

PUBLIC HEALTH LAWS IN INDIA: ISSUES AND CHALLENGES

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INTRODUCTION

Covid-19 signified the inevitability of the right to health of the people. Right to health is not a recent phenomenon in the legal system. Right to health is recognized as a fundamental human right by the World Health Organization. The right to health for all people means that everyone should have access to the health services they need, when and where they need them, without suffering financial hardship.ⁱ The simple reason behind emphasizing the significance of right to health is no one should get sick as well as die due to poverty or because non availability of access to public health care system. The right to health is wider concept which includes several aspects such as right to good health, right to control their own health and body, right to privacy, right to live with dignity and medical experimentation, right to access to health system etc.ⁱⁱ Overall approach of the WHO in this context is people centric health care system. In this context, it is expected that states will formulate their health policies in tune with WHO and accordingly, India has introduced several public laws and different policies to provide access to people to health care system.

A systematic understanding of public health law requires a careful examination of what is public. A public entity acts on behalf of the people and gains its legitimacy through a political process. A characteristic form of public or state actions occurs when a democratically elected government exercises powers or duties to protect and promote the population's health.ⁱⁱⁱ Public health is the science and the art of preventing disease, prolonging life and promoting physical health and efficiency through organized community efforts for the sanitation of the environment, the control of community infections, the education of the individual in principles of personal hygiene, the organization of medical and nursing service of the early diagnosis and

preventive treatment of disease and the development of social machinery which will ensure to every individual in the community a standard of living adequate for the maintenance of health.^{iv} Public health law is a field that focuses legal practice, scholarship and advocacy on issues involving the government's legal authorities and duties "to ensure the conditions for people to be healthy,"^v and how to balance these authorities and duties with "individual rights to autonomy, privacy, liberty, property and other legally protected interests."^{vi}

The Public Health Law is a wider connotation which covers legislations, policies, judicial interpretations as well as issues relating to social justice and ethics as well. Taking into consideration the various aspects involved in the topic public health laws, researcher will discuss mainly the Drugs and Cosmetics Act, 1940, The Food Safety and Standards Act, 2006 and The Epidemic Diseases Act, 1897 in this research paper.

Researcher in this paper attempts to study various constitutional provisions and lacuna exist relating to the right to health and various relevant provisions to right to access public health care system, various other laws enacted by the center and State of Maharashtra and Public Health Policies issued by the Center and State of Maharashtra. Also, researcher intends to provide the probable legal solutions to address the issues and extend the benefits to the public at large.

INTERNATIONAL APPROACH

WHO: The right to health was first articulated in the WHO Constitution (1946) which states that: "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being..."? The preamble of the Constitution defines health as: "... a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".^{vii}

UDHR: Art.25 declares that everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

International Covenant on Economic, Social and Cultural Rights: Article 12 states that the States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

These are the major international instruments wherein right to health is described expressly.

Constitutional Provisions: The Constitution of India does not provide any direct and express provision for the right to health to the individual but Supreme Court of India after Maneka Gandhi's case has recognized the right to health under article 21^{viii} in the various landmark judgments. Later on The Supreme Court has held that the right to live with human dignity, enshrined in Article 21, derives from the directive principles of state policy and therefore includes protection of health.^{ix} Further, it has also been held that the right to health is integral to the right to life and the government has a constitutional obligation to provide health facilities.^x It is the responsibility of the government to make it available public health care system available to the public at large and hence Supreme Court has held that failure of a government hospital to provide a patient timely medical treatment results in violation of the patient's right to life under article 21 of the Indian Constitution.^{xi}

The preamble to the Constitution sets out the aims and aspirations of the people of India and these have been translated into various provisions of the Constitution. The ultimate aim of the constitutional makers was to have a welfare state and an egalitarian society projecting the aims and aspirations of the people of India.^{xii} The preamble of the Indian Constitution embodies the principle socialism. The idea of socialism is to improve the condition of health care of the people. This principle reflected in various through different provisions such as Art. 38^{xiii}, 39(e)^{xiv}, 41^{xv}, 42^{xvi}, 47^{xvii} etc.

Paschim Bangal Khet Mazdoor Samity & Others V State of West Bengal & Others^{xviii} held that in a welfare state, primary duty of the government is to secure the welfare of the people and more

over it is the obligation of the government to provide adequate medical facilities for its people.

The government discharges this obligation by providing medical care to the persons seeking to avail those facilities.

These are the provisions cast an obligation upon the state to maintain public health and provide access to public health care system. With these sources of the Constitutional Provisions, Center

and Maharashtra State has enacted several public health laws to provide the enjoyment of the right to health to the people.

LEGAL FRAMEWORK FOR PUBLIC HEALTH CARE

The Parliament of India passed several legislations relating to the public health laws. Around 67 laws are applicable to public health laws however some major enactments are studied here.

- 1. The Drugs and Cosmetics Act, 1940:** This Act is passed with an object to regulate the import, manufacture, distribution and sale of drugs and cosmetics.^{xix} Without the permission of the Drug Controller, drug cannot be imported or manufactured in India. The Act has laid down the different kinds of standards of quality to be maintained by the drug manufacturer. Without the clinical trial, drugs cannot be manufactured. The procedure to get the approval for clinical trial is laid down under the New Drugs and Clinical Trials Rules, 2019 which has been recently enforced.

Under the New Drugs and Clinical Trials Rules, 2019, it is made it compulsory to obtain the informed consent of the proposed research participant. But unfortunately, concept of Informed Consent is not well defined. Jurisprudentially, five essential elements of informed consent should be present during the process such as voluntariness, information about the subject matter, competency, capacity to consent and disclosure of the information. After analyzing the procedure laid down under the New Drugs and Clinical Trials Rules, 2019, it is found that the procedure is very vague and unambiguous as well as it does not cover the five aspects of informed consent. It would be the responsibility of the sponsors or the investigators to obtain the informed consent. But the rules are failed to provide the exact procedure or mechanism which will contain the five essential elements of informed consent during the obtaining the informed consent of the proposed research participant. This is the major drawback exist in the rules which gives scope for the invalid procedure of informed consent and gives scope for the injustice to research participant.

Also, the most important issue is about the implementation of the enactment and maintenance of the standard of drugs. Along with this, the punishment provided under the Drugs and Cosmetics Act, 1940 is very low. Due to less punishment, there is no fear in mind of the culprits which paves the way to manufacture the low quality drugs.

2. Food Safety and Standards Act, 2006:

The object of the enactment is to consolidate the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto.^{xx}

Under this enactment, it is the duty of the Food Authority to regulate and monitor the manufacture, processing, distribution, sale and import of food with an object to ensure the safe and wholesome food to all.^{xxi} This provision has entrusted an obligation upon the Food Authority to check the safety of foods for human life. Sec. 21 of the Food Safety and Standards Act, 2006 deals with the prohibition of the Pesticides, Veterinary Drugs residues, antibiotic residues and microbiological counts excessively.

The question is here for the discussion is the implementation of the enactment. It is commonly found that while using pesticides to the plants, as per the ratio or standard fixed are not usually observed strictly. Further, there is no mechanism to inspect the excessive use of pesticide to the plants. Due to the lack of such mechanism, unsafe food is produced largely which is hazardous to the health of the people. This is the major drawback exist in this legislation. Although, it is not possible to visit each farm personally on the part of the Food Authority, but several preventive majors can be adopted to prohibit excessive use of the pesticide to maintain the safe food. Due to this reason, it could be consider as the biggest failure of the state to provide the safe food to the people at large due to the excessive use of pesticide in the farm. Strict majors are required to be taken to avoid such use in the farm.

3. The Epidemic Diseases Act, 1897:

The object of the Epidemic Diseases Act, 1897 is to provide for the better prevention of the spread of dangerous epidemic diseases. Sec. 2 of the Epidemic Diseases Act, 1897 empowers the State Government to take adequate measures to prevent the outbreak of such disease or spread and also power is vested with the State Government to frame the policy for compensation as well.

Apparently, the Epidemic Diseases Act, 1897 is the prime legislation in public health laws which have given enormous power to the state government to take appropriate measures to prevent the outbreak in the society. Considering the object the Act, The

Epidemic Diseases Act, 1897 is the appropriate legislation to tackle such type of situation.

Accordingly, during the covid-19, Government of Maharashtra declared lockdown in the month of March, 2020 to prevent the spread of Covid-19 and the subsequently Central Government announced lockdown for the entire nation and crore's of people stuck on the same place. Many of the people lost their jobs and small scale businessmen ended their business which ultimately resulted into unemployment to lacs of people across India.

Considerably, the Act has two major issues: 1) Compensation to be paid to the affected person and 2) loss of income or employment. Due to the epidemics, many of the people got infected. Application of Section 2 of the Epidemic Diseases Act, 1897 merely declares the compensation policy to be prepared by the state but does not expressly fix the legal obligation upon the state to provide it which ultimately creates injustice upon the public who suffers largely due to the preventive measures adopted by the state. Without the remedial measures, it would not be legally appropriate to give preferences to the right to health or life of people over the other rights such as right to go for employment, property or compensation etc.

Law has to make a balance between these two conflicting interests. Unfortunately, this current legislation fails to address these most crucial issue and made unfair provision in the Epidemic Diseases Act, 1897 which is urgently required to be removed.

In nutshell, to extend the benefits to the society, law has to be formulated in such a manner otherwise it would be just a formality to frame laws on paper. Above discussed legislations and major legal issues clearly highlights that the Public Health Laws are very crucial topics to enjoy the right to life and the real meaning of right to life cannot be attained without the healthy body hence, public health laws are required to be strengthened on urgent basis to accord right to health to the public.

CONCLUSION

Right to health is a basic fundamental human right of every person which has been well articulated and recognized by the WHO and Indian Constitution under Art. 21. Accordingly, the legal obligation is confirmed upon the state to offer health related services to the public

such as access to public health care system, establishment of health care centers, It is the legal powers and duties of the state to formulate such conditions in the interest of the people to maintain them healthy and sound and to respect their legal rights such as autonomy, privacy while promoting the public health. Therefore, the concept public health law has a wider connotation which has been discussed earlier. Based on the discussion of various laws and observations marked by the researcher, following are the recommendations to be implemented to overcome the addressed issues.

1. **The Drugs and Cosmetic Act, 1940:** Under the Drugs and Cosmetics Act, 1940, without the clinical trial, drug cannot be manufactured. For the clinical trial, informed consent of the research participant is essential. Without the informed consent, research participant or subject cannot be admitted for the clinical trial. To overcome the issues discussed earlier, Ethics Committee should be formulated by the Government. Sponsor or Investigator intends to do clinical trial, should seek approval from the Government and then Government may constitute Ethics Committee and the legal obligation of Ethics Committee would be to inspect the presence of essentials of Informed Consent during the entire procedure of the obtaining informed consent.

Definitely, this procedure will resolve all the issues discussed above and ensure the removal of probable biasness during the obtaining the informed consent also Government constituted Ethics Committee will function without biasness and make sure the real presence of all five essential elements of informed consent during the process of the getting informed consent.

Further, it is advisable to increase the punishment for not maintaining the standards of drugs as prescribed. For the violation of not maintaining the standards of drugs, at least 10 years rigors imprisonment should be fixed. This will give deterrent effect upon the other manufacturer of drugs to maintain the standard of drugs as prescribed.

2. **The Food Safety and Standard Act, 2006:** The advancement of science and technology has modified the living pattern of human being including the food as well. Agricultural sector has left the traditional approach and observed the international advancement for the manufacturing the foods and other agricultural products. Ultimately, farmers have started using various pesticides for the growing crops, fruits and other products. These methods put a question mark on the food safety due to excessive use of pesticide to get maximum production of the crops, fruits etc. Although,

law has prescribed the formulas to use the pesticide but the moot question is for supervision and implementation of the pesticide by the farmers. To avoid this issue, awareness about the how to use pesticide among the farmers will certainly proved to be effective and better mechanism to resolve this issue. Formal education to the farmer as well as the distributors will be helpful in this regard. Also, after giving the education and creating awareness to each farmer and villages, surprise inspection is to be made by the Farmer Officer appointed at each village. Such officer should be empowered to collect the food for the inspection and stringent provision for the excessive use of the pesticide should be penalized with at least 10 years rigors imprisonment. In this manner, the ambiguity can be resolved and people will get health food accordingly.

3. **The Epidemic Diseases Act, 1897:** The major drawback discussed earlier is the compensation. Due to the announcement of the any preventive measure under the Epidemic Diseases Act, 1897, compensation should be paid to the victims immediately. Annually such budget should be fixed by the Center and State separately. It should be made it mandatory that whenever this Act is made it active, such state or central government will prepare a policy which will contain the nature of the order, tentatively affected area and people and how the compensation will be paid to them. This provision will ensure the real justice to the people and the use of the Epidemic Diseases Act, 1897.

To conclude, the above discussed solutions will definitely increase the utility of the enactment in real sense and will offer justice to the people and the realization of the welfare state as well.

ENDNOTES

ⁱAvailable at <https://www.who.int/news-room/commentaries/detail/health-is-a-fundamental-human-right> (Last accessed on 3rd January, 2021)

ⁱⁱAvailable at <https://www.who.int/news-room/commentaries/detail/health-is-a-fundamental-human-right>

ⁱⁱⁱ Public Health Law in a New Century, Lawrence O. Gostin, Health Law and Ethics, 2000 American Medical Association JAMA, June 7, 2000-Volumbe 283, No. 21, Pg. No. 2837-2841.

^{iv} Ethics, Prevention and Public Health, Edited by Angus Dawson and Marcel Verweij, Oxford University Press, Oxford, 1st Publication, 2007, Pg. 7.

^vGostin LO. *Public Health Law: Power, Duty, Restraint*. 2nd ed. Berkeley, CA: University of California Press; 2008: 4.

^{vi}Public Health Law Center [Internet]. St. Paul, MN: Public Health Law Basics; 2010 [cited 2012 Dec. 1]. Available from <http://phlc.stylefish.com/topics/public-health-law-basics>.

^{vii} Available at <https://www.wma.net/what-we-do/human-rights/right-to-health/> Right to Health Right to Health: An Inclusive Right for All, World Medical Association (Last accessed on 4th January, 2021).

viii No Person shall be deprived of his life and personal liberty except according to the procedure established by law.

ix *Bandhua Mukti Morcha v. Union of India* (AIR 1984 SC 802).

x *State of Punjab v. Mohinder Singh Chawla* (1997) 2 SCC 83

xi *Paschim Banga Khet Mazdoor Samity v. State of West Bengal* (AIR 1996 SC 2426).

xii V.N.Shukla, *Constitution of India*, Revised by Mahendra Singh, Lucknow, Eastern Book Company, Reprinted July 2006, Pg. A-24.

xiii Art. 38 imposes liability upon the state to secure a social order for the promotion of welfare of the people but without public health, it would be difficult to achieve it.

xiv Art. 39(e) deals with principles of Policy to be observed by the State that the health and strength of workers, men and women and children.

xv Art. 41 imposes duty upon the state to provide public assistance to those who are sick, old and disablement.

xvi Art. 42 deals with the provision that the State shall make provision for securing just and human conditions of work.

xvii It is the primary duty of the state to increase the level of nutrition and the standard of living and to improve the public health.

xviii 1996 SCC (4) 37, JT 1996 (6) 43

xix The Drugs and Cosmetics Act, 1940

xx Object of the Food Safety and Standards Act, 2006

xxi Sec.16 of the Food and Safety and Standards Act, 2006.