Biomedical Waste Management and its impact: Legislative and Judicial Development in India.

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Abstract

Biomedical waste is highly hazardous which can give rise to serious diseases that may be fatal for the human health and natural resources of the environment. Biomedical waste management is of great importance to reduce the serious health implications. It is very important to know the concept of waste and its management. Effective BMWM is not only a legal necessity but also a social responsibility. Inadequate management of biomedical waste may be associated with risks to healthcare employees, patients, communities, and their environment. In India, Biomedical waste management is regulated by the biomedical Wastes (Management & Handling Rules, 1998).

Keywords: Biomedical waste, Environment protection, Health Care, and Sustainable Development.

I. Introduction

With the mushrooming growth of health care centers, biomedical waste has become a serious health hazard in many countries. However, several difficulties are being confronted with the execution of waste management rules. Unsympathetic and haphazard disposal of biomedical waste by healthcare establishments spread of serious diseases such as hepatitis, cholera, and AIDS (HIV). It is a hazard not only to human health but also to the environment for the present and future generations which is adversely affected sustainability in the environment by adding toxic pollutants to water, air, and soil. This environmental pollution hypothetically injured flora, fauna, and our ecosystem. The environment ties people’s surrounding and it includes physical, biological, social, and cultural factors.² Mere protection and conservation of the land, air, and water are not enough for the realization of the right to life. The proper management of Biomedical waste ensures that an individual is assured ‘Right to Life’ as envisaged under Article 21 of Indian Constitution and Article 25(2) of the Universal Declaration of Human Rights advocating the right to a standard of adequate living for health and well-being of the individual including medical care, sickness, and disability. With the growth of population, there are

mushrooming of healthcare establishment in private as well as the government sector. Environmental governance has been taken into consideration by the international community for the first time by adopting the principles at the Stockholm Conference in 1972 for the protection and improvement of the human environment at the global level. It was in the year 1996 the Supreme Court of India for the first time in *B.L. Wadhera v. Union* of India, while dealing with the Municipal solid waste emphasized on the management of new menace originated from the health care institution that is called biomedical waste.

India is one of the first developing countries, which has shown a great concern for the menace of bio-medical waste and has made an exhaustive attempt to regulate it. Of late, the MoEF Government of India in the exercise of powers under sections 3, 6, and 25 of the *Environment (Protection) Act, 1986* had framed the Rules, the Bio-Medical Waste (Management and handling) Rules, 1998. Further, the *National Environment Policy, 2006* develop and implement viable models of public-private partnerships for the disposal of toxic and biomedical waste. Further, to effective and speedy disposal of cases relating to environmental protection and effective enforcement of the biomedical waste rules including any legal right relating to environment and compensation for damages to persons and property, the Indian parliament enacted the *National Green Tribunal Act, 2010*, and created alternative institutional mechanisms in the form green tribunal.

Therefore, effective BMWM is not only a legal necessity but also a social responsibility. Under this backdrop, the present article draws a panoramic perception of law and judicial contributions in the area of biomedical waste management for realizing the goals of the outcome of the UN Conference on Sustainable Development to recycle and reduce waste.

### II. Problematic Scenario

In the new emerging challenges for the protection of the environment and human health, biomedical waste management affects much bigger environment issues including the release of persistent organic pollutants (POPs,) which are released during medical waste incineration. It is witnessed by the United Nations (UN) human rights that medical waste was becoming an increasing problem with the mushrooming growth of the health care sector. A global initiative has taken by the WHO and UNICEF to ensure that all health care facilities have adequate water, sanitation, and hygiene services which include addressing health care waste in the year 2015.

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3 AIR 1996 SC 2969
Further, as part of monitoring Sustainable Development on safely managed water and sanitation, they jointly monitoring programmed on the safe management of biomedical waste and sanitation in health care facilities.

As a developing nation, India is the seventh-largest country in the world and the second most populated. The average annual exponential growth rate stands at 1.64% during the period 2001–2011. As the researches outlined that out of total waste produced from the hospital waste approximately 10% is hazardous, 85% is general waste while a small percentage (5%) is labeled as highly hazardous.6 The serious problem to waste management is that all biomedical waste is being disposed of along with municipal solid waste due to inadequate management and awareness. A nationwide survey performed by the International Clinical Epidemiology Network observed that improper pretreatment of BMW at source and improper terminal disposal was the major challenge. In the absence of effective and credible biomedical waste management, there is around 82% of primary, 60% of secondary, and 54% of tertiary care health facilities.7 According to the Ministry of Housing and Urban Affairs is estimated that the total generation of solid waste is approximately 1, 50,000 T/day in the year 2016-17.8 According to a study conducted jointly by industry body ASSOCHAM and Velocity have estimated that India likely to generate about 775.5 tons of medical waste per day by 2022 from the current level of 550.9 tons daily.9

As per the Uttar Pradesh, Pollution Control Board reported that 16,075 healthcare facilities have been identified in the state while authorization has been granted only to 9,540 facilities in the year 2019.10

III. Meaning and Concept of biomedical waste

Basel Convention11 is an international treaty that specifically deals with the transboundary movement of hazardous wastes at the international level defines “Wastes are such substance, which is intended and essential to be disposed of by the provisions of national legal instruments”12. It can be categorized into different types subject to their source.13 It encompasses

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5 Goal No6, Sustainable Development Goals 2030.
innumerable wastes like a household waste, industrial waste, biomedical waste, or hospital waste.14

According to the United Nation health agency known as World Health Organization has given inclusive definition of biomedical waste as it includes waste generated by healthcare facilities as wastes from physician’s offices, hospitals, dental practices, laboratories, medical research facilities, and veterinary clinics.

Environmental Protection Agency working especially for the development of environmental law and policy define biomedical waste means “all waste materials generated at health care facilities, such as hospitals, clinics, physician’s offices, dental practices, blood banks, and veterinary hospitals/clinics, as well as medical research facilities and laboratories.”

Biomedical waste as waste generated during medical research, testing, diagnosis, immunization, or treatment of either human beings or animals.15 According to the parent rules on bio-waste it considered in the numerous categories as human anatomic waste, animal waste, microbiology and biotechnology waste; waste sharps; discarded medicines and cytotoxic drugs, soiled waste, liquid waste, incineration ash, and chemical waste.16

IV. International legal framework

The relevancy of environmentalism required to be heavily seated under environmental policy and laws. It can be achieved only when a significant number of the people showing their political and ideological mindset become conscious of the common stake of human beings and moved to peruse the government to act in conformity with ecological integrity, global commonality, and universal heritage of mankind.17 In this regard, the international environmental consciousness was developed in 1960 and finds a kind maturity only in the post-1970s in the form of various conventions having sectoral approaches to arrest the problem.18

The International Covenant on Economic Social and Cultural Rights, the Universal Declaration of Human Rights, and the International Covenant on Civil and Political Rights are collectively known as the International Bill of Rights. The right to effective enjoyment of the

15 Rule 3(f) Biomedical Waste (Management and Handling) rules 1998.
right to life in the context of management and disposal of medical waste realized as the protection of civil and political rights as well as an economic, social, and cultural right.\(^\text{19}\)

The depletion of natural resources, environmental deterioration, and pollution has drawn the serious attention of the global community for the first time in 1972 to develop green fraternity was the *Stockholm Conference\(^\text{20}\)* which also raised its voice concerning the conservation and protection of the environment. While enjoying the fundamental right to freedom, equality and adequate conditions of life in an environment of quality, it imposes duty as to 'discharge of toxic substance or other substance and the release of heat in such quantities or concentrations as to exceed the capacity of the environment to render them harmless must be halted to ensure that serious or irreversible damage is not inflicted upon the ecosystem.'\(^\text{21}\) To scientific research and development\(^\text{22}\) required to apply the *precautionary principle\(^\text{23}\).*

Thereafter, *the Brundtland Commission\(^\text{24}\)* in its report entitled 'Our Common Future' in 1987 has mentioned industrial wastes and toxic substances as one of the major 'common challenges,' the world is facing today. It led to the first *Earth Summit\(^\text{25}\)* at Rio de Janeiro in 1992, emphases to think how human lives affect the natural environment and after this other following treaty continuously forced the global community to take appropriate and effective measures for safeguarding the human environment and particularly relatable in BMWM, environment protection, and sustainable development.

The primary objective of the *Basel Convention\(^\text{26}\)* is to protect human health and the environment against the adverse effects of hazardous wastes, specifically clinical wastes from health care in hospitals, health centers, and clinics. The Convention was adopted in March 1989 in Basel, Switzerland, and entered into force in 1992. The Secretariat of the Basel Convention under the United Nations Environment programmed provides the technical guidelines on the Environmentally Sound Management of Biomedical and Healthcare Wastes\(^\text{27}\).

The *Aarhus Convention\(^\text{28}\)* grants the public rights regarding access to information, public participation, and access to justice, in governmental decision-making processes on matters

\(^{19}\) Article 6 of the International Covenant on Civil and Political Right 1966.

concerning the local, national, and transboundary environment. The Aarhus Convention is a rights-based approach, the public, both in the present and in future generations, have the right to know and to live in a healthy environment.

Persistent organic pollutants are toxic chemicals that accumulate in the fatty tissue of living organisms and cause damage. Stockholm Convention on Persistent Organic Pollutants in 2004 that aims to eliminate or restrict the production and use of persistent organic pollutants.

The Rotterdam Convention\(^{29}\) covers pesticides and industrial chemicals that have been hazardous for human health or environment and to promote shared responsibilities about the importation of hazardous chemicals.

The Minamata Convention 2017 on Mercury is a global treaty to protect human health and the environment from the adverse effects of mercury and includes the phasing out of certain medical equipment in health-care services, including mercury-containing medical items such as thermometers and blood pressure device.

Within the current global policy frameworks, to achieve sustainable development goals, 2030 needs to properly handle and treat chemical and other hazardous waste\(^{30}\)

V. National Legal Framework

(a) Constitutional Perspective

The Constitutional law of country consists of both legal as well as non-legal norms.\(^{31}\) The Constitution envisions establishing an egalitarian social order rendering to every citizen, social, economic, and political justice. India is the country to provide constitutional protection to the environment.\(^{32}\) Originally it did not contain a specific provision for the protection and promotion of the environment. But by way of a constitutional amendment, the Indian Constitution became one of the pious constitutions where specific provision was made in the supreme law putting obligation of the State under Article 48-A as well as Citizens under Article 51A (g) to protect and improve the environment. The phrase 'protect and improvement' in both the articles seems to contemplate an affirmative government action to improve the quality of the environment and not just to prevent the environment in its degraded form in the interest of the present and future generations.\(^{33}\) The right to live in a healthy environment was specifically recognized under

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\(^{29}\) Rotterdam Convention, 2004.

\(^{30}\) SDG 11, Sustainable development Goals 2030.

\(^{31}\) M. P. Jain, Indian Constitutional Law 3(2016)

\(^{32}\) J.J.R. Upadhyay, Environmental Law 41 9(2012)

Article 21 of Constitution as "No person shall be deprived of his life or personal liberty except according to the procedure established by law."

(b) The Environment (Protection) Act, 1986

This is a small piece of legislation consisting of only twenty-six sections and is divided into four chapters. This Act was enacted under the provision of Article 253 of the Constitution of India to implement the decisions of the United Nations Conference on the Human Environment, which was held in the Stockholm in the year 1972. This is an Act to provide for the protection and improvement of the environment and matters connected therewith. By protecting and improving the environment it aims at the prevention of hazard to human beings, other living creatures, plants, and property. This was also enacted to supply the differences of the Water Act and Air Act. The Environment Protection Act comprehensively deals with environmental problems. Section 6 expressly empowered the Central Government to make rules on various items including (a) the procedures and safeguards for the handling of hazardous substances, and (b) the prohibition and restriction on the handling of hazardous substances in different areas.

Further, in the exercise of the powers conferred by sections 3, 6, and 25 of the Environment (Protection) Act, 1986 the Central Government passed the Bio-medical Waste (Management & Handling) Rules.

(c) Bio-Medical Waste (Management and Handling) Rules, 1998

The Ministry of Environment and Forests, in the exercise of the power conferred under sections 3, 6, and 25 of the Environment (Protection) Act, 1986 has notified parent rule called, Bio-Medical Waste (Management and Handling) Rules, 1998. It consists of thirteen rules and two schedules. With the due course of time, there are various amendments took place in these rules. Further, the Ministry of Environment Forests and Climate Change, Government of India, notified the Bio-Medical Waste (Management and Handling) Rules, 2016 which is amended in 2018 and 2019 under the provisions of EPA, 1986. Now with the amendment, it consists of eighteen rules, four schedules, and five forms. These rules apply to all persons who generate, collect, receive, store, transport, treat, dispose, or handle biomedical waste in any form. But it is not applicable on radioactive wastes, hazardous chemicals, solid wastes, lead-acid

36 http://envfor.nic.in/hazardous_substances_management accessed on 03.04.2020 at 12.30 pm.
38 Atomic Energy Act, 1962(33 of 1962)
batteries\textsuperscript{40}, hazardous waste,\textsuperscript{41} waste covered under the e-Waste\textsuperscript{42}, hazardous microorganisms, and genetically engineered microorganisms. The parent rule of 1998 is silent about the Common Bio-medical Waste Treatment Facility (CBMWTF) which is defined by the 2016 amended rule as a person who owns or controls a Common Bio-medical Waste Treatment Facility (CBMWTF) for the collection, reception, storage, transport, treatment, disposal or any other form of handling of bio-medical waste\textsuperscript{43}. The duties of operator of a common bio-medical waste treatment and disposal facility as to occupier\textsuperscript{44}. The rules provide the occupier\textsuperscript{45} is a person having administrative control over the institution and the premises generating bio-medical waste? It shall be the duty\textsuperscript{46} of every occupier that to take all necessary steps to ensure that biomedical waste is handled without any adverse effect to human health and the environment, segregated biomedical waste in colored bags, phase out the use of chlorinated plastic bags, not to give treated bio-medical waste with municipal solid waste, provide training to all its health care workers, establish a Bar-Code System for bags or containers and maintain all record for the operation of incineration. Further, it is provided that every occupier or operator of a common bio-medical waste treatment facility shall submit an annual report to the prescribed authority in Form-IV, on or before the 30th June of every year.\textsuperscript{47} Despite mandatory duties impose on the occupier there are various incidents where the illegal infringement of the duty to legally dispose of the biowaste as Uttar Pradesh Pollution Control Board imposes the fine on four Noida Hospital for not segregating biomedical waste.\textsuperscript{48} Recently the as per the National Green Tribunal order Forty-eight health care facilities, including Ram Manohar Lohia Hospital and Hindu Rao Hospital, in the national capital, were not following the Bio-medical Waste Management Rules, 2016 and a penalty of R 1.34 crore has been levied on them for violation of the provisions.\textsuperscript{49} The rule makes liable to occupier and operator for all the damages caused to the environment or the public due to improper handling of biomedical wastes.\textsuperscript{50}

For the proper execution of such rules, it further provides the prescribed authority. State Pollution Control Board shall be the prescribed authority for the state and Pollution Control

\textsuperscript{40} Batteries (Management and Handling) Rules, 2001.
\textsuperscript{41} Hazardous and Other Wastes(Management and Transboundary Movement) Rules, 2016 as amended in 2018.
\textsuperscript{43} Rule 2(n) Bio-Medical Waste (Management and Handling) Rules, 2016.
\textsuperscript{44} Rule 5
\textsuperscript{45} Rule 2(m)
\textsuperscript{46} Rule 4
\textsuperscript{47} Rule 13
\textsuperscript{48} https://www.hindustantimes.com/noida/in-a-first-uppcb-imposes-fine-on-four-noida-hospitals-for-not segregating-bio-medical-waste/story-8cgeONUP
\textsuperscript{50} Rule 18
Committees in respect of Union territories.\textsuperscript{51} It shall comply with the responsibilities as stipulated in Schedule III of the rule. Further is to provide that every State Government or Union territory Administration shall constitute an Advisory Committee for the respective State or Union territory under the chairmanship of the respective health secretary to oversee the implementation of the rules.\textsuperscript{52} Every occupier or operator handling bio-medical waste shall make an application in Form II to the prescribed authority for grant of authorization and the prescribed authority shall grant the provisional authorization in Form III.\textsuperscript{53} It is binding that the application must be disposed of by prescribed authority within 90- days from the date of receipt of a duly completed application. Any person aggrieved by an order made by the prescribed authority under these rules may prefer an appeal\textsuperscript{54} in Form V to the Secretary (Environment) of the State Government or Union territory administration within a period of thirty days from the date on which the order is communicated to him. For the proper management of biomedical waste, the rule provides the treatment and disposal\textsuperscript{55} of it under the first schedule in compliance with the standards provided in the second schedule by the health care facilities and common bio-medical waste treatment facility. The bio-medical waste shall be segregated\textsuperscript{56} into containers or bags at the point of generation. The Ministry of Environment, Forest and Climate Change shall review the implementation of the rules in the country once in a year through the State Health Secretaries and Chairmen or Member Secretary of State Pollution Control Boards and Central Pollution Control Board and the Ministry may also invite experts in the field of bio-medical waste management.\textsuperscript{57} Every authorized person shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal or any other form of handling of bio-medical waste, for five years, following these rules and guidelines issued by the Central Government or the Central Pollution Control Board or the prescribed authority.\textsuperscript{58} Further, it also provides that in case of any major accident at any institution or facility or any other Site while handling bio-medical waste, the authorized person shall intimate immediately to the prescribed authority about such accident and forward a report within twenty-four hours in writing regarding the remedial steps taken.\textsuperscript{59} 

\textsuperscript{51} Rule 9  
\textsuperscript{52} Rule 11  
\textsuperscript{53} Rule 10  
\textsuperscript{54} Rule 16  
\textsuperscript{55} Rule 7  
\textsuperscript{56} Rule 8  
\textsuperscript{57} Rule 12  
\textsuperscript{58} Rule 14  
\textsuperscript{59} Rule 15
(d) Environment policy 2006

The National Environmental Policy, 2006 seeks to extend the coverage and fill the gap that still exists in the light of present knowledge and accumulated experience. The principal objective of the policy as, "to the conservation of critical environmental resources, to intergeneration equity, to international equity, to the integration of environmental concerns in economics and social development, to efficiency in environmental resources use, to environmental governance, to enhance of resources for environmental conservation." The policy embodied some principles like the precautionary approach, legal liability, public trust doctrine, integration, etc.

VI. Judicial response

Judicial response in the field of environment is not arbitrary as it is inspired by the humanitarian approach. The judiciary has sought to strike a balance between social interests in development and social interests in the environment which is in accord with the concept of sustainable development. The Supreme Court of India was also confronted with the problem of handling, management, and disposal of biomedical waste in public interest litigation and the court pronounced a detailed judgment in this regard. The Supreme Court in M.C. Mehta v. Union of India 61 clear that Indian waste management rules are founded on the principles of "sustainable development", "precaution" and "polluter pays". These principles form an integral part of Indian environmental law jurisprudence.

In Environment Monitoring Forum and Anr. Vs. Union of India (UOI) and Ors62 the court held that it is the duty of the institutions generating biomedical waste to take all steps to ensure that such waste is handled without any adverse effect on human health and environment.

In the case of Maitree Sansad Vs. The state of Orissa and Ors 63 judiciary observe the improper practices such as dumping of bio-medical waste in municipal dustbins, open spaces, water bodies, etc., leads to the spread of diseases. Emissions from incinerators and open burning also lead to exposure to harmful-gases-which can cause cancer and respiratory diseases. Exposure to radioactive waste can in the waste stream can also cause serious health hazards. An often-ignored area is an increase in in-home healthcare activities. An increase in the number of diabetics who inject themselves with insulin, home nurses taking care of terminally ill patients, etc., all generate bio-medical waste which can cause health hazards.

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60 Section 3, The National Environmental Policy, 2006.
61 AIR 1987 SC
62 MANU/KE/0894/2003
The National Green Tribunal has been given the power to regulate the procedure by itself. It does not follow the principles of civil procedure code instead it follows principles of natural justice.\textsuperscript{64} In \textit{National Green Tribunal Principal Bench, New Delhi in Krishan Lal Gera Vs. The state of Haryana and Ors}\textsuperscript{65} Physical injuries may occur to the hospital personnel as well as waste handlers outside the hospital due to improper handling of various Bio-Medical Wastes. Chemical injuries can occur due to hazardous - toxic, corrosive, flammable, and reactive and genotoxic wastes that are likely to cause chemical burns on accidental exposure, or toxicity to cells cytotoxic materials National Green Tribunal Principal Bench, New Delhi in \textit{Haat Supreme Wastech Pvt. Ltd. & Ors. Vs. State of Haryana &Ors}.\textsuperscript{66} Swatanter Kumar, J. (Chairperson) held that "Units are carrying on the activity of handling bio-medical waste treatment plants shall be required to obtain environmental clearance in as per provision of law" 

In \textit{Pandalaneni Srimannarayana and Ors. Vs. State of Andhra Pradesh and Ors}\textsuperscript{67} it is required that waste must necessarily segregate waste at the source and process entire biodegradable waste by composting.

In \textit{Mahesh Dubey vs. Chattisgarh Environment Conservation Board and Ors}\textsuperscript{68}. The State of Chhattisgarh consists of 27 districts and it has only four CBWTFs though there should be one such plant every 150 km. The respondents are not even aware as to how much of biomedical waste is being generated by the health care facilities which are in existence and being run in the State.

In \textit{Amrish Gupta, President, Dushit Paryavaran Vs. State of Uttar Pradesh}\textsuperscript{69} National Green Tribunal principle bench, New Delhi ordered regarding an allegation of illegal activities in the disposal of infected bio-medical waste, discharge of untreated hazardous effluents, and causing air pollution by M/s Synergy Waste Management Pvt. Ltd., Barabanki, Lucknow, Uttar Pradesh.

\textbf{VII. Conclusion}

After analyzing the whole gamut of the waste problems from the international and national level we reach to the conclusion that India is one of the first developing countries, which has shown a great concern for the threat of bio-medical waste and has made an exhaustive attempt to regulate

\textsuperscript{64} Section 18(2), National Green Tribunal Act, 2010.
\textsuperscript{65} MANU/GT/0140/2015
\textsuperscript{66} MANU/GT/0089/2015
\textsuperscript{67} MANU/GT/0124/2017
\textsuperscript{68} MANU/GT/0140/2016
it but because of lack of education, trained personnel, awareness, poor urban infrastructure, and financial management the problem still unattended. There are following suggestions as:

1. To empowering healthcare professionals on biomedical waste management by the training programs periodically.
2. To organize the awareness of the effect of improper disposal of biomedical waste.
3. To educate the society also the effect of improper disposal of it in the natural resources of the environment.
4. To promote concepts like *Green Consumerism and Green Marketing* for obtaining the goal of Sustainable development.