provides for coordination and assistance among all concerned departments towards Secretary[286]. As per the Act the Secretary in every four years shall prepare and submit to the relevant committees of Congress a coordinated Strategy known as the National Health Security Strategy accompanied by an implementation plan for public health emergency preparedness and response[287]. The secretary shall establish a real-time electronic nationwide public health situational awareness capability to share data and information to enhance early detection of rapid response to, and management of, potentially catastrophic infectious disease outbreaks and other public health emergencies[288]. The Act also regulates development of drugs and vaccines during a PHE[289].

4.2.3 Legal protection and immunity of healthcare workforce

The second issue in a PHE is the legal protection and immunity of healthcare workforce. There is no specific legislation dealing with protection of healthcare workforce during a PHE. Generally, it

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[281]PHSA, Section 313 sub section (a)
[282]DSCSA, Section 581.
[283]DSCSA, Section 581 sub-section 24.
[284]PAHPA amended the Public Health Service Act to define the term “covered countermeasures”, “qualified pandemic and epidemic products” under Section 319F-3.
[285]PAHPA, Section 101.
[286]PAHPA, Section 102.
[287]PAHPA, Section 103.
[288]PAHPA, Section 202.
[289]PAHPA, Section 401-406.

is guaranteed through the Federal Employees Compensation Act[290]. United States shall pay appropriate compensation for disability or death of an employee resulting from personal injury sustained during discharge of their duty[291]. It is presumable that the provision would be applicable during a PHE, however, there is no explicit indication regarding the issue. The Pandemic Readiness and Preparation Act[292] authorizes the Secretary to issue a declaration for immunity from tortious liability in matters of loss caused by countermeasures against diseases or other threats of public health emergencies[293]. There is substantial difference between the declaration under section 319 and declaration under the Pandemic Readiness and Preparation Act. A declaration under Section 319 is based on the nature of as disease or disorder presenting a PHE, while a declaration under Pandemic Readiness and Preparation Act is made in advance of a PHE and provides liability immunity for activities both before and after a declared PHE. The declaration under Pandemic Readiness and Preparation Act does not require a declaration under Section 319. The Volunteer Protection Act 1997 also comes into play during a PHE. It provides for protection to volunteers, nonprofit organizations, and governmental entities in lawsuits based on the activities of volunteers[294].

4.2.4 Assistance to States

Another challenge in PHE is provisioning of technical, financial, logistical and other assistance to State. It is conveyed by virtue of Robert T Stafford Disaster Relief and Emergency Assistance Act, 1988. The Legislation aims to provide an orderly and continuing means of assistance by the Federal Government to State and local governments[295]. The assistance is arranged to alleviate the suffering and damages that results from disasters are carried out through methods including: revising and broadening the scope of existing disaster relief programs[296]; development of comprehensive disaster preparedness and assistance plans, etc.[297], enabling coordination and responsiveness of disaster preparedness and relief programs[298]; encouraging individuals, States, and local

[290] Association of State and Territorial Health Officials, https://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Authority-and-Immunity-Toolkit/Key-Federal-Laws-and-Policies-Regarding-Emergency-Authority-and-Immunity/, ,(last visited on July 7, 2021).
[291]FECA, Section 102.
[292] Pandemic Readiness and Preparation Act inserted Section 319F-3 dealing with “targeted liability protections for pandemic and epidemic products and security countermeasures and Section 319F-4 dealing with “covered countermeasure process”.
[293]PHSA, Section 319F-3
[294]VPA, Section 2.
[295] DREAA, Section 101, sub-section b.
[296] DREAA, Section 101, sub-section b, clause 1.
[297] DREAA, Section 101, sub-section b, clause 2.
[298] DREAA, Section 101, sub-section b, clause 3.

governments to protect themselves by obtaining insurance coverage to supplement or replace governmental assistance[299]; encouraging hazard mitigation measures to reduce losses from disasters, including development of land use and construction regulations[300]; and providing Federal assistance programs for both public and private losses sustained in disasters[301]. For the effective application of the provision, the Act defines the terms "emergency" and "major disasters".

The term emergency is defined as[302]:

"Emergency means any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe in any part of the United States."

The term Major Disaster is defined as:

"Major disaster means any natural catastrophe (including any hurricane, tornado, storm, high water, wind driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought), or, regardless of cause, any fire, flood, or explosion, in any part of the United States, which in the determination of the President causes damage of sufficient severity and magnitude to warrant major disaster assistance under this Act to supplement the efforts and available resources of States, local governments, and disaster relief organizations in alleviating the damage, loss, hardship, or suffering caused thereby."

The Act provides for Federal and State Disaster Preparedness Programs[303] , Disaster Warnings[304] Pre-disaster Hazard Mitigation[305] and Interagency Task Force[306]. The Act thus, obligates the federal government to provide for a systematic mechanism for protection of life and property of people of USA from emergencies and major disasters by providing timely assistance to State and local governments. The federal government issues necessary guidelines, direction and instructions for coordination and comprehensive emergency preparedness[307].

[299] DREAA, Section 101, sub-section b, clause 4.
[300] DREAA, Section 101, sub-section b, clause 5.
[301] DREAA, Section 101, sub-section b, clause 6.
[302] DREAA, Section 102 clause 1.
[303] DREAA, Section 201.
[304] DREAA, Section 202.
[305] DREAA, Section 203.
[306] DREAA, Section 204.
[307] DREAA, Section 601.

4.2.5 Provisions to deal with expenses during PHE

A ''Public Health Emergency Fund'' is established in the treasury to provide for accompanying expenses[308]. The PHE Fund is used to facilitate coordination between and among Federal, State, local, Tribal, and territorial entities and public and private health care entities; make grants, provide for awards, enter into contracts, and conduct supportive; facilitate and accelerate advanced research and development of security countermeasures, qualified countermeasures or qualified pandemic or epidemic; strengthen bio-surveillance capabilities and laboratory; support initial emergency operations, preparation and deployment of intermittent disaster response personnel; and the Medical Reserve Corps and carry out other related activities. The Act also addresses the issue bioterrorist attack and Public Health Countermeasures to it under Section 319-F.

4.2.6 Deployment of military to deal with PHE

The Public Health Services Act also provides for deployment of military to deal with undesired health risks during an emergency[309]. Under Section 315 of the Public Health Services Act, the Secretary may establish a program to provide for consultation and collaboration with military occupational specialties related to medical care or who have completed certain medical training while serving in the Armed Forces of the United States.

4.2.7 The effect of 9/11 WTC Attack demanding model law to deal with PHE

Model State Public Health Act, 2003 read with Model State Emergency Health Act, 2001[310] is a model legislation to increase state powers in responding to bioterrorism or other outbreaks of diseases. It is based on the requirements of Centers for Disease Control and States to be passed into law[311]. The purpose of such a model law was recognized on occurrence of September 11 terrorist attack, which demanded effective response to deal with mass influx of patients requiring emergency care[312]. On occurrence of 11/9 WTC attack the New York Department of Health focused on three aspects, *vis-a-vis*, surveillance, maintenance of routine functions and communication. The

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[308]PHSA, Section 313 sub section (b)

[309] US Department of Health and Human Services, https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx, (last visited on July 7, 2021).

[309]DSCSA, Section 581.

[310] Hereinafter referred to as MSEPHA.

[311] American Civil Liberties Union, https://www.aclu.org/other/model-state-emergency-health-powers-act, visited on August 3rd, 2021.

[312] Kitzman S, Freudenberg N, *Implication of World Trade Center Attack for Public Health and health care Infrastructure,* AJPH, 400-406, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1447752/, visited on August 3rd, 2021.

department had set up four surveillance systems: a rapid assessment of injuries related to attack, a hospital needs assessments, a reporting system of injuries among rescue and recovery of workers and a syndromic surveillance system for monitoring symptoms associated with biological or other agents. The occurrence of 11/9 attack also compelled the government to consider the mental health related aspects as terrorism is an assault on mental health and well-being of the general public[313]. The attack has created psychological distress for millions, exacerbated or precipitated mental disorders among some smaller groups, and threatened social cohesion[314]. The disaster has not only affected people physically and mentally but has also drastically affected hospital finances. Therefore, in order to assist victims New York State established Disaster Relief Medicaid to provide medical benefits to low-income New Yorkers[315].

The 9/11 attack pointed out the following implications on public health provisioning and regulations. The ambiguity in the structure of government has caused difficulty in determining the level of government responsible for dealing with a PHE like 9/11 attack. Lack of previously established mechanism resulted in lacunae in emergency planning and preparedness. It showed need to implement post hoc efforts to identify, screen and track affected persons[316]. It highlighted the redundancy of the then communication systems between health and other departments. It pointed out the inevitable connection with mental health care during PHE. The hampered health emergency provisioning called for novel approaches in education and training of health care professionals. And the most striking lesson was to balance between the routine or normal day to day health care provisioning while ensuring specific health care services to persons affected by the PHE[317].

The efficacy of the Model State Public Health Act has been recognized by World Health Organization in its report[318]. Under Article 6 of the Model State Public Health Act, it is stated that the governance of Public Health Emergencies, is based on the Model State Emergency Health Powers Act. Section 104 defines the term "public health emergency" as follows:

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[313] *Ibid* at 402

[314] Susser E, mental Health Impact of 9/11, http://www.hunter.cuny.edu/health/uph/911.program.htm, visited on August 3rd, 2021.

[315] Sheldon S, Gottfried RN, *Assembly rewrites health care packages,* NYSA, 2002, https://assembly.state.ny.us/comm/Health/20020222/, visited on August 3rd, 2021.

[316] *Ibid* at 403

[317] *Ibid* at 404

[318] WORLD HEALTH ORGANIZATION, *supra* note at 14.

"A public health emergency is an occurrence or imminent threat of an illness or health condition, caused by bioterrorism, epidemic or pandemic disease, or novel and highly fatal infectious agent or biological toxin, that poses a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability. Such illness or health condition includes, but is not limited to, an illness or health condition resulting from a natural disaster[319]."

The purpose of MSEPHA is given in section 103 as follows:

- Authorize the collection of data and records
- Control of property and management of persons, during a health emergency
- To ensure access to communication
- To facilitate the early detection of a health emergency and allow for immediate investigation
- To allow State officials to use and appropriate property as necessary for the care, treatment and housing of patients, and for the destruction of contaminated materials.
- To grant the State officials the authority to provide care and treatment to persons who are ill or have been exposed to infection and to separate affected individuals from the population at large for preventing transmission, in case of infectious disease,
- To fully address the needs of infected or exposed persons possible,
- To enable State officials to prevent, detect, manage and contain emergency health threats without unduly interfering with civil rights and liberties,
- To develop a comprehensive plan to provide for a coordinated appropriate response in event of public health emergency.

4.3.8. Measures to prevent and mitigate PHE

The measures to detect and track potential and existing PHE is prescribed in Article II of the Act. The first step is reporting to the public health authority[320]. A health care provider, or medical examiner or a pharmacist shall report all cases of persons who harbor any illness or health condition or unusual or increased prescription rates, unusual types of prescriptions, or unusual trends in pharmacy visits, that may result in PHE. The second step is tracking[321]. The health authority shall conduct investigation of all cases, its sources, and identify affected persons. Such persons shall be

[319] MSEPHA, Article I, Section 104 clause l.
[320] MSEPHA, Article II, Section 201.
[321] MSEPHA, Article II, Section 202.

interviewed to obtain more details. They shall also examine the affected area and take steps to close, evacuate or decontaminate such premises. The Act provides for safe disposal of corpses[322] and control of health care supplies through procurement, rationing, and equitable distribution[323].

When a PHE is noticed, the Governor by an executive order shall declare a State of Public Health Emergency[324]. The Governor shall consult with the public health authority and may consult with any public health and other experts as required. The declaration shall indicate the nature of PHE, the affected areas, and the conditions that have brought about the public health emergency. The Act also provides for the methods of termination of PHE when such PHE no longer poses a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability or that the imminent threat of such an occurrence has passed.[325]. It could be terminated via an executive order by Governor, or through an automatic termination[326], or termination by State legislature[327], or by content termination order[328].

4.4 LEGAL FRAMEWORK GOVERNING PUBLIC HEALTH DURING A PUBLIC HEALTH EMERGENCY IN UNITED KINGDOM

Public Health Governance in United Kingdom is based on powers and functions of National Health Services under Civil Contingencies Act, 2004[329] read with the provisions of Public Health (Control of Diseases) Act, 1984. The Public Health (Control of Diseases) Act, 1984 is responsible for the procedural management of an emergency in United Kingdom[330]. In order to tackle the COVID-19 pandemic, UK has enacted a legislation titled, "Coronavirus Act, 2020". The Coronavirus Act, 2020 forms the foundation for public health emergencies. It provides for emergency registration of

[322] MSEPHA, Article IV, Section 404
[323] MSEPHA, Article IV, Section 405
[324] MSEPHA, Article III.
[325] MSEPHA, Article IV
[326] A state of public health emergency shall be terminated automatically thirty days after its declaration unless renewed by the Governor under the same standards and procedures set forth in this Article for a declaration of a state of public health emergency.
[327] It carried out by a two-thirds vote of both chambers after sixty days from the date of original declaration upon finding that the occurrence of an illness or health conditions.
[328]All orders terminating a state of public health emergency shall indicate the nature of the emergency, the areas that were threatened, and the conditions that make possible the termination of the state of public health emergency.
[329] Emergency Response and Recovery, Cabinet Office, Civil Contingencies Secretariat, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/253488/Emergency_Response_and_Recovery_5th_edition_October_2013.pdf,(last visited on July 7, 2021).
[330] UK, PHA. Sec. 45R r/w Section 45Q.

health professionals such as nurses[331], medical practitioners[332], and pharmaceutical chemists[333]. It also provides for temporary registration of social workers[334] and volunteers[335].

4.3.1 Concept and scope of public health emergency

Section 1 of the Civil Contingencies Act, 2004 defines the term emergency. As per the Section it means an event or situation which threatens serious damage to human welfare or to the environment in a place in the United Kingdom, or war, or terrorism, which threatens serious damage to the security of the United Kingdom[336]. For the purpose of subsection 1(a) an event or situation threatens damage to human welfare only if it involves, causes or may cause, loss of human life, human illness or injury, homelessness, damage to property, disruption of a supply of money, food, water, energy, or fuel, or disruption of services relating to health and disruption of a system of communication and facilities for transport[337].For the purposes of subsection (1)(b) an event or situation threatens damage to the environment only if it involves, causes or may cause contamination of land, water or air with biological, chemical or radio-active matter, or disruption or destruction of plant life or animal life[338].

The scope of emergency regulations is provided in Section 22 of the Civil Contingencies Act, 2004. Emergency regulations are made for the purpose of preventing, controlling or mitigating an aspect or effect of the emergency in respect of which the regulations are made[339]. It is required for protecting human life, health or safety, treating human illness or injury, as well as, protecting or restoring the provision of services relating to health, etc.[340].There are eight guiding principles of effective response and recovery; they are anticipation, preparedness, subsidiarity, direction, information, integration, co-operation and continuity[341].

4.3.2 Preparation of emergency response plan

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[331] UK, CA. Sec. 2.
[332]UK, CA. Sec. 3.
[333]UK, CA. Sec. 5.
[334]UK, CA. Secs. 6 & 7.
[335]UK, CA. Secs. 8 & 9.
[336] UK, CCA, Sec. 1 sub-section 1.
[337]UK, CCA, Sec. 1 sub-section 2.
[338]UK, CCA, Sec. 1 sub-section 3.
[339]UK, CCA, Sec. 22 sub-section 1.
[340]UK, CCA, Sec. 22 sub-section 2.
[341]*Id* at 16-23.

The emergency response plan should be coherent to find out the potential risks and emergencies. It is achieved through a well-structured and maintained surveillance system. Anticipation allows the concerned authorities to meet required demand on staff, resources and management attention during the everyday routine. It also ensures to address the recovery issues at the earliest. Under Section 2 it is the duty of the local and other authorities under Parts 1 and 2 of Schedule I to the Act maintain plans to continue to perform his or its functions if an emergency occurs[342] or to prevent the emergency, or to reduce, control or mitigate its effects and to take necessary action[343]. Section 1 of the Public Health Act, 1984 has listed local authorities as administers of the Act. They are obliged to discharge functions that are related to public health risks and crisis[344].

The role and responsibility of such persons and such agencies that could be associated with the emergency should be defined. It is achieved through proper preparedness. Such persons and authorities shall be given appropriate training to meet with the immediate requirements arising out of the emergency. As aforementioned the Civil Contingencies Act provides for categories of responders to emergency in Part 1 and 2 of the I Schedule. Such authorities include the local authorities[345]. Paragraph 3 of the I Schedule enlists officers under the Police Act, 1996 as emergency services. Paragraph 5 of the I Schedule provides for establishment and functioning of National Health Service for providing ambulance services, and hospital accommodation and services in relation to accidents and emergencies. The abovementioned authorities have the duty to assess, plan and advice in the event of an emergency[346] and to provide assistance to general public[347]. Section 14 to 17 of the Coronavirus Act, 2020 deals with the powers and functions of local authorities and National Health Service during COVID-19 pandemic.

4.3.3 Cooperation among different departments

[342] UK, CCA, Sec. 2 sub-section 1 clause c.
[343] UK, CCA, Sec. 2 sub-section 1 clause d.
[344] UK, PHA, Section 1.
[345] As per Para 1, 2 and 13 of the I Schedule: - For England, it includes a County Council, District Council, London Borough Council, the Common Council of the City of London, and the Council of the Isles of Scilly; in relation to Wales it includes a County Council and a County Borough Council; and for Walers For Scotland it is the Council constituted under Section 2 of the Local Government Act, 1994 respectively.
[346] UK, CCA, Sec. 2.
[347] UK, CCA, Sec. 4.

The principle of preparedness of authorities is intertwined with the principle of subsidiarity, integration and cooperation. Subsidiarity is a Latin concept meaning "assistance" or "aid"[348]. It means a central authority should have a subsidiary function, performing only those tasks which cannot be performed at a more local level[349]. Thus, UK's emergency responsiveness is based on bottom-up approach, where decisions are made at the lowest appropriate levels. The role and authority of Central Government is devolved, and it supports the local governments. The latter are allotted response and recovery operations. As aforementioned I Schedule provides for different categories of services and its interdependence with one another. Unless the various departments work hand in hand with one another, it would be difficult to combat an emergency. A quintessential feature of emergency response and recovery plan is the effective integration of operation of multiple agencies. Different agencies and departments shall combine and act as a coherent multi-agency system. The concept of multiple agencies and its integration is one of the primary features of the Civil Contingencies Act which is evident from the I Schedule and sections 2 and 4. The emergency response and recovery are based on multi-agency operation, which further requires cooperation irrespective of hierarchy. The agencies involved shall understand each other's' functions and manner of working and plan according to such interrelated requirements.

The demands and requirements during an Emergency vary according to the event and situation that caused the emergency, the speed of its onset, affected area, concurrent or interdependent events, and other factors. These requirements can only be achieved through clear and unambiguous strategic aims and objectives. The powers and functions discharged by various authorities will be under the supervision and direct monitoring of the Government[350]. The Regional and Emergency Coordinators are under the obligation to comply with a direction of a senior Minister of the Crown[351].

4.3.4 Collection and dissemination of information

Collection and management of information is essential to ensure preparatory measures and create situational awareness at local, sub-national and national levels. The mechanism for information management should be based on national standards rather than local initiatives and inventions. The authorities shall also take measures to make sufficient communications with media to reach general public. They shall give appropriate advice, warnings and information to provide reassurance and a

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[348] Schutze R, *Subsidiarity after Lisbon: Reinforcing the safeguards of Federalism,* 68(3), CLJ, 525-530, (2009).
[349]Oxford English Dicitionary, https://www.lexico.com/definition/subsidiarity, (last visited on July 7, 2021).
[350]UK, CCA, Sec. 9.
[351]UK, CCA, Sec. 24 sub-section 4 clause a.

basis for necessary action. The responders under I Schedule has the duty to maintain arrangements to warn the public, and to provide information and advice to the public, if an emergency is likely to occur or has occurred[352].

UK's strategy is based on the notion that those organizations undertaking functions on a day-to-day basis are best to deal with emergencies. They will be more able to meet with the demanding circumstances of an emergency due to experience, expertise, and resources. Thus, giving adequate preparation and training during the day-to-day functioning, such agencies would be capable of functioning proficiently during an emergency.

4.5 CONCLUSION

The chapter as aforementioned has dealt with the mechanisms adopted by different countries to tackle public health emergencies. In the nations above discussed, the legal instruments have acknowledged the role of state in ensuring the health and well-being of its citizens during an emergency. In China, the issue is dealt by the way of proclaiming national emergency, while in USA, there are specific provisions for declaration of public health emergency, and in UK, it is dealt under the concept of civil contingencies. The above-mentioned nations have effectual mechanism for monitoring of the concerned departments involved in the prevention and mitigation of PHE. They have also made provisions to deal with the post-emergency scenario. The legislations above discussed provides precise provisions for both determination and termination of PHE. While China and UK deal with the prevention and mitigation of public health emergency by virtue of a single legislation, namely, Emergency Response Law of Republic of China and Civil Contingencies Act, respectively; USA, meets the requirements by virtue of numerous legislations. In case of UK, and China, there are no specific public health law legislations to deal with the raising concerns of PHE, but in USA, there are specific public health legislations to deal with the same. All three nations have not only identified the role and functions of the centre and state governments, but also recognize and grant responsibilities to local governments, so that the services are availed by every citizen, including those at the grass root level.

The peculiar features that are common to the legal responses to public health emergency is the above-mentioned countries are several. The foremost step taken by every nation is to establish an efficient health surveillance system for collection of information, as well for anticipation and

[352]UK, CCA, Sec. 2 sub-section 1 clause g.

assessment of risk. When a PHE occurs, the governments of the respective nations are equipped with measures to create awareness among its citizens to avoid panic and spread of false information. Both USA and China have specific legal provisions to deploy members of military and armed forces to meet with the undesired and uncertain circumstances arising out of a public health emergency. Every method provided by the nation states, ensures proper management of health care facilities as well as provides for regulations and protection of health care workforce, and other voluntary workers during a PHE.

As already mentioned, the purpose of the comparative analysis in this chapter is to conduct an examination of efficacy of Indian Laws prevailing in the area of PHE. Based on the above discussion, the challenges before Indian legal system about PHE can be ascertained. It begins from defining the federal structure of government in the wake of a PHE, to post-emergency management, based on definitive role of levels of government. The comparative analysis helps to determine whether the application of criminal law to a PHE situation. In addition to this, the comparative analysis helps to make provisions in India that could be particularly applied in Public Health Emergency situations. The result of comparative analysis would be complete only after examining the legal response to public health emergency in India. The comparative analysis also helps to determine whether India needs a comprehensive legislation to deal with the public health emergency.

CHAPTER 5

GENERAL OVERVIEW OF LEGAL RESPONSE TO PUBLIC HEALTH EMERGENCY IN INDIA

5.1 INTRODUCTION

Chapter 2 has identified three instances of Public Health Emergency for this study. The first category consists of an occurrence or threat of an infectious or communicable disease, including pandemic and epidemics. Second category consists of occupational accident or a chemical accident including radio-active disasters or biological accident, causing health consequences for many populations seeking immediate or emergency medical care. Third and last category consists of emergency medical care arising out of natural calamities, or otherwise. In all these instances the State will be compelled to take immediate measures to provide health care facilities to the affected persons. In such cases, the State measures will be different from ordinary public health measures. The challenges before State in the events of PHE are already discussed in the second chapter. This chapter analyses whether Indian Laws have succeeded in dealing with such challenges.

The chapter deals with the legal challenges before the State during occurrence of PHE. The primary responsibility of State is to deal with the prevention and mitigation of PHE in context of its compliance with International Health Regulation. In Chapter 3 that deals with International Regulations over PHE has in detail discussed the duties of Member States under International Health Regulations. This chapter examines whether Government of India has incorporated the said provisions to deal with PHE. The second issue is the examination on observance of guidelines issued by World Health Organization to deal with epidemics and pandemics by Government of India. The third issue is regarding role of each level of Government, i.e, to determine whether there is a need to declare emergency under Article 365 of the Constitution of India, since PHE like, COVID-19 pandemic affects the entire nation. The next area is checking the adequacy of legal mechanism for prevention and mitigation of PHE in India. It includes disaster management as well as the management of biological wastes during PHE. And lastly, the chapter discusses the justiciability of invoking criminal law during PHE. Based on the analysis of the above-mentioned legal issues, a conclusion will be reached regarding the adequacy of legal framework in India that deals with the primary issues during a PHE.

5.2 LEGAL PROVISIONS GOVERNINNG THE PREVENTION AND MITIGATION OF PUBLIC HEALTH EMERGENCY IN CONTEXT OF ITS COMPLIANCE WITH INTERNATIONAL HEALTH REGULATIONS

As aforementioned right to health has been brought under the wider ambit of Article 21 granting it fundamental right status. Yet, in India, there is no comprehensive public health legislation. Management of health during disasters falls under the larger umbrella of public health[353].There are disaster specific statutes prescribing norms for tackling a particular type of disaster[354].

Based on International Health Regulations the State has several legal obligations. The first and foremost is establishment of National Focal Point. Secondly, there shall be an adequate health surveillance mechanism. Thirdly, the State shall notify WHO about the occurrence of PHE. Fourthly, the States have an obligation to share information regarding PHE to WHO and the Public Health response to PHE to WHO constantly and the States shall also comply with temporary recommendations issued by WHO.

As aforementioned, the implementation IHR 2005 demands setting up of an integrated global alert and response system for epidemics and other PHEs. It is based on national public health systems and capacity and coordinated response from international system. The two-fold functions of National Focal Point are sending urgent communications concerning the implementation of IHR to WHO IHR contact points and disseminating information to, and consolidating input from, relevant sectors of administration of the State Party concerned[355]. Thus, the National Centre for Disease Control[356] is the National IHR focal point in India[357]. It covers services, trained health manpower development and research. The services include employment of epidemiological and diagnostic tools, referral diagnostic services, ensuring availability of scientific research material, teaching aids, storage and supply of vaccine and quality control[358]. It recommends control measures for outbreak of communicable diseases in States and Union Territories and NCDC monitors such outbreaks and its effects. As part of referral services, it provides for special diagnostic facilities that

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[353] Health and Disaster Risk Management in India, https://www.nipfp.org.in/media/medialibrary/2018/10/WP_2018_241.pdf, (last visited April 15th 2021).

[354] National Disaster Management Authority, Government of India, https://cdn.s3waas.gov.in/s38757150decbd89b0f5442ca3db4d0e0e/uploads/2018/07/2018071024.pdf,(last visited April 19th 2021).

[355] IHR, Article 4.

[356] Hereinafter referred to as NCDC.

[357] Integrated Health Information Platform, https://ihip.nhp.gov.in/idsp/#!/block12, (last visited August 19th, 2021).

[357] IHR, Article 4.

[358] National Centre for disease Control, https://ncdc.gov.in/index1.php?lang=1&level=1&sublinkid=158&lid=167, (last visited August 19th, 2021).

are not ordinarily available in hospitals and medical colleges. It gives special emphasis to trained health man-power development, which is, an essential component in ensuring quality health care services. The training programmes so developed, helps to improve necessary need-based skills. It also conducts applied integrated research in areas of communicable and non-communicable diseases and part of preparation for prevention and mitigation of diseases[359]. The NCDC, has in confirmation with WHO recommendations have passed guidelines for the prevention and mitigation of pandemic[360]. India has also succeeded in reporting the public health assessment during COVID-19 consistently to WHO[361].

As per Article 1 of IHR,2005 Surveillance means the systematic ongoing collection, and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary. The Ministry of Health and Family Welfare has also established a Central Bureau of Health Intelligence[362]on recommendation of Health Survey and Planning Committee known as Mudaliar Committee[363]. It is the health intelligence wing under the Directorate General of Health Services[364]. It aims to strengthen health information system in each of the district in the country up to the facility level for evidence-based decision making in the Health Sector. It functions on collaborating with WHO. The major functions of CBHI includes collection, analysis, and dissemination of data, identify, and disseminate innovative practices for health sector reforms, develop human resources, carrying out need based operational research, and to collaborate with national and international institutes for imparting knowledge and skill development. To meet the criteria laid down by IHR, the Central government grants fund to States to maintain surveillance system, and the states then report monthly to CBHI[365]. In addition to CBHI, with an aim to strengthen the disease surveillance, and to initiate timely and effective public health actions, the Government has established a decentralized State based surveillance system for epidemic prone diseases to detect early warning signals, namely, Integrated Disease Surveillance Programme[366][367]. IDSP was launched with World Bank assistance in November 2004 to detect and

[359] *Id.*
[360] NCDC, https://ncdc.gov.in/index1.php?lang=1&level=1&sublinkid=703&lid=550, (last visited Augusr 19th 2021).
[361] World Health Organization, https://www.who.int/countries/ind, (last visited Augusr 19th 2021).
[362] Hereinafter referred to as CBHI.
[363] National Health Portal of India, http://nhp.gov.in/mudaliar-committee-1962_pg, (last visited April 20th 2021).
[364] CBHI, https://www.cbhidghs.nic.in/index4.php?lang=1&level=0&linkid=35&lid=36, (last visited April 20th 2021).
[365] Katz R, *Comparative Analysis of National Legislations in support of revised IHR: potential models for implementation in US*, AJPH, (2010), 2347-2353, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2978189/#bib41, (last visited April 20th 2021).
[366] Hereinafter referred to as IDSP.
[367] Integrated Disease Surveillance Programme, https://www.idsp.nic.in/index1.php?lang=1&level=1&sublinkid=5778&lid=3707, (last visited August 19th, 2021).

respond to disease outbreaks quickly. It functions under the National Health Mission Programme[368]. The 2016 report of IDSP mentions outbreak of H1N1, Viral Hepatitis A and E. However, the IDSP is not involved in dealing with Pandemics, such as COVID-19 as the 2020 reports does not mention the same.

5.3 OBSERVANCE OF BASIC PRINCIPLES OF EPIDEMIC AND PANDEMIC MANAGEMENT IN INDIA

In this regard, the present legal framework's efficacy could be analyzed based on Epidemic and Pandemic Management's basic principles[369]. Anticipation of disease is the first one. There should be a well-functioning information and communication system with proper data collection and research. Based on this, the State needs to take adequate measures to predict an outbreak and its prevention. The second principle is preparation. It cannot be said that the spread of a pathogen can be prevented entirely. The State shall be ready to take adequate steps to reduce the spreading of the disease. Thirdly, detection of the outbreak. When an unusual disease starts spreading among the population, the Government shall detect it and study it. If the spreading goes undetected, it will lead to catastrophic consequences and may go out of control. For this, the Government requires systematic surveillance. Establishment of efficient Health Surveillance system as recommended by IHR[370] is an essential component in ensuring right to health during a PHE. It is the ongoing systematic collection, compilation, analysis and dissemination of date on reportable diseases and other events that present a potential threat to public health security[371]. The next is prevention and control of the disease and its spreading. It involves coordinated and rapid investigation and a well-organized health workforce. Next is the response. The Government shall have a response plan. It requires knowledge and expertise in epidemiology, health education, clinical and laboratory medicine. The response plan to a pandemic or an epidemic should be based on the above principles

Along with this, the State shall regulate the availability of essential medicines, including vaccines, drug prices, clinical and laboratory prices and provide adequate financial support for preparation and response. The Government shall take steps to create awareness among people, prevent the spread of false information about the disease, prevent violence against healthcare personnel

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[368] Monthly Surveillance Report, 2016, https://idsp.nic.in/showfile.php?lid=3720, (last visited April 19th 2021).

[369] WORLD HEALTH ORGANIZATIONS, https://www.who.int/emergencies/diseases/managing-epidemics-interactive.pdf, (last visited April 19th 2021).

[370] IHR, *Supra.*

[371] Definition by Thacker and Berkleman obtained from Public Health Surveillance System, USAID, https://www.measureevaluation.org/resources/hisdatasourcesguide/module-10-public-health-surveillance-system. (Last visited on August 20th, 2021).

exposed to the disease, and prevent discrimination among populations against those affected by the disease.

The primary goals of a government shall include the following:

- the establishment of a proper communication system,
- well trained and prepared health workforce,
- adequate availability of pharmaceutical and laboratory facilities,
- availability of essential support services, including psychological and social support services,
- ensure surge capacity of health systems, i.e., the ability of the hospitals to meet increased demand for health services,
- maintenance of logistics, i.e., to provide the right resources at the right time in proper quantities and in the right place to satisfy the increasing demand without compromising hospitals' normal functioning,
- collection and maintenance of evaluation, feedback, and reports.

5.4. ROLE OF STATE AND NEED FOR EMERGENCY LAW

India, on multiple times throughout its history has met public health risks during natural disasters, man-made disasters and pandemic and epidemics. Examples include Bhopal Gas Tragedy[372], Kedarnath Floods 2013[373], and the current pandemic situation. However, in none of these situations, the provisions of Chapter XVIII of the Indian Constitution were not invoked. The emergency provisions under Chapter XVIII provide a simple way of transforming the normal federal fabric into an almost unitary system to meet national emergencies effectively. National emergency is declared under Article 352. National Emergency is declared when the President is satisfied that a grave emergency exists whereby the security of India or any part of the territory thereof is threatened by war or external aggression or armed rebellion[374]. Since, pandemic does not fall under the ambit of war or external aggression or armed rebellion though the entire nation was affected National Emergency was not declared in India during COVID-19 pandemic. The government of India Following a public curfew on 22nd March 2020, under the provisions of the Disaster

[372] 200,000 persons were exposed, and 3598 deaths were caused during Bhopal Gas Tragedy, Dhara R, Health Effects of Bhopal Gas Leak: a review, Epidemiol, 1992,https://pubmed.ncbi.nlm.nih.gov/1306166/, (last visited on August 21st, 2021).
[373] Epidemic, 128 cases of fever and diarrhea was reported in 2 days, obtained from in Times of India https://timesofindia.indiatimes.com/india/uttarakhand-floods-epidemic-looms-as-people-complain-of-fever-diarrhoea/articleshow/20770540.cms , (last visited on August 21 , 2021).
[374] Ind. Const. Art. 352(1).

Management Act, the Government of India imposed a nationwide lockdown from March 2020[375]. The lockdown has imposed restrictions on the civil liberties of citizens. Sarkaria Commission had earlier recommended that the breakdown of constitutional machinery includes a physical breakdown in earthquakes, cyclone, epidemics, flood, etc.[376]. However, the recommendations of Sarkaria Commission had not been incorporated into Indian Constitution. In China, there is a specific legislation namely, Emergency Response Law, is applicable during public health emergency. Under this law, Article 3 defines the term "emergency". It includes natural disasters, calamitous accidents, public health accidents and public security incidents, which occur abruptly and cause or may potentially cause serious social harm[377]. The Emergency Response Law enumerates the role and functions of different levels of Government, responsibilities of Armed forces, healthcare preparedness to be adopted by State governments, creation of risk assessment system, ensuring proper communication with public, management of resources, identifying the duties of citizens, and post-emergency measures. The legislation is not limited to imposing restrictions on civil liberties of citizens but also clearly demarcates the role of State. In USA, they have enacted a Model Law to deal with PHE, which could be adopted by its states. In UK, it is based on Civil Contingencies Act. Thus, in India, there is no need to invoke provisions of Article 352 during a PHE, for the reason, it might not affect the entire nation, and curtailing the civil liberties could not be the greatest method to prevent and mitigate the disease or the public health risk. From the examples of Bhopal Gas leakage, Floods in Kerala, Chennai, Uttarakhand, though, there were severe public health risks, there was no need for a national emergency nor even a State emergency under Article 365 of the Constitution of India, as the disaster was limited to a particular region. Therefore, instead of invoking emergency powers under the Constitution, the State may enact a model law, like in USA, which could be adopted by the States and Union Territories with necessary changes suitable to them.

In *Sachin Jain* v *Union of India*[378], it was noted that a few States have enacted laws regarding Public Health. It includes the Travancore-Cochin Public Health Act, 1955, the Madras Public Health Act, 1939, the Goa, Daman and Diu Public Health Act, 1985, the Madhya Pradesh Public Health Act,

[375375]No.40-3/2020, Government of India, Ministry of Home Affairs, dated 24.03.2020, https://www.mha.gov.in/sites/default/files/MHAorder%20copy_0.pdf

[376]Report of Sarkaria Commission, Ministry for Home Affair, Government of India, http://interstatecouncil.nic.in/report-of-the-sarkaria-commission/, (last visited May 31st, 2021).

[377] Emergency Response Law, Article 3.

[378] WP(C) No. 489/2020

1949, the Puducherry Public Health Act, 1973, the Gujarat Public Health Act, 2009 and the Assam Public Health Act, 2010.

Following is a brief discussion on public health legislations containing provisions dealing with PHE.

- The Travancore-Cochin Public Health Act provides for prevention and treatment of infectious diseases. Section 51 deals with appointment of additional health staff to deal with such circumstances. Section 69 talks about prohibition for acts leading to exposure to diseases. The provisions are applicable in matters of outbreak of infectious diseases. The Madras Public Health Act, the Goa, Daman and Diu Public Health Act, 1985, have similar provisions. The Act does not mention other instances of PHE rendering it inadequate in modern epoch.

- The Gujarat Public Health Act, 2009is more accurate comparing to the abovementioned legislations. It defines the terms "communicable diseases"[379], "condition of public health importance"[380], "contagious disease"[381], "disaster"[382], "essential drugs"[383], "Health Care establishment"[384], "infectious disease"[385], "infectious waste[386]", "isolation"[387], "medical treatment"[388], "public health"[389], and "right to health"[390]. The Act defines PHE under Section 2(34).

> *"Public health emergency" means an occurrence or imminent threat, including owing to degraded environmental conditions, of an illness or health condition that: (a) Poses a high probability of any of the following harms: (i) a large number of deaths or illness in the affected population; (ii) a large number of serious or long-term disabilities in the affected population, including teratogenic effects, or ; (iii) widespread exposure to an infectious or toxic agent that poses a significant risk of substantial future harm to a large number of people in the affected population; (b) And can be caused by any of the following: (i) the appearance of a novel or*

[379]GPHA, Section 2(3)
[380]GPHA, Section 2(4)
[381]GPHA, Section 2(5)
[382]GPHA, Section 2(9)
[383]GPHA, Section 2(12)
[384]GPHA, Section 2(14)
[385]GPHA, Section 2(16)
[386]GPHA, Section 2(17) – it includes biomedical wastes.
[387]GPHA, Section 2(19)
[388]GPHA, Section 2(23)
[389]GPHA, Section 2(30)
[390]GPHA, Section 2(39)

previously controlled or eradicated infectious agent or biological toxin, or; (ii) any disaster, including major accidents.

Explanation: Public health emergency can be due to communicable infectious diseases, chronic non-infectious, non-communicable conditions affecting large population, notifiable diseases, conditions of public health importance or locally endemic diseases.

Chapter II deals with health planning during disasters. Section 25 prescribes the Planning for public health emergencies caused due to disasters. Section 26 provides for services in cases of epidemics, disasters and conflict situations. The Act under Chapter III specifically deals with PHE. It includes detecting and tracking PHE[391], declaration of a state PHE[392], termination of PHE[393] and Emergency powers of the State Government[394].

- The Assam Public Health Act is another comprehensive legislation in this area. It defines the terms such as "endemic", "epidemic", "healthcare establishment", "public health emergency", public health emergency of international concern". A public health emergency under the Assam Act is defined as an unusual or unexpected occurrence or imminent threat of illness which affects or likely to affect a large population which needs immediate Public Health intervention to prevent death or disability to a large number of people[395].A "public health emergency of international concern" is defined as a PHE which is determined, under specific procedures under International Health Regulations, to constitute a public risk to other countries that potentially requires a coordinated international response[396]. The Act is appreciable for bringing human rights aspects of healthcare under Chapter III. It includes individual as well as collective rights. It identifies right to health[397] and its various dimensions. It includes users' right to information[398], to medical records and data[399], to prior autonomy and prior voluntary informed consent[400], to confidentiality, information, disclosure, and privacy[401]. The Act under Section 10 identifies the duties of the users. As per Section 2(u) a user means a person who seeks, access

[391]GPHA, Section 27
[392]GPHA, Section 28
[393]GPHA, Section 29
[394]GPHA, Section 30
[395]APHA, Section 2(s)
[396]APHA, Section 2(t)
[397]APHA, Section 5
[398]APHA, Section 6
[399]APHA, Section 7
[400]APHA, Section 8
[401]APHA, Section 9

or receives any health care, as outpatient or inpatient, from any healthcare establishment, facility, or provider, public or private, which operates for profit or not. Section 11 postulates the rights of healthcare workers. Chapter IV from sections 12 to 18 provides mechanism for implementation and monitoring of the provisions through State Public Health Board. The duties and functions of the authority are also clearly mentioned in the Act.

From the above discussion on state legislations dealing with Public Health risks reflects the need for a model central legislation as they have in USA, to avoid ambiguities and create uniformity.

5.5 LEGAL MECHANISM FOR PREVENTION AND MITIGATION OF PUBLIC HEALTH EMERGENCY

The National Disaster Management Act, 2005 is a not a public health legislation. It is an Act to provide for the effective management of disasters and for matter connected therewith or incidental thereto. Under Section 2(d) of the National Disaster Management Act, 2005, disaster means:

"A catastrophe, mishap, calamity or grave occurrence in any area, arising from natural or manmade causes, or by accident or negligence which results in substantial loss of life or human suffering or damage to, and destruction of, property, or damage to, or degradation of, environment, and is of such a nature or magnitude as to be beyond the coping capacity of the community of the affected area".

In India following a public curfew on 22nd March 2020, the government of India under the provisions of Disaster Management Act, imposed a nation-wide lockdown from March 2020[402]. The lockdown-imposed restrictions on the civil liberties of citizens. By the virtue of the Government Order, pandemic was brought under the purview of the Disaster Management Act. The provisions of the Act were again invoked to ensure unobstructed interstate movement of medical oxygen in 2021[403]. Under Section 35 of the Act the Central Government is empowered to take measure to deal with the disaster. It includes coordination of actions, integration of measures for prevention of disasters and mitigation, appropriate allocation of funds for prevention disaster, mitigation, capacity building and preparedness, ensuring preparedness to promptly and effectively respond to any threatening disaster situation or disaster, deployment

[402] *Supra note* at 8.
[403] No.40-3/202, Government of India, Ministry of Home Affairs, dated 22.04.2021, https://www.mha.gov.in/sites/default/files/MHADMAct_22042021.pdf

of naval, military and air forces and other armed of Union, coordination with UN Agencies, establishment of institutions for research, training, and developmental programmes in the field of disaster management and such other matters as it deems necessary.

Section 3 provides for the establishment of National Disaster Management Authority (hereinafter NDMA). NDMA is responsible for formulating the policies, plans and guidelines and envisions the development of an ethos of Prevention, Mitigation, Preparedness and Response[404]. NDMA has recognized Cyclone, Tsunami, Heat Wave, Landslide, Urban Flood, Floods, and Earthquakes as Natural Hazards. The man-made Hazards includes Chemical, Biological and Nuclear disasters[405]. The provisions of the Act are implemented by NDMA through its guidelines, policies, and plans. Section 8 provides for establishment of National Executive Committee. One of the members of the committee include Secretary to the GOI in the Ministries or Department having administrative Control over healthcare. It is a measure to ensure health during a disaster. Under the powers and functions of State Executive Committee[406], District Authorities[407], State Governments[408] and GOI[409] they may provide healthcare services along with shelter, food, drinking water and essential provisions.

In 2019, a National Disaster Management Plan has been drafter. It strengthened the Disaster Resilient Development and ensures enhancement of our capacity to recover from such disasters[410]. National Disaster Management Guidelines for Management of Biological Disasters, 2008 issued by NDMA has given several directions towards the emergency response plan[411]. It includes establishment of pre-hospital care, training in PPE and collection of samples with the help of mock drills etc., implementation of well- organized communication and surveillance system, and developing mechanisms for checking the status of coordination in planning, operations and logistics management will be developed. It provides measures for transportation, decontamination, facilities for isolation, prioritization based on the assessment by the clinical team. It also talks about psycho-social care needed by patients. major mental health issues reported during pandemic. State played an important role in enabling

[404] https://ndma.gov.in/
[405] *Id.*
[406] Section 24
[407] NDMA, Section 34, 2005
[408] NDMA, Section 39, 2005
[409] NDMA, Section 36, 2005
[410] NATIONAL DISASTER MANAGEMENT AUTHORITY, GOVERNMENT OF INDIA, NATIONALDISASTER MANAGEMENT PLAN (2019).
[411] NATIONAL DISASTER MANAGEMENT AUTHORITY, GOVERNMENT OF INDIA, NATIONAL DISASTER MANAGEMENT GUIDELINES-MANAGEMENT OF BIOLOGICAL DISASTERS (2008).

telepsychiatry consultations, toll free number particularly for psychological and behavioral issues. The guidelines for Management of Biological Disasters says that the health system should conduct the present as well post disaster conditions.

5.6 APPLICATION OF CRIMINAL LAW TO PREVENT SPREAD OF DISEASES

The most important function of the State is to act as the guardian of law and order, preventing all injuries to itself and all disobedience to the rules which it has laid down for the common welfare[412]. The State ensures it by identifying certain acts as punishable. This branch of law is known as Criminal law, and in India it has been codified in Indian Penal Code,1860 (hereinafter referred to as IPC) and Code of Criminal Procedure, 1973 (hereinafter referred to as CrPC). The former specifically deals with offences and states what matters will afford an excuse or a defense to charge an offence[413]. The provisions under IPC and CrPC are also used to tackle PHE. They are discussed hereunder.

Section 3 of Epidemic Diseases Act, 1897 prescribes punishment under Section 188 of IPC for violation of former's provisions[414]. The objective of the provision is to prevent any act or omission resulting in danger to human life, health or safety. The conditions under Section 188 are as follows:

i. there is an order duly promulgated by a public servant,
ii. such public servant is lawfully empowered to promulgate such order,
iii. that a person who was directed by this order has knowledge about it and had disobeyed it,
iv. such disobedience has caused or tended to cause injurious consequences and
v. such disobedience causes or tends to cause obstruction, annoyance or injury, or risk of obstruction, annoyance, or injury, to any persons lawfully employed.

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[412]RATAN LAL &DHIRAJ LAL, INDIAN PENALCODE,5, (Wadhwa Publication, 1992).
[413]*Id.* at 6.
[414]Section 188 of IPC reads as follows: -*"Whoever, knowing that, by an order promulgated by a public servant lawfully empowered to promulgate such order, he is directed to abstain from a certain act, or to take certain order with certain property in his possession or under his management. disobeys such direction, shall, if such disobedience causes or tends to cause obstruction, annoyance or injury, or risk of obstruction, annoyance or injury, to any persons lawfully employed, be punished with simple imprisonment for a term which may extend to one month or with fine which may extend to two hundred rupees, or with both: and if such disobedience causes or tends to cause danger to human life, health or safety, or causes or tends to cause a riot or affray, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine which may extend to one thousand rupees, or with both. Explanation - It is not necessary that the offender should intend to produce harm or contemplate his disobedience as likely to produce harm. It is sufficient that he knows of the order which he disobeys, and that his disobedience produces, or is likely to produce, harm."*

Orders issued under Sections 144 and 145 of CrPC comes under this ambit[415]. Several state governments including State of Kerala has invoked Section 144 to deal with the Pandemic. Under Section 144 a District Magistrate, a sub - Divisional Magistrate or any other Executive Magistrate specially empowered in this behalf on satisfaction have the power to issue order in urgent cases of nuisance or apprehended danger. It is a branch of preventive jurisdiction that deals with cases, urgent in their character, of either nuisance or apprehended danger[416]. In *Kushumkumaree Debee* v *Hemalinee Debee*[417], it was made clear that the Magistrate is only entitled to make a restrictive order preventing a person from doing an act and it doesn't extend to a mandatory order directing a person to do some act. In *Babulal Paratte* v *State of Maharashtra*[418], the SC observed that the power under Section 144 could be used even in anticipation of danger based on sufficient materials to show requirement of immediate prevention of certain acts are necessary to preserve public safety. Section 144 was invoked by the States to prevent assembly of any kind including demonstrations, processions, protests; social, cultural, and political gatherings, tour, and travels, etc.[419]. Certain states have excluded essential services such as hospitals, diagnostic centers, pharmacies, veterinary services, grocery shops, vegetable vendors, cold storages, banks, transport of goods, water supply, agriculture-related services, e-commerce, petrol pumps, electric and gas supply, ATMs, Postal Services[420]. From the above reading it is understood that Section 144 was invoked to prohibit the gathering of people to prevent the spread of disease. During the 2019 Floods, State of Maharashtra has imposed orders prohibiting assembly of people under Section 144, CrPC in districts affected by flood[421]. It is because the natural calamities may give rise to spread of infectious diseases including diarrhea, acute respiratory infections, malaria, leptospirosis, measles, dengue fever, viral hepatitis[422]. Therefore, to get back to normal life the State is required to take measures to prevent the spread of diseases during a PHE.

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[415] KA PANDEY, BM GANDHI'S INDIAN PENAL CODE, 210 (Easter Book Company, 2019).
[416] RATAN LAL &DHIRAJ LAL, CODE OF CRIMANLPROCEDURE, 202, (Lexis Nexis, 2013).
[417] (1933) 63 Cal 11.
[418] AIR 1961 SC 884
[419] LIVE LAW, https://www.livelaw.in/news-updates/covid-section-144-imposed-in-delhi-till-march-31-demonstrations-gatherings-prohibited-154204?infinitescroll=1, (last visited April 19th 2021).
[420] LIVE LAW, https://www.livelaw.in/news-updates/section-144-in-maharashtra-advocates-offices-allowed-to-open-with-50-capacity-if-courts-are-working-172565, (last visited April 19th 2021).
[421] HINDUSTAN TIMES, https://www.hindustantimes.com/mumbai-news/in-flood-hit-kolhapur-district-state-prohibits-assembly-of-people-to-bring-back-normalcy/story-nkZUyX2zbW5bXGutD8cQBI.html, (last visited April 19th 2021).
[422] Isidore Koudio, Syed Alijunid, Taro Kamigaki, Karen Hammad & Hitoshi Oshitani, *Infectious diseases following natural disasters: prevention and control measures,* TAYLOR AND FRANCIS ONLINE,(APRIL 19th 2021),

Section 269 to 271 IPC are public health law provisions. These provisions penalize certain acts likely to spread infection of disease dangerous to life. Section 269 deals with negligent acts while section 271 deals with malignant acts likely to spread infection of diseases dangerous to life. In *State of Maharashtra* v *Devahari Devasingh Pawar*[423], the doctors and technicians of a Government Hospital were prosecuted for supply for HIV contaminated blood because of which some patients who were given blood transfusion tested HIV positive. It was held by the Supreme Court that the prosecution of the accused for the offence under this section does not require the sanction of the government in terms of Section 197 of CrPC. Offence under section 270 is an aggravated form of an offence shown under section 269, due to the presence of the term "malice" in a person's conduct[424]. In *Queen Empress* v *Krishnappa*[425] , accused persons were held liable under the provisions of section 269. In this case, Krishnappa knowing that he was suffering from cholera travelled by a train without informing the railway officers of his condition. Murugappa, his friend, knowing the situation purchased his ticket and travelled with him. It was held that Krishnappa is liable under section 269 and Murugappa is liable for abetment of the offence. Section 271 deals with disobedience to quarantine rule. The motive for disobedience of quarantine rule is immaterial[426]. The disobedience is punishable whether any injurious consequence flows from it. These provisions are construed in a manner to indorse welfare of the society[427]. In *State v Egemnazaro v Myheybek*[428], the accused person was charged for offences punishable under Section 3 of the Epidemic Diseases Act, 1897, Section 51 r/w section 58 of the Disaster Management Act, 2005 and Sections 188, 269, 270, 271 and 120B of IPC. However due to lack of evidence the accused persons were acquitted. In the 1902 case, *Niadar mal*[429],the accused was held guilty under section 188. He resided in a plague-stricken house and negligently met a plague patient, which lead to the death of such patient. Next day, he travelled by rail to a neighboring town and from there to another village. His actions were dangerous and likely to spread infection of a disease dangerous to life.

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tandfonline.com/doi/full/10.1586/eri.11.155#:~:text=Natural%20disasters%20including%20floods%2C%20tsunamis,%2C%20dengue%20fever%2C%20viral%20hepatitis%2C

[423]SLP(Crl) No. 1268 of 2006.

[424]KA PANDEY, *supra note* 39 at 260

[425] (1883) 7 Mad 276.

[426]RATAN LAL &DHIRAJ LAL, *supra note* 36 at 276

[427]*Id.* at 277

[428] FIR No. 63/2020 PS Crime Branch

[429] (1902) PR No. 22, https://cdn.s3waas.gov.in/s38757150decbd89b0f5442ca3db4d0e0e/uploads/2018/07/2018071024.pdf, last visited on May 21st 2021.

Section 505[430] was also made applicable during the pandemic to curb publication and circulation of statements, rumor or reports conducing to public mischief. States used section 54 of Disaster Management Act, that imposes penalty on whoever makes or circulates a false alarm or warning as to disaster or its severity or magnitude, leading to panic.

Though, several State governments including State of Kerala has widely used criminal law to deal with pandemic, it cannot be regarded as an effective mechanism in a public health sector. In UK, the emergency response was based on interdepartmental cooperation. There should be effective integration of operation of multiple agencies, while giving prominence to department of health, with other departments aiding the same. However, in India, the duties with respect to mitigation of disease was delegated to Department of Police, which was not a useful measure, as it has led to several human rights violations. There were several accounts of police brutality towards vulnerable classes of society[431] which raises the question whether application of criminal law is the answer to a public health crisis? In, *Dr. Vikram Singh v Union of India*[432], a public interest litigation under Article 32 seeking direction to quash FIRs registered under Section 188 of IPC during the pandemic for violation of lockdown and other petty offences was dismissed. SC in this case observed that it is difficult to implement lockdown if these provisions are not invoked. Also, the raise in number COVID-19 cases also show that the deployment of Police Force was not the right approach to deal with Public Health Emergency. In USA and China there are specific legal provisions to deploy members of military and armed forces to meet with the undesired and uncertain circumstances arising out of a public health emergency. However, such duties are limited to participation in emergency rescue, relief, and handling. It was a draconian approach to deploy police forces to restrict the civil liberties of people without properly demarcating the powers of Police force. In countries like, USA and China, the powers of armed forces during a PHE is well-defined which ensures enforcement of basic rights of people.

5.7. CONCLSUION

From the above discussion it is understood that India has successfully implemented the IHR Guidelines and have adopted the recommendations of WHO to deal with PHEs. However, it is

[430] CrPC, S. 505.
[431] Open Global Rights, https://www.openglobalrights.org/addressing-police-brutality-in-india-during-COVID-19/, (last visited 23rd August, 2021)
[432] WP(Crl) Diary No. 10953/2020.

met with several lacunae. There is no well-defined role of State which was evident during the vaccination policy during COVID-19. In *Re Distribution of Essential Supplies and Services During Pandemic*[433], the Federal nature of Indian Polity was taken into consideration while criticizing the current vaccine policy, which lead to the procurement of vaccine by Centres for distribution for States[434]. In USA the role of Federal Government and the States are clearly demarcated. As per item 6 of State list under 7th Schedule of Constitution of India, "public health" comes under the purview of "State" functions. Thus, unless, an emergency is proclaimed, constitutionally it is difficult for the Central Government to interfere with health-related matters. However, proclamation of national emergency under Article 352 is not a solution to public health risks. Instead, likewise, in USA, the Central Government shall draft a Model PHE Legislation, which may be adopted by the State Legislatures. A similar approach is seen in the case of Clinical Establishments Act. It is a central legislation, and the same has been adopted by several State legislatures, suitable to their needs and requirements. Thus, while drafting such a model law, the Government shall make sure to clearly identify the functions and responsibilities of three levels of governments, i.e., Centre, State and Local self-government as per the nature of PHE. Most importantly, it shall give a proper and uniform definition to the term "public health emergency". It shall clearly define the responsibilities of the State to ensure healthcare preparedness, distribution and management of resources, proper communication with public to create awareness, define the duties of citizens, provide for interdepartmental coordination giving prominence of department of health, provisions for regulation and protection of healthcare workforce, powers of Police Force and Armed force during PHE ensuring that it would not curtail the fundamental rights of people, and they shall create an adequate emergency response plan according to the nature and impact of PHE.

[433] WP(C) no. 3 of 2021
[434] Livelaw, https://www.livelaw.in/top-stories/centre-to-procure-vaccines-for-states-free-vaccines-for-18-44-years-says-pm-modi-175355,(last visited on July 7, 2021).

CHAPTER 6

CRITICAL EVALUATION OF APPLICABILITY OF PUBLIC HEALTH LEGISLATIONS IN INDIA DURING A PUBLIC HEALTH EMERGENCY

6.1 INTRODUCTION

Generally, as a provider, the State ensures medical care to every person, including the times of PHE. It is facilitated through sub-centers, primary health care centers, community health centers, Sub-district hospitals and district hospitals, based on Indian Public Health Standards[435]. Nevertheless, the inadequacy of public health care system has been exposed, during the COVID-19 pandemic. It leads majority of Indian population to seek medical care under private sector. By the virtue of Directive Principles of State Policy under Part IV of the Constitution of India, there are several laws applicable to medical practice and hospitals in India. State has come up with several legislations, that are applicable to government health institutions as well as private health institutions. These legislations include the Clinical Establishments (Registration and Regulation) Act, 2010, the Epidemic Diseases Act, 1897 and 2020 Amendment Ordinance, the National Medical Commission Act 2019, the National Commission for Indian System of Medicine Act, 2020, the Indian Nursing Council Act, 1947, and the Mental Health Care Act, 2017.In addition to these legislations, there are certain legislations that deal with health care systems and maintenance and regulation of clinical establishments. The other legislations include Consumer Protection Act, 2019[436], Certain provisions of Indian Penal Code[437], The Maternity Benefits Act[438], Drugs and Cosmetics Act, The Pharmacy Act, 1948 etc. In this regard, it is also necessary to examine the Government Initiative regarding control and regulation of drug prices in India. Under the Essential Commodities Act, 1955, drugs have been enlisted as an essential commodity. Also, under section

[435] CHOOKSHI.M, PATIL.B, *Health Systems in India,* JOP, 2016, 9-12.
[436] In the Case of *Indian Medical Association* v *V.P Shantha,* 1956 SCC 651, Supreme Court has brought the medical profession within the ambit of a service defined under Section 2(1) (o) of the Consumer Protection Act, 1986. Since then, the Consumer protection Act is applicable to medical negligence cases. In 2019, the 1986 Act was repealed when it was found obsolete.
[437] Under Section 52, 81, 91, 337,338, a medical practitioner can be brought under the ambit of negligence and acts causing injuries or endangering the life during service. Also, sections 269, 270 and 271 of Indian Penal Code for the prevention and control of infections and other similar diseases. The latter were invoked during the COVID-19 pandemic crisis to control and regulate the Indian Population.
[438] It is a social-welfare legislation that protects the employment of women during pregnancy. It does not provide any regulations with respect to health care system.

3 of the Essential Commodities Act, the Central Government has the power to issue orders for the same.

However, the abovementioned legislations neither have any reference to public health emergencies nor address the challenges faced by health care system. Healthcare provisioning during a PHE differs significantly from the medical care provisioning during ordinary course. Therefore, in this chapter the researcher will be evaluating the present legal framework applicable in the events of PHE, in reference to preparedness and management of health care institutions.

6.2 PREVENTION AND MITIGATION OF DISEASES

The Epidemic Diseases Act, 1897, was enacted by the British Government to combat the Bubonic Plague[439]. Originally the Act only had four sections in total. In 2020 the GOI inserted specific new provisions to deal with the violence against health care personnel during the COVID-19 pandemic.

Primarily the Epidemic Diseases Act, 1897 focuses on better prevention of the spread of Dangerous Epidemic Diseases. Section 2 grants power to State Governments to take special measures and prescribe regulations to contain dangerous epidemic diseases. There are two conditions for invoking the provisions of the Epidemic Diseases Act 1897. First, the State Government is satisfied that the State or any part thereof is visited by, or threatened with, an outbreak of any dangerous epidemic disease. Second, the State Government thinks that the ordinary provisions of the law for the time being in force are insufficient for the purpose. In such situations, the State Government, may take, or require or empower any person to take, such measures and, by public notice, prescribe such temporary regulations to be observed by the public or by any person or class of persons as it shall deem necessary to prevent the outbreak of such disease or the spread thereof. It may determine in the manner and by whom any expenses incurred shall be defrayed. The expenses include compensation too. The regulations also include inspection of persons travelling by railway or otherwise, as well as the segregation, in hospital, temporary accommodation or otherwise, of persons suspected by the inspecting officer of being infected with any such disease. Section 2A of the Act[440] empowers the Central Government to prescribe regulations for the inspection of any bus or train or goods vehicles or ship or vessel or aircraft are leaving or arriving at any land port or aerodrome in the territory of India.

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[439]Deshpande. P, *India: The Epidemic Act of India 1897: AN Analysis Vis-à-vis The Covid-19 Pandemic,* MONDAQ, https://www.mondaq.com/india/government-measures/928706/the-epidemic-act-of-india-1897-an-analysis-vis-vis-the-covid-19-pandemic, (Last visited on April 16th2021,7:39am),

[440] Inserted in 1920.

6.3 REGULATION OF HEALTHCARE WORKERS

Regulation of healthcare workers is an important aspects of every public health system. In India it is dealt under National Medical Commission Act, 2019. Prior to the enactment of National Medical Commission Act 2019, the National Medical Council was responsible for the regulation of medical education and practices. The Act repealed the National Medical Council Act, thereby dissolving the national medical council and accordingly, National Medical Commission was set up. This change was made due to the allegations of corruption, lack of accountability, and insufficiency in performance of its regulatory functions.

Objectives of the Act are to provide for improvement in access to quality and affordable medical education, ensuring the availability of high-quality medical professionals in all parts of the country, promotions of equitable and universal healthcare and national health goals to achieve community health perspective, encourage medical professionals to adopt latest medical research in their work and to contribute towards it. It also includes conducting of periodic and transparent assessment of medical institutions, facilitation and maintenance of medical registers, and enforcement of high ethical standards.

6.4 PROTECTION OF HEALTHCARE WORKERS

There are no specific labour laws protecting the interests of healthcare workforce. The state had to amend the provisions of EDA to curb the attacks against the healthcare workers. On 22nd April 2020, the President of India promulgated the Epidemic Diseases Amendment Ordinance 2020 for amending the Epidemic Diseases Act. New sections were added to tackle violence against health care personnel. S.2B expressly prohibits violence against a healthcare service personnel or cause any damage or loss to any property during an epidemic. S.1A was inserted into the Act to tackle violence against healthcare personnel. It talks about the act of violence includes any harassment impacting the living or working conditions of healthcare personnel, obstruction of discharge of duty, either within the premises of clinical establishments or otherwise, causing harm, injury, hurt, intimidation, to their life or causing loss or damages to the property or any document in their custody. It further says that no person can commit or abet the commission of an act of violence against a healthcare service personnel or abet or cause damage or loss to any property during an epidemic. They will also be liable to pay compensation.

The healthcare service personnel are defined as any person who, while carrying out his duties in relation to epidemic related responsibilities, who may come in direct contact with affected patients and thereby is at the risk of being impacted by such diseases and includes any public and clinical

healthcare provider such as a doctor, nurse, paramedical worker and community health workers, any other person so empowered under the Act or authorized by the state government to take measures to prevent the outbreak.

To avoid ambiguities, the term property was also defined in this ordinance. Property includes a clinical establishment as defined in Clinical Establishments (Registration and Regulation) Act. It includes any facility identified for quarantine and isolation of patients during an epidemic, a mobile medical unit, and any other property in which a healthcare service personal directly relates to epidemic.

6.5 REGULATION OF CLINICAL ESTABLISHMENTS DURING PHE

Clinical Establishments (Registration and Regulation) Act, 2010 is one of the legislations that has direct influence on public health institutions. The Act regulates and allows registration of clinical establishments on fulfilment of minimum standards as prescribed the Act. It is applicable to all types of clinical establishments including therapeutic and diagnostic services and to both public and private sector. The Parliament has no power to make laws for the States with respect to any of the matters aforesaid except as provided in articles 249 and 250 of the Constitution. Some of the important provisions of the Act are discussed hereafter.

Section 2(c) defines[441] the term clinical establishments in its widest scope to include every facility that provides for a health care service. The term "clinical establishment" means a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or a

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[441]Clinical Establishments (Regulation and Registration) Act, 2010, Section 2(c) defines the term "clinical establishment" as follows: *"A clinical establishment means a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or a place established as an independent entity or part of an establishment as referred above in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not, and shall include a clinical establishment owned, controlled or managed by the Government or a department of the Government; a trust, whether public or private; a corporation ,including a society registered under a Central, Provincial or State Act, whether or not owned by the Government; a local authority; and a single doctor, but does not include the clinical establishments owned, controlled or managed by the Armed Forces."*

place established as an independent entity or part of an establishment as referred above in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not, and shall include a clinical establishment owned, controlled or managed by the Government or a department of the Government; a trust, whether public or private; a corporation ,including a society registered under a Central, Provincial or State Act, whether or not owned by the Government; a local authority; and a single doctor, but does not include the clinical establishments owned, controlled or managed by the Armed Forces.

The Act defines the term "emergency medical condition" under Section 2(d). It means a "medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain of such nature that the absence of immediate medical attention placing the health of the individual or, with respect to a pregnant woman, the health of the woman or her unborn child in serious jeopardy; or serious impairment to bodily functions; or serious dysfunction of any organ or part of a body. Earlier in *Paschim Banga Khet Mazdoor Samity* v *State of WB*[442], the SC has directed the state to ensure the Constitutional duty of government-owned hospitals to provide timely emergency treatment.

The Clinical Establishments (Registration and Regulation) Act, 2010 is silent about the preparedness and training of medical professionals and is limited to the procedure for registration of clinical establishments. The Central Government under Section 52 is empowered to make laws. Thus, the Department of Ministry of Health and Family Welfare has issues Clinical Establishments Rules, 2012(hereinafter referred to as Rules, 2012). In addition to the conditions under Section 12 of the Act, the Rules, 2012 provides that the hospitals shall display the rates of each procedure, maintain electronic records, and ensure compliance with Standard Treatment Guidelines. The Standard Treatment Guidelines deals with treatment of cardiovascular diseases, critical care, tuberculosis control, mental health care, oral health, AIDS Control. Rabies Control, hypertensions, etc. **However, the guidelines do not provide for measures to meet epidemic or pandemic diseases.** The definition of clinical establishments under the Act lacks uniformity and is ambiguous albeit it brings in different health care facilities under its purview. The Act does not provide for a

[442] 1994 SCC (4) 37

meaningful categorization of the different kinds of establishments brought under it. The Act says that the National Council has the power to make classifications of Clinical Establishments.

6.6 PROTECTION OF MENTAL HEALTH

In Chapter IV, it was observed that the occurrence of 11/9 attack also compelled the government to consider the mental health related aspects as terrorism is an assault on mental health and well-being of the general public[443]. A PHE has severe impact on mental health of individuals. This issue was identified during the COVID-19 pandemic in India.

WHO has opined that:

> *"The new realities of working from home, temporary unemployment, home-schooling of children, and lack of physical contact with other family members, friends and colleagues take time to get used to. Adapting to lifestyle changes such as these and managing the fear of contracting the virus and worry about people close to us who are particularly vulnerable, are challenging for all of us. They can be particularly difficult for people with mental health conditions[444]."*

WHO as a part of promoting mental health during COVID-19 pandemic, has also recommended not to discriminate people having mental health issues due to changing world scenario. WHO has given guidelines to adults, parents, and persons having mental health condition. In India on outbreak of COVID-19 the GOI has implemented telemedicine services to deal with mental health issues[445]. The outbreak of COVID-19 pandemic has pointed out the importance of mental wellbeing which led to telehealth in mental health care. Most of the nations have relied on teleconsultations to maintain the mental well-being of their citizens. Clinicians have expressed concerns about its impact on rapport building, the therapeutic relationship, privacy, and safety issues[446]. The reduced non-verbal communications (e.g., inflection, tone, gestures and mannerisms) can be a deterrent for some. Some therapists are also of the view that it is less effective than in-person therapy and lack experience or interest in technology-delivered interventions[447].The official website of GOI has

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[443]*Ibid* at 402

[444] WOLRD HEALTH ORGANIZATION, https://www.who.int/campaigns/connecting-the-world-to-combat-coronavirus/healthyathome/healthyathome---mental-health?gclid=EAIaIQobChMIibrjkvTW8gIVhbaWCh2GQAZ8EAAYAyAAEgKN-PD_BwE, (last visited on August 28th 2021).

[445]GOI, https://www.mygov.in/covid-19,(visited on August 28th 2021).

[446] NCBI, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7387833/, (last visited May 22nd 2021).

[447]*Id* at 12.

given a telephone number to which any person having mental health issues can call and seek remedies[448].

In this regard, the Mental Health Act, 2017[449] could also be analyzed which has identified the rights of persons with mental health issues. It is a revolutionary attempt to systematize the mental healthcare provisioning in India. It aims to provide for mental healthcare and services for persons with mental illness and to protect, promote and fulfil the rights of such persons during delivery of mental healthcare and services and for matters connected to it. It has replaced the Mental Health Act, 1987.The primary goal of MHA is to provide mental health care and services for persons with mental illness and to protect and fulfil the rights of such persons during delivery of such services and connected or incidental matters. It defines the terms, clinical psychologist, mental healthcare, mental health establishment, mental health nurse, mental health professional, mental illness, and the psychiatrist. Section 3 talks about the determination of mental illness. This is one of the modern and efficient legislation in India that deals with health care services. It not only provides for the administrative set up for the regulations but conveys the methods of administration.

MHA, however, does not have any specific provisions in respect of public health emergency, and the Act is more inclined towards protection of persons with mental illness in the mental health institutions. Nevertheless, on outbreak of COVID-19 pandemic, the Ministry of Health and Family Welfare, Government of India in collaboration with National Institute of Mental Health and Neurosciences had issued Guidelines on Managing Mental Illness in Hospital Setting during COVID-19[450][451] . The guidelines aim at managing psychiatric disorders, both pre-existing and new onset not induced directly by the pandemic. The guidelines have identified the key challenges faced by mental health service providers considering the COVID-19 pandemic. It includes effect of isolation or quarantine of persons with active symptoms of mania, acute psychosis, psychiatric disorders, mental health emergencies, because of which, the mental health staff shall keep close contact with such persons, and may invoke provisions of Mental Health Care 2017, National Disaster Management Act and Epidemic Diseases Act, when necessary.

The Guidelines provide for reorganization of Infrastructure and administration. It recommends that all Mental Health Establishments to constitute a Hospital Infection Committee that ensures the implementation of the newer norms during COVID-19 pandemic. It shall ensure adequate human

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[448]GOI, https://www.mygov.in/covid-19,(last visited on August 28th 2021).
[449] Hereinafter referred to as MHA.
[450] Hereinafter referred to as the Guidelines.
[451] Government of India, #IndiaFightsCorona COVID-19 in India, Vaccination, Dashboard , Corona Virus Tracker | mygov.in, (last visited on September 12th 2021).

resources and other resources. All personnel need to be trained on hand hygiene, physical distancing, donning, and doffing of the complete PPE kit. It also provides provisions for disinfection and waste management. The guidelines also provide provisions for protection of health care personnel.

Thus, the Guidelines, provide a comprehensive legislative response to protection of mental health by defining and demarcating the duties of health care personnel as well as the management of out-patient, in-patient and emergency care services.

6.7 REGULATION OF TELEMEDICINE AND OTHER DIGITAL HEALTHCARE PRACTICES DURING PHE

The World Health Organization defines digital health as "*a broad umbrella term encompassing eHealth, as well as emerging areas, such as the use of advanced computing sciences in 'big data', genomics and artificial intelligence*"[452]. Telemedicine in a simpler way, means healing at a distance[453]. Telemedicine is a kind of digital health. According to American Telemedical Associations, it is the natural evolution of health care in digital world. Telemedicine is basically the use of telecommunications technology to provide health care. It helps to overcome the issues about access to health care. Many hospitals and physicians have adopted the public-private partnership route to render services through telemedicine. It includes tele-diagnosis, and consultations, special services, and e-prescriptions. Telemedicine is not a separate specialty in itself; its standout is the use of various technologies in providing traditional healthcare services. It is a broad concept that covers within its ambit various aspects such as tele-radiology, tele-consultation, tele-nursing, tele-ICU and tele-surgery[454].

Telemedicine plays an important tole at the time of PHEs. Telemedicine practices have been found beneficial during the pandemic situation[455]. The Studies find telemedicine as a promising tool for better clinical care to patients at home, saving time, providing cost-effective and prompt access to healthcare services[456]. Telemedicine and other e-health services are beneficial also at the times of

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[452]WORLD HEALTH ORGANIZATIONS, https://www.who.int/health-topics/digital-health, (last visited April 21st2021).
[453] Chellaiyan. VG, , *Telemedicine in India: Where do we stand?,* NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6618173/(last visited April 21st2021).
[454]NISHITHDESAI.COM, https://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research%20Papers/e-Health-in-India.pdf(last visited April 21st2021).
[455] Monaghesh. E, Hajizadeh. A, *the role of telehealth during COVID-19 outbreak: a systematic review based on current evidence, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7395209/,* (last visited April 21st2021).
[456] Geetanjali S, Sharma. M, *Evolution of Smart Healthcare: Telemedicine During Covid-19 Pandemic, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8019338/,* (last visited April 21st2021).

natural calamities and other disasters[457]. Telemedicine Services promote the use and development of telemedicine services and the essential points such as the need to ensure quality and efficiency as well as supervision and oversight in the performance of such services.

In India there are no legislations to regulate telemedicine practices albeit its increasing importance. The telemedicine and other e-health services are regulated by virtue of Telemedicine Practice Guidelines, 2020[458]. It was founded in partnership with NITI Ayog. It defines the terms, telemedicine, telehealth, and registered medical practitioners to avoid ambiguity. Telemedicine is the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research, and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities. **Telehealth** is the delivery and facilitation of health and health-related services, including medical care, provider and patient education, health information services, and self-care via telecommunications and digital communication technologies. According to the guidelines, Registered Medical Practitioner is a person who is enrolled in the State Medical Register or the Indian Medical Register under the Indian Medical Council Act 1956. However, there is a question regarding its applicability since IMC Act 1956 has been replaced by NMC Act. A Registered Medical Practitioner is entitled to provide telemedicine consultation to patients from any part of India. As per the Guidelines, telemedicine is classified into four categories based on mode of communication, information, purpose of consultation and interaction. Here the telemedicine can be practiced by video, audio or in text-based format. The guidelines also talk about kinds of consultation, list of medicines for prescription and lays down the duties and responsibilities of RMP. RMP is required to collect all the necessary information from the patient to be able to exercise proper clinical judgment; decide the type of and ensure Patient management. It also covers health education, counseling and medication or prescribing medicines. During the Pandemic, telemedicine practices even extended to mental health services[459].Section 24(2) of the Mental Health Act, 2017 while dealing with restriction on release of information in respect of mental illness states that the right to confidentiality of person with

[457]Doarn. CR, Merrel. R, *Telemedicine, and e-health in Disaster Response,* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4074740/, (last visited April 21st2021).
[458] Ministry of Health and Family Welfare, https://www.mohfw.gov.in/pdf/Telemedicine.pdf, (last visited April 21st2021).
[459]Reay. RE, Keightley. P, *Telehealth mental health services during COVID-19: summary of evidence and clinical practice,* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7387833/, (last visited April 21st2021).

mental illness shall also apply to all information stored in electronic or digital format in real or virtual space.

However, there is one more issue to be addressed by the law, which end-of-life decision making process through digital platform. End-of-life decision making is the process that healthcare providers, patients, and patients' families go through when considering what treatments will or will not be used to treat a life-threatening illness. Several forms of this decision making are possible[460]. Due to the pandemic and nationwide lockdown, it is extremely challenging to provide a quality end-of-life care (EOLC) to all patients[461]. When a patient's prognosis for meaningful survival is poor, physicians' traditional goals to preserve life, benefit patients, and respect patient autonomy often conflict. The end-of-life decision making via digital medium give rise to lack of psychosocial support to the relatives of the patients, it is difficult to make proper communications, and difficulty in continuous monitoring of the patients to reach a decision. Also, the declaration of consent also becomes complex when it is done through digital media. Contemporary ethics, law, and public policy have prioritized patient self-determination in these situations, affirming patients' right to refuse medical treatments and to complete advance directives. Patients often lack sufficient knowledge of health states, interventions, and prognoses to make informed treatment choices.

One of the most important problem with the guidelines is that it does not have any binding effect. In *State of Odisha* v *Orissa Trust of Technical Education*[462]**,** the implementation of telemedicine guidelines was discussed. In *Priyanka Singh* v *State of Maharashtra*[463]it was held that telemedicine guidelines allow of prescription of drugs. The Government of India has proposed the DISHA Bill (Digital Information Security in Healthcare Act) and Personal Data Protection Bill, 2019 to deal with the matter of digital health[464]. DISHA is the legislation that seeks to formally establish National Electronic Health Authority of India. It also aims to facilitate the online exchange of patient information with a view to prevent duplication of work and streamline resources. Personal Data Protection Bill, 2019demands sensitive personal data such as medical records to be processed

[460] Critical Care Nurse, https://aacnjournals.org/ccnonline/article-abstract/25/6/28/11685/End-of-Life-Decision-Making-in-Intensive-Care?redirectedFrom=fulltext#:~:text=What%20Is%20End%2Dof%2DLife,this%20decision%20making%20are%20possibl, (last visited May 22nd 2021)..

[461]Adams C, *Goals of Care in a Pandemic: Our Experience and Recommendations,* PubMed 60(1) JPSM, 15-17, 2020. https://pubmed.ncbi.nlm.nih.gov/32240752/, (last visited May 22nd, 2021).

[462]SLP (C) No. 15315.

[463] WP 2712 of 2020.

[464] National Health Portal, https://www.nhp.gov.in/NHPfiles/R_4179_1521627488625_0.pdf, (last visited April 20th, 2021).

only with the explicit consent of the data principal or to respond to a medical emergency involving a threat to the life or a severe threat to the health of the data principal or any other individual. It is high time that the Government shall legislate in this matter. If the practice remains unregulated, it may result in unauthorized practices adversely affecting the interests of the patients.

6.8 REGULATION OF CLINICAL TRIALS AND PROTECTION OF RIGHTS OF HUMAN PARTICIPANTS

Every PHE have devastating effects on the health, social and economic conditions of a state. Inequality in income and difficulty in affording drugs, leads to lack of proper access to healthcare. About the regulations on drugs and clinical trials, the state shall ensure the drugs are available to fair prices, and the clinical trials are conducted in ethical manners without violating the fundamental rights of subjects. There are two major aspects to this area.

According to WHO, clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes[465]. The pandemic has reflected the need for regulations to ensure optimal methods for clinical trials to produce vaccine and other drugs to combat the infectious disease. Vaccination has several disease controlling benefits[466]. It includes eradication, elimination, control of mortality, morbidity and complications, mitigation of disease severity, and prevention of infection.

Central Drugs Standard Control Organization[467] is responsible for regulating Clinical trials and approval of drugs, as well as the for the maintenance of quality and standard. CDSCO has the power to regulate conduct of clinical trials and Central Government has the power to make rules.

The 2019 Rules aims to promote clinical research adhering to international standards. It changed the existing regulatory landscape for the approval of new drugs and the process to conduct clinical trials in the country. Rule 2(j) defines the term “clinical trial” in relation to a new drug or investigational new drug. It means any systematic study of such new drug or investigational new drug in human subjects to generate data for discovering or verifying its: clinical or pharmacological including pharmacodynamics, pharmacokinetics, or adverse effects, with the objective of determining the safety, efficacy or tolerance of such new drug or investigational new drug. Rule

[465] WORLD HEALTH ORGANIZATIONS, https://www.who.int/health-topics/clinical-trials/, (last visited April 20th, 2021).
[466] WORLD HEALTH ORGANIZATIONS, https://www.who.int/bulletin/volumes/86/2/07-040089/en/, (last visited April 20th, 2021).
[467] Hereinafter referred to as CDSCO

2(w) defines the term "new drug" to include a vaccine, making the Rules applicable during the Pandemic. It identifies four phases of Clinical trials. Phase 1 estimates the safety and tolerability with initial administration of an investigational new drug into humans. Phase II evaluates the effectiveness of a drug for a particular indication in patients with the condition under study and determine the common short term side effects and risks associated with the drugs. Phase III deals with demonstration and confirmation of therapeutic benefits. Phase IV deals with post-marketing trials of new drugs. The Second Schedule to 2019 Rules provides for special situations for a new drug where approval is granted before conclusion of clinical trial. Such provisions are relevant in the event of a PHE It is applicable to drugs intended to be used the following situations:

- in life threatening or serious disease conditions or rare diseases
- diseases of special relevance
- unmet medical needs
- disaster or special defense use, for e.g., hemostatic, and quick wound healing, enhancing oxygen carrying capacity, radiation safety, drugs for combating chemical, nuclear, biological infliction.

6.9 AVAILABILITY OF DRUGS AT REASONABLE AND AFFORDABLE PRICES DURING PUBLIC HEALTH EMERGENCY

The development of a new drug is a time -consuming and expensive process. The process to develop superior versions of existing drugs further adds to the overall Research & Development expenditure[468]. It implies the necessity for legal regulations to ensure unauthorized duplication of products. It is attained through patent protection, where the patent holder is granted some exclusive rights which cannot be exercised by a third party without the consent of patent holder. two major legislations that aims at drug price control are Essential Commodities Act, 1955 (hereinafter referred to as ECA) and Drugs and Cosmetics Act, 1940 (hereinafter referred to as DCA). It is also necessary to examine the conflict with Intellectual property rights.

[469]Drugs have been enlisted as an "essential commodity" under the Schedule to the Essential Commodities Act, 1955 as per Section 2A of the Act. Section 2A of ECA defines essential commodity as a commodity specified in the schedule. Under Section 3 of ECA, the Central Government has the power to control production, supply, distribution, and availability of drugs at

[468] Midha. S, *Compulsory License its impact on innovation in Pharmaceutical Sector,* IJAEIM, 226, 2013.
[469] Hereinafter referred to as ECA.

fair prices. Its objective is to control the production, supply and distribution and trade and commerce of those listed as essential commodities. In the case of *Lt.Col. K S Gopinath* v *Union of India*[470], the Supreme Court has directed the Union of India to consider and formulate criteria for ensuring essential drugs in a manner not to fall out of the price control.

The Drugs and Cosmetics Act, 1940[471] aims to regulate the import, manufacture, distribution, and sale of drugs. Section 3(b) of DCA defines the term "drugs". It includes all medicines, substances, and devices which is intended for internal or external use in the diagnosis, treatment, mitigation or prevention of diseases or disorder in human beings or animals. DCA regulates manufacturing, storage, and transportation of drugs in different systems of medicine. The Central Drugs Standard Control Organization is responsible for approval of Drugs, Conduct of Clinical Trials, laying down the standards for drugs, control over quality of imported drugs in the country as well as for coordinating the activities of State Drug Control Organizations by providing expert advice with a view to bring about uniformity in the enforcement DCA[472]. The Drugs Technical Advisory Board[473], The Central Drugs Laboratory[474] and The Drugs Consultative Committee[475] have been established under the Act to carry out the functions envisaged in DCA.DCA is read in lines with the Drugs and Cosmetics Rules, 1945. Sections 12 and 33 deals with power of Central Government to makes rules after consultation with Drugs Technical Advisory Board. Schedule Y provides guidelines for import and manufacture of new drugs for sale and clinical trials.

Central Government has made several Rules to deal with the current pandemic situation. Due to the increased demand for drugs and sanitizing products during the time. The provisions of NDMA, 2005 and ECA were used to ensure price regulation and availability of surgical and protective masks, hand sanitizers, and gloves[476]. Exemptions to hand sanitizers from sale licensing in public interest based on Drugs and Cosmetics Act was given through SO 2451[477].

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[470]LAWS(KAR)-2002-11-64
[471] Hereinafter referred to as DCA
[472]Central Drugs Standard Control Organization https://cdsco.gov.in/opencms/opencms/en/Home/#:~:text=Under%20the%20Drugs%20and%20Cosmetics,with%20a%20view%20of%20bring, (last visited April 20th 2021).
[473] Section 5
[474] Section 6
[475] Section 7
[476]Ministry of Chemicals and Fertiziliers, Press Note, https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1606405 , (last visited April 20th 2021).
[476] Section 5
[477]Central Drugs Standard Control Organizationhttps://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/ (last visited April 20th 2021).

Under Section 26B the Central Government has the power to regulate, or restrict, manufacture sale or distribution of certain drugs that are essential to meet the requirements of an emergency arising due to epidemic or natural calamities and that in the public interest. Under this provision several orders have been made by the GOI. SO.1511(E) issued by Government of India, under Section 26B of Drugs and Cosmetics Act,1940 and New Drugs and Clinical Trial Rules,2019 (hereinafter referred to as 2019 Rules) imposed regulations on manufacture and stock for sale or distribution of vaccines for prevention and treatment of COVID-19. The 2019 Rules supersede Part XA and Schedule Y of the Drugs and Cosmetics Rule, 1945. The SO 2450(E) under Section 26B of Drugs and Cosmetics Act,1940 implemented regulations on import of drugs for sale or distribution.

In India, the patent is granted under the Patent Act, 1970. There is no comprehensive definition for a patent under the Act. Section 2(m) only states that patent means a patent granted under this Act. Section 3 provides what are not inventions under this Act. As per section 2(p), the person for the time being entered on the register as the grantee or proprietor of the patent is known as the patentee. According to section 53 the term of patent is 20 years. The patentee's rights include the right to make, use, sell or offer to sell, assign, and prevent third parties from exercising his or her rights. These rights are exclusive and can be exercised by the patentee or by his agents or licensees. Section 2(ta) defines pharmaceutical substance as any new entity involving one or more inventive steps. In *Novartis AG* v *Union of India*[478], SC made it clear that India being a developing country, availability of medicines at a cheaper rate is necessary for the guarantee of health and well-being of people. The application of Novartis for patent was rejected to prevent the ever-greening of patented products and to ensure that lifesaving drugs are available at affordable price. In *Kikloskar Bros Ltd* v *ESI Corpn*[479], it was observed that right to health care at affordable prices have become a universally recognized right. The grant of exclusive patent rights adversely affects right to affordable medicine. India being a member state of WTO was obliged to comply with the provisions of TRIPS Agreement which led to the 1999 Amendment of Patent Act. As per the Amendment the grant of product patent had extended to the field of pharmaceuticals and provided for Exclusive Marketing Rights[480] under Chapter IVA. Article 70.9 of the TRIPS Agreement provides for the conditions for grant of EMR. It includes filing of patent application in the concerned member country after its entry into force of WTO Agreement, filing of patent application in another member country after its entry into force of WTO Agreement and a patent has been

[478] (2013) 6 SCC 1
[479] (1996) 2 SCC 682.
[480] Hereinafter referred to as EMR

granted, the marketing approval has been obtained concerned member country as well as the other Member country. The strict implementation of the TRIPS Agreement contradicted the human rights aspects of access to health. It led to conflict between health and welfare of society and the economic rights of the individual patent holders. However, this was overcome by the Doha Declaration. It gave a pro-health interpretation to TRIPS Agreement[481].Brazil and India can no longer reverse-engineer patented foreign medicines and sell them at low prices in developing country markets[482]Doha Declaration asserted that the TRIPS Agreement should be interpreted and implemented in context of protection of public health and promoting access to medicines for all. It held that each member states have the right to grant compulsory licenses and freedom to determine the grounds upon which such licenses are granted.

The rights of patentee are not absolute. They are subject to certain limitations on the grounds of use for experiment, research, and teaching, use by government, for defense purposes, use in foreign vessels, and compulsory license. Compulsory License is often used to tackle the problems of rise in drug price. The term Compulsory license is however not explained in both Paris Convention and TRIPS Agreement but allows it at domestic and international level[483].

Any person having sufficient interest may make an application to the Controller for grant compulsory license on patent. The application shall be filed only after the expiration of three years from the date of the grant of a patent. The grounds for application under Section 84 of the Patent Act 1970 are as follows:

- that the reasonable requirements of the public with respect to the patented invention have not been satisfied
- that the patented invention is not available to the public at a reasonably affordable price
- that the patented invention is not worked in the territory of India

Compulsory license was granted to a pharmaceutical product for the first time in India in 2012. This was established through the case *Bayer* v *NATCO*[484]. In this case it was observed that only 2% of the cancer patient population had easy access to the drug and that the drug was being sold by Bayer at an exorbitant price of Rs.280,000 for a month's treatment. On grant of compulsory license

[481] Nadia Natasha Seeratan, *The negative impact of intellectual property patent rights on developing countries: An examination of the Indian Pharmaceutical Industry*, 3 SCHOLAR 339 (2001).
[482] Eric Bondy and Kamal Saggiz, *Compulsory Licensing, price controls, and access to patented foreign products, https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_4_12/wipo_ip_econ_ge_4_12_ref_saggi.pdf,* (last visited April 20th, 2021).
[483]Socretes.K, *Compulsory Licensing under the Patent System in India*, 6 INDIAN J.L. & Just. 63 (2015).
[484] Order no. 45 of 2013(IPAB)

to NATCO, the company sold it for Rs.8800 per month. Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country. It is given in Section 92A. The ground for compulsory license it has insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems and when the compulsory license has been granted by such country or such country has allowed importation of the patented pharmaceutical products from India.

The most important provision of Indian Patent Act regarding PHE is section 92. Section 92 says that, in circumstances of national emergency or in circumstances of extreme urgency or in case of public noncommercial use, that it is necessary that compulsory licenses should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect, by notification in the Official Gazette. The Act does not define the terms, reasonable requirements, national emergency, and extreme urgency. The vagueness and ambiguity in provisions limit the scope of its application. The purpose of Section 84 and 92 is to assure that the patented inventions are worked on a commercial scale in India's territory, complying with public requirements and that any concerned person's interest is not prejudiced. In*re: Distribution of essential supplies and services during pandemic*[485], considering the sudden surge in number of covid patients in 2021, the SC has taken suo motu case to ensure availability of certain essential elements of covid treatment. SC has sought the response of Central Government in matters of allocation of supply of oxygen, essential drugs and method and manner of vaccination, declaration of such essential medicines as essential commodities. The Bench has also pointed out invoking section 92 or section 100 of the Patents Act in this regard.

6.10 MANAGEMENT OF BIO MEDICAL WASTE

As discussed in Chapter III, Management of health care waste is an important issue having effect on environment and public health in general[486].Biomedical waste Management is a rising concern during PHE. Biomedical waste[487] (BMW) is any waste produced during the diagnosis, treatment, or immunization of human or animal research activities pertaining thereto or in the production or testing of biological or in health camps[488] It includes infectious waste among which are sharps waste, body part waste, chemical or

[485] Suo Motu WP 3 of 2021
[486] Supra, WHO Guidelines on Health Care Waste Management, Paragraph 1.3.
[487] Hereinafter referred to as BMW
[488] Priya Dutta, Gursimran kaurMohi, & Jagdish Chander, *Biomedical Waste Management in India: Critical Appraisal*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5784295/, (last visited on May 2nd 2021).

pharmaceutical waste and radioactive and cytotoxic waste or broken thermometers[489]. Inept disposal of biomedical waste results in unhygienic conditions leading to several health hazards. The WHO Guidelines on Health care Waste management provides for management of healthcare waste including radio-active wastes[490], human anatomical waste[491], pharmaceutical waste[492], etc. Radioactive waste includes liquids, gases and solids contaminated with radionuclides whose ionizing radiations have genotoxic effects.

In India Biomedical waste management is facilitated by virtue of Biomedical Waste Management Rules, 2016. However, the Rules does not come under the scope of Public Health Law as it is made under the power of Central Government under Environment Protection Act,1986.

As per the 2016 Rules, bio-medical waste" means any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps, including the categories mentioned in Schedule I appended to these rules. The Rules are not applicable to radioactive wastes, hazardous ,solid wastes covered under the Municipal Solid Waste (Management and Handling) Rules, 20 00 made under the Act, the lead acid batteries covered under the Batteries (Management and Handling) Rules, 2001 made under the Act, hazardous wastes covered under the Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008 made under the Act; waste covered under the e-Waste (Management and Handling) Rules, 2011 made under the Act; and hazardous micro-organisms, genetically engineered microorganisms and cells covered under the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms, Genetically Engineered Micro-organisms or Cells Rules, 1989 made under the Act. According to the 2016 Rules, bio-medical waste treatment and disposal facility" means any facility wherein treatment, disposal of bio-medical waste or processes incidental to such treatment and disposal is carried out and includes common bio-medical waste treatment facilities. The 2016 Rules provide for duties of occupier, operator of a common bio-medical waste treatment and disposal facility, as well the provisions for treatment of biomedical waste. The 2018 Amendment to the Rules have added provisions with regard management plastic wastes including bags and gloves. The 2016 Rules are

[489] KK Padmanabhan & Dedabrata Bank, *Health Hazards of Medical Waste and its Disposal*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7152398/, (last visited on May 2nd 2021).
[490]WHO Guidelines on Health Care Waste Management, Paragraph 1.3.
[491]*Id.*
[492]*Id.*

containing general provisions to deal with biomedical waste management, however, in the changing circumstances, based on the gravity of infections caused by pandemic, such as COVID-19, specific provisions shall be inserted to the 2016 Rules, to deal with management of biomedical wastes on occurrence of PHE.

6.11 LEGISLATIVE MEASURES TO PREVENT, CONTROL AND MANAGE EPIDEMICS, BIOTERRORISM AND DISASTERS

In 2017 the Ministry of health and Family Welfare had drafted the Public Health (Prevention, Control and Management of Epidemics, Bioterrorism, And Disasters) Bill, 2017[493]. The 2017 Bill aimed at taking into consideration the instances of public health emergencies and the repeal of the Epidemic Diseases Act. The Bill had defined several terms including "bio-terrorism", "bio-hazardous material", "clinical establishments", "drugs", "epidemic disease", "epidemic prone disease", "isolation", "outbreak", "public health emergency", etc. The Bill had identified and defined two kinds of PHE, they are "public health emergency of international concern" and "public health emergency of national concern". The bill had given provisions about the powers of Central and State Governments and also prescribed the penalties for violation of the Act. The Bill was accompanied with two Schedules. The first Schedule enlists the diseases that fall under Epidemic Prone Diseases. The Second Schedule enlists potential bio-terrorism agents.

The public health measures include prevention and control through prohibition of activities likely to inimical to public health; provisions for quarantine; restriction of movement; isolation of persons infected or suffering from such diseases, conduct of medical examination; treatment and vaccination or other prophylaxis; removal of infection through disinfection, decontamination, etc. The Bill also provided for management of bio-hazardous materials.

The 2017 Bill was an effective method to tackle PHE however did not see light. Though the Act was a novel movement in India. It had several shortcomings as it had not given mention to several other challenges during a PHE, such as preparedness of healthcare sector, protection of medical professionals and their liability in cases of medical negligence, telemedicine practices, provisions for mental health care to affected persons through public health care system.

6.12. HUMAN IMMUNODEFICIENCY VIRUS AND ACQUIRED IMMUNE DEFICIENCY SYNDROME (PREVENTION AND CONTROL) ACT, 2017 AS AMODEL

[493] Hereinafter referred to as the 2017 Bill.

LEGISLATION FOR THE PURPOSE IDENTIFYING THE ESSENTIAL COMPONENTS OF A LEGISLATION DEALING WITH PUBLIC HEALTH RISKS

By the end of 2019, according to WHO about 38 million people were diagnosed with HIV/AIDS[494]. It has been therefore recognized as a global public health issue[495]. Through various years, the health system has had developed methods for diagnosis, treatment, and care, making it a manageable chronic health condition.

The Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017[496] in its provisions ensures the major dimensions of right to health. Provisions of 2017 Act could be taken as a model law to frame a new legislation to deal with public health emergency. The Act defines the term discrimination under Section 2(a)[497] and prohibits certain acts under Section 3 and 4. However Sections 3 and 4 are oriented towards prohibition of discrimination in matters of employment, insurance, education, etc. Section 5 talks about informed consent for undertaking HIV tests or treatment. The informed consent for HIV test includes pre-test and post-test counselling to the person being tested or his or her representative[498]. The Act has laid down conditions regarding disclosure of HIV status under Section 8. No person shall be compelled to disclose HIV status or other private status. The issue in *Mr. X* v *Hospital Z*[499], was resolved through

[494]WORLD HEALTH ORGANIZATION, https://www.who.int/health-topics/hiv-aids#tab=tab_1, last visited on August 31st, 2021.
[495]WORLD HEALTH ORGANIZATION, https://www.who.int/news-room/fact-sheets/detail/hiv-aids, last visited on August 31st, 2021.
[496] Hereinafter referred to as the HIV/AIDS Act.
[497]Discrimination means *"any act or omission which directly or indirectly, expressly or by effect, immediately or over a period of time – (i) imposes any burden, obligation, liability, disability or disadvantage on any person or category of persons, based on one or more HIV-related grounds or (ii) denies or withholds any benefit opportunity or advantage from any person or category of persons, based on one or more HIV-related grounds, and the expression "discriminate" to be construed accordingly."*
[498] HIVAIDSA, 2017, S. 5(2).
[499] CA 4641 of 1998.

Section 9[500]. The Act provides for duty of HIV positive person in prevention of its transmission[501] and obligations of establishments to keep confidentiality[502].

Healthcare workers are constantly exposed to complex variety of health and safety hazards during work ranging from infectious diseases such as tuberculosis to chemical reactions. Section 19 specifically deals with obligation of establishments to provide safe working environment. There shall be safe working environment ensuring universal precautions. It is the obligation of the establishments to provide Post Exposure Prophylaxis to all persons working in such establishments who may be exposed to such diseases. The occupational safety of healthcare workers is relevant not only during the event of pandemic. The large influx of patients from different parts may result in spread of infectious diseases during natural calamities and other disasters. As a part of training the healthcare workforce is directed to be informed, educated, and trained in universal precautions.

The 2017 Act has offered mechanism for grievance redressal by appointment of a Complaint Officer to deal with violations of the provisions of the Act[503]. Sections 23 to 28 deal with appointment of Ombudsman. The procedure for complaint, as well as the powers of Ombudsman were also given. Chapter XII, Sections 34 to 36 deals with special procedure in Courts concerning suppression of identity, maintenance application and sentencing.

The Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017 is a comprehensive legislation dealing with prevention and control of an infectious disease. It ensures obligations on part of clinical establishments and guidelines related to preparedness to meet such difficulties raised by the disease.

6.13 CONCLUSION

The above discussions deal with examination of legislative measures taken in public health area that could be applied to tackle PHE. In India, as aforementioned, there is no uniform legislation to

[500] Only a physician or a counsellor could disclose the HIV status of a person to her or her partner if such physician or counsellor reasonably believes that the partner is at the significant risk of transmission; the HIV positive person has been counselled to inform such partner. Dissatisfied that the HIV positive person will not inform the partner, or the physician or counsellor has informed the HIV person of the intention to disclose the HIV positive status to such partner. The physician or counsellor however does not have the obligation to identify or locate the partner of an HIV positive person and shall not inform the partner of a woman where there is a reasonable apprehension that such information may result in violence, abandonment or actions which may have a severe negative effect on the physical or mental health or safety of such woman, her children, her relatives, or someone who is close to her. The section also protects the healthcare provider from any criminal or civil action for disclosure or non-disclosure of confidential HIV-related information made to a partner.

[501] HIVAIDSA, 2017, S.10

[502] HIVAIDSA, 2017, S.11

[503] HIVAIDSA, 2017, S.21

deal with PHE. However, as discussed in Chapter V, certain states including Kerala, Orissa, Gujarat have enacted public health legislations and PHE Acts.

The chapter have conducted a critical examination of legal provisions dealing with management of clinical establishments, regulation of healthcare workers, legal protection to healthcare workers, management of clinical establishments, protection of mental health, telemedicine practices, management of biomedical wastes and regulations on clinical trials and availability of drugs. These abovementioned provisions are evaluated based on the present COVID-19 scenario, to identify the lacunae in it.

Unlike in countries like China, USA, and UK[504], there are no specific legislative provisions for risk assessment, communication with public. There are no specific criteria for the determination and termination of Public Health Emergency, which is in non-compliance with the WHO Guidelines as well[505]. Lack of specific legislative provision to deal with protection of healthcare workers, has severe adverse effect. There were several reported cases of assault on doctors on COVID duty[506]. Even though such actions are prevented by Epidemic Diseases Act, it is only applicable during the occurrence of an epidemic or pandemic, and during other forms of PHE, such provisions would not be applicable. In USA, though there are no specific legislation in this regard, The Pandemic Readiness and Preparation Act[507]and the Federal Employees Compensation Act provides for declaration for immunity from tortious liability in matters of loss caused by countermeasures against diseases or other threats of public health emergencies[508] and compensation for disability or death of an employee resulting from personal injury sustained during discharge of their duty [509]. The laws are also silent about providing specific training to health care workforce to deal with PHEs.

Even though there are several lacunae, Indian legal provisions dealing with Clinical trials, affordable medicine, mental health, and telemedicine practices, are decent enough to deal with the contemporary issues raised during a PHE.

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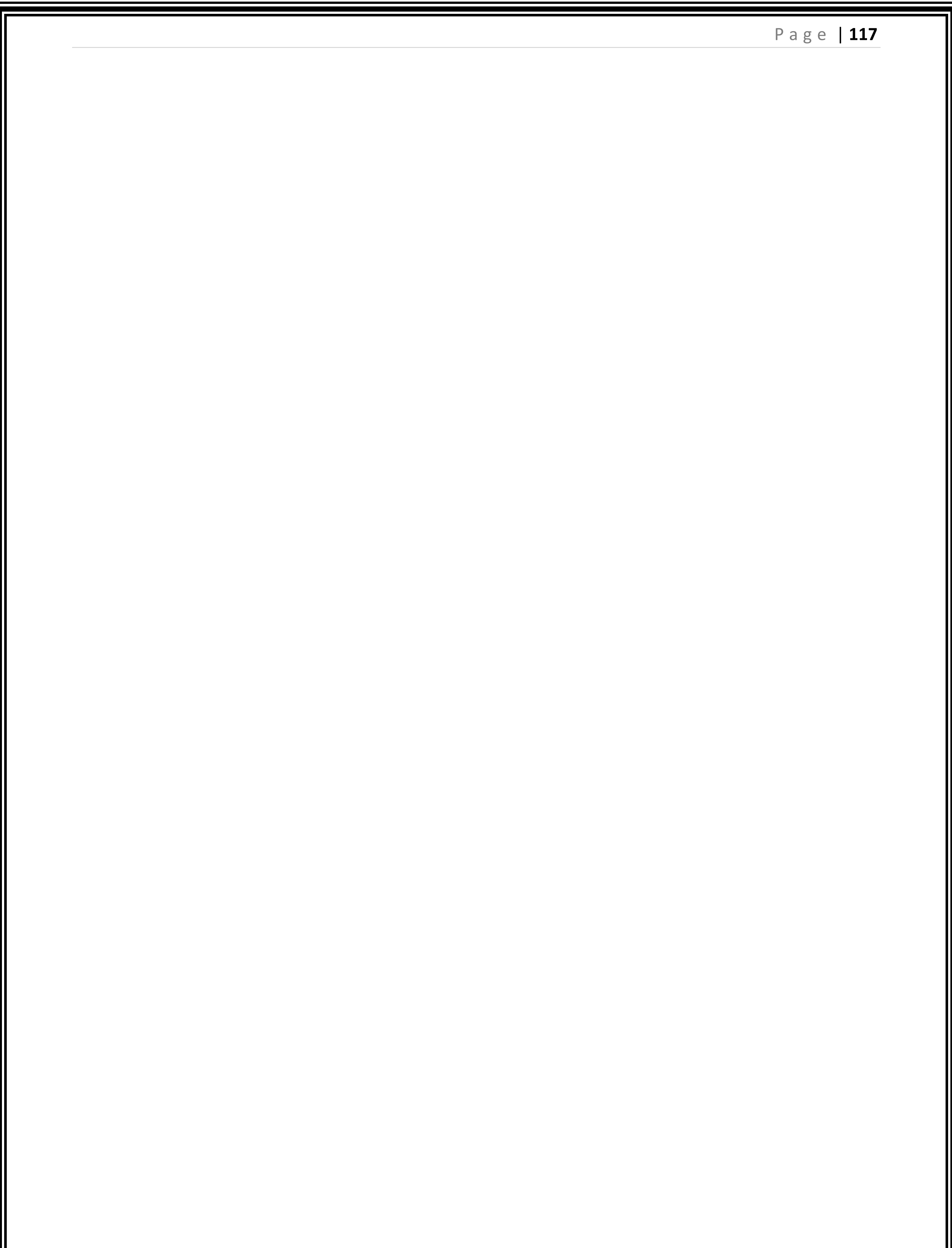
[504] As discussed in Chapter IV.
[505] Supra, Chapter III.
[506]NDTV,https://www.ndtv.com/india-news/horrific-assault-on-doctor-by-family-of-covid-victim-caught-on-camera-2454178,(last visited August 29th 2021).
[507] Pandemic Readiness and Preparation Act inserted Section 319F-3 dealing with “targeted liability protections for pandemic and epidemic products and security countermeasures and Section 319F-4 dealing with “covered countermeasure process”.
[508]FECA, Section 102.
[509]PHSA, Section 319F-3



CHAPTER 7

CONCLUSION AND RECOMMENDATIONS

7.1 INTRODUCTION

The gravity of a public health emergency is based on their causes and precipitating events, where such events may annihilate the ordinary course of life. T9/11 attack in New York, Bhopal Gas Leakage Disaster, COVID-19 pandemic, are some of the examples of Public Health Emergencies. Basically, a PHE results in severe health consequences, and is a pure public health concern, that should be adequately dealt by the Department of Health and medical professionals. However, occurrence of PHE not only affects the health of society, but it also has devastating effect of social and economic conditions of a region. The COVID-19 pandemic has taught that, the State has a pivotal role in the prevention and mitigation of a PHE, where, the State has to undertake extraordinary measures, which are distinct and separate from normal course of functioning.

The primary legal question about public health emergency, is whether it is necessary to enact a comprehensive legislation in India to deal with public health emergency. To resolve this issue, in the previous chapters, the adequacy of present legal framework in India to prevent and mitigate PHE has been discussed based on protection of right to health during PHE, examination of present laws based on its compliance with International Regulations and conducting comparative analysis with PHE laws in nations such as China, USA and UK. Such examination of PHE laws in India has helped to find out the gaps in India legal framework governing PHE. Thus, it is proved that there is an immediate need for a public health legislation dealing with PHE.

This chapter discusses the inadequacy in present PHE Laws in India, attempts to give definitions for the important terms associated with PHE and conclusions reached upon on various legal issues such as role of state in establishment of Emergency response plan, determination of PHE, protection and regulation of health care workers, health

surveillance, interdepartmental coordination, regulation of clinical trials, mental health establishments and telemedicine practices.

This chapter basically contains the proposed conceptual framework for a Model Law to be enacted by the Central Government, directed to be adopted by the State Governments accordingly.

7.2 CONCLUDING REMARKS

On the basis of the International Regulations and the Indian Legislations along with examination of the legislative responses in China, USA, and UK, the following conclusions are derived. India is in dire need of a need of a new and comprehensive legislation to deal with public health law, which would include a separate chapter for public health emergency. The present Epidemic Diseases Act has become obsolete, and Disaster Management Act is not sufficient to deal with public health emergencies as it is silent about the management, prevention, and mitigation of PHEs. The areas that require attention are as follows.

The role and responsibilities of each level of government, i.e., Centre, State and Local Governments, should be clearly defined. In India currently, there is no such demarcation which creates ambiguity and adversely affects the prevention and mitigation. It is evident from the present confounds in vaccine policy, and interpretation by the Hon'ble Supreme Court. Also, the PHE may or may not affect the entire nation, for example, in case of COVID-19 pandemic, the entire nation was affected, but in case of Bhopal Gas Leakage, only a particular area was affected. Therefore, there is no need for proclamation of emergency as per Articles, 352 and 356. Instead, of proclaiming emergency, the Central Government shall enact a new Legislation in the Model of US Model Legislation, which would contain provisions for public health preparedness and management inn ordinary times as well as during PHEs. Enactment of separate legislation for PHE would cause ambiguities, because, even when a PHE takes places, the Clinical establishments have to make sure that, the prevention and mitigation of PHE, does not affect the ordinary course of clinical practices. Therefore, the Central Government shall, make a Model Public Health

Legislation, which is inclusive of Public Health Emergency, which may be adopted by the State Governments accordingly.

7.3 SUGGESTIONS AND RECOMMENDATIONS

A. Inadequacy of the present PHE laws in India

In India there is no comprehensive legislation dealing with Public Health Emergency. On occurrence of PHE, the provisions of Epidemic Diseases Act or National Disaster Management Act are often invoked. The examination of the above-mentioned legislations, show that, there is no specific provisions to protect the public health concerns arising out of PHE. The second issue is that there is no comprehensive public health legislation in India. There is, Clinical Establishments Act, Epidemic Diseases Act and Drugs and Cosmetics Act, however, there is only little scope for its application during a PHE. The Clinical Establishments Act only deals with registration and regulation of Clinical Establishments in India. The Epidemic Diseases Act is only applicable in cases of epidemics and pandemics, making it not applicable during a PHE caused by chemical or biological incidents or natural disasters. And the Drugs and Cosmetics Act does not contain provisions to deal with availability of drugs and other essential medicine during a PHE. The third issue is regarding lack of uniformity in nomenclature. Chapter 5 has discussed the Public Health Legislations of States including Kerala, that contains provisions for prevention and mitigation of PHE, however, there is no uniformity in definition of PHE as well as other important terms such as communicable diseases, epidemics, etc.

In addition, absence of a uniform PHE has also led to ambiguity regarding the issues concerning emergency response plan, determination of PHE, protection and regulation of health care workers, health surveillance, interdepartmental coordination, regulation of clinical trials, mental health establishments and telemedicine practices. The following conceptual framework addresses the above-mentioned issues.

B. Important Definitions

In such legislation, there should be a proper definition for the following concepts:

- Appropriate Government: It means the Central and State government of a Nation[510].
- Bioterrorism: the intentional release or threat of release of biological agents, such as viruses, bacteria, fungi, or their toxins, to cause disease or death among human population or food crops and livestock to terrorize a civilian population or manipulate the government.
- Chemical Incident: It is the uncontrolled release of a toxic substance, which may occur as a result of natural events, or as a result of accident or intentional events, potentially resulting in harm to public health and the environment.
- Clinical Establishments: it shall have the same meaning as given in the Clinical Establishments Act.
- Communicable diseases: It includes such illness caused by viruses or bacteria that may spread among population due to due to the transmission of a specific infectious agent or its toxic products from an infected person, animal, or inanimate source to a susceptible host, either directly or indirectly through contaminated surfaces, bodily fluids, blood products, insect bites or through the air.
- Emergency medical care: It is a specialty medical service concerned with the care and the treatment of acutely ill or injured patients who need immediate medical attention.
- Epidemic: the occurrence of more cases of disease, injury or other health conditions than expected in a given area or among a specific group of persons during a particular period.
- Health as already mentioned is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity[511].
- Pandemic: an epidemic occurring worldwide or over a very wide area, crossing international boundaries and usually affecting large number of people.
- Public Health Emergency of International Concern: extraordinary event which is determined as provided in these regulations; to constitute a public health risk to other States through the international spread of diseases and to potentially require a coordinated international response

[510] Please see Chapter II.
[511] As defined by World Health Organization. Please see Chapter II.

- Public Health Emergency: an occurrence or imminent threat of an illness or health condition, caused by bio-terrorism, epidemic or pandemic diseases or a novel and highly fatal infectious agent or biological toxin that poses a substantial risk of a significant number of human facilities or incidents or permanent or long-term disability, or emergency medical care arises due to man-made or natural disasters, causing a large number of deaths or illness in the affected populations, or widespread exposure to an infectious or biological or chemical or radioactive or toxic agent that poses significant risk of substantial future harm to a large number of people in the affected area.

C. Role and responsibilities of Government: Distribution of Powers and function among three levels of Government, vis-à-vis, Central, State and Local Self Government.

In India, because a PHE may not affect the entire nation, there is no need to invoke provisions of Article 352[512]. For example, the Bhopal Gas leakage, Floods in Kerala, Chennai, Uttarakhand, though, constituted severe public health risks, it has only affected a particular region. Thus, there is no need for a national emergency nor even a State emergency under Article 365 of the Constitution of India, as the disaster was limited to a particular region. Therefore, instead of invoking emergency powers under the Constitution, the State may enact a model law, like in USA, which could be adopted by the States and Union Territories with necessary changes suitable to them.

Also, such Model Law shall clearly define the powers and functions of the three levels of Government. The phrase "three levels of Government" is particularly, used, to give prominence to responsibilities of Local Self Governments. For an event like COVID-19 pandemic, if the Local Self Governments are given their own powers, it might help to contain such contamination within such smaller area itself. For example, a COVID-19 case is reported in a ward of panchayat X. Then, if the Local Self Government of that particular area has been given the power to declare a Public Health Emergency concerning such area, and impose restrictions, subject to the directions of State

[512] Please see Chapter 5

Government and provisions of Model Law, then, they might succeed in preventing and mitigating the spread of such contamination within that area itself. This approach is like reporting of PHE to World Health Organization, as per the International Health Regulation, 2005[513]. Likewise, when a PHE affects a State as a whole, or part of such State, it may be reported to the Central Government at the earliest.

A clear demarcation of such powers and functions among the three levels of government will help to contain and limit the spread of contamination.

D. Establishment of Emergency Response Plan

Like in China, the Central Government State establishes a precautionary system for emergency response, as part of health care preparedness. The State Governments shall report any unusual public health risks to Central Government in a timely manner. It shall have timely modifications according to changing needs and demands. There shall be both urban and rural planning to meet the need for prevention and handling of emergency. The local government shall be entrusted with the duty to check and register sources of danger within their administrative area which may give rise to emergencies. The health departments under State Governments shall assess the risk, regularly inspect, and monitor such sources and areas, and order the units concerned to take safety and prevention measures. The emergency response plan shall be operative during times other than the occurrence of PHE. It shall also contain provisions for the management of material resources. It ensures mobilization of resources to facilitate rescue and relief missions. It should also contain Public Health Emergency Fund' is provide for accompanying expenses like they have in USA. Along with this, there should be a mechanism for collection and communication of information among different levels of government, for which a unified national information system for emergencies shall be set up. The authorities shall also take measures to make sufficient communications with media to reach public.

E. Determination of PHE

[513] Please see Chapter 3.

The State and local governments are responsible for reporting PHE to the central Government. It should be based on the above proposed definition for PHE. In case of a public health emergency of international concern, the Central Government shall report the same to World Health Organization based on IHR, 2005.

F. Health Surveillance

As per Article 1 of IHR,2005 Surveillance means the systematic ongoing collection, and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary. The functions of Central Bureau of Health Intelligence shall be strengthened to give importance of PHEs.

G. Regulation of Healthcare workers

The PHE law should specifically determine the regulations upon the health care workers and should also establish the mechanism for determination of Medical Negligence. Appropriate regulation and healthcare workers are required to improve the quality of medical care. It shall be done in consultation with National Medical Commission. It shall also follow the basic principles of medical ethics. Under this, the medical professionals shall be given adequate and specific training to deal with PHE.

H. Protection of Healthcare workers

Provisions like Section 2B and 1B of Epidemic Diseases Act should be incorporated to. prohibit violence against a healthcare service personnel or cause any damage or loss to any property during an epidemic. Also, like in US Federal Employees Compensation Act, they shall be paid, appropriate compensation for disability or death of an employee resulting from personal injury sustained during discharge of their duty.

I. Interdepartmental cooperation

It is one of the most important aspects of public health emergency, which is seen in United Kingdom. It means a central authority should have a subsidiary function, performing only those tasks which cannot be performed at a more local level. Like, in UK, the decisions should be made at the lowest level, according to the needs and

requirements of a particular area, where the State governments with the assistance of Central government would aid and advice the local governments. Also, there should be coordination between health department with other departments like, fire and safety, police force or armed force, in matters of rescue and relief. There shall integration of operation of multiple agencies on occurrence of PHE.

J. Regulation on Telemedicine practices during PHE

In the events of COVID-19 pandemic, telemedicine practices have been widely used. It basically helps to ensure contactless medical consultation, diagnosis, and treatment. Presently, the Telemedicine Practice Guidelines, regulate the telemedicine practices. These guidelines shall be given legislative effect and be incorporated into a new legislation bringing it under public health law, by clearly defining the role and responsibility of registered medical practitioner and ensuring the patient's rights. In addition to this, due to the outbreak of pandemic and nationwide lockdown, it is extremely challenging to provide a quality end-of-life care (EOLC) to all patients. The legal position is clear that a patient cannot demand a treatment that is not in their best interests and that doctors need not strive to preserve life at all costs. The end-of-life decision making via digital medium give rise to lack of psychosocial support to the relatives of the patients, it is difficult to make proper communications, and difficulty in continuous monitoring of the patients to reach a decision. Also, the declaration of consent also becomes complex when it is done through digital media. Thus, the State shall take measures to incorporate the above-mentioned matters associated with telemedical practices during a Public Health Emergency.

K. Regulation of Clinical Establishments

Clinical establishments are to be properly maintained and regulated to ensure emergency medicine, isolation wards, quarantine facilities, and other infrastructural provisions. The health care workers shall be prepared to deal with unforeseen situations arising out of PHE. There should be adequate management of medical records. Also, there should be provisions for disposal of biomedical wastes.

L. Regulations on clinical trials, pharmaceutical products and

There should be provisions for conduct of clinical trial of vaccines and other necessary drugs during PHE. Provisions of drugs and cosmetics Act does not speak about PHE; however, this should also be incorporated to PHE legislation. Also, the State shall make sure the pharmaceutical products are available at reasonable prices.

M. Protection of Mental Health

The COVID-19 pandemic as well as other natural and man-made disasters have showed the importance of mental health of people. The mental health of people shall be given utmost importance along with protection and maintenance of physical well-being. Mental health care provided shall be of high quality, with provisions for improvement of access to care. The outbreak of COVID-19 pandemic has pointed out the importance of mental wellbeing which led to telehealth in mental health care. Most of the nations have relied on teleconsultations to maintain the mental well-being of their citizens. There shall be specific provisions in legislation relating to PHE incorporating protection of persons with mental illness in mental health establishments as well as through digital medium.

N. Mechanism for grievance redressal

The model legislation should have appropriate mechanism for dealing with grievances of the patients and other consumers due to the insufficiency in service. Presently, medical negligence cases are dealt under the Consumer Protection Act, based on the decision in *VP Shantha* v *IMA*[514]. Medical Negligence cases and other consumer grievances cannot be weighed by the same measures. Therefore, a body may be established to deal with medical negligence cases distinctly. The Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017 may be adopted in this regard, as it establishes complaint officer and ombudsman to deal with deal with violations of the provisions of the Act[515].

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[514] (1995) 6 SCC 651, Please see chapter 2.
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