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REGULATORY BODIES INVOLVED IN PHARMACEUTICAL AND BIOMEDICAL WASTE MANAGEMENT

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ABSTRACT

Pharmaceutical waste management is an integral part of pharmaceutical industries as well as healthcare system. Effective management of pharmaceutical waste pose high significance in safeguarding and promoting public health and environmental sustainability. This paper delves deeper into the regulatory landscape which governs pharmaceutical waste management, focusing on the key regulatory bodies and their key roles and responsibilities in waste management process. We focuses on various regulatory bodies such as the Environmental protection Agency and its Indian counterpart, The Ministry of Environment, Forest, and Climate Change (MoEFCC) as the central authority for overseeing environmental regulations, the contributions of Department of Transportation and Ministry of Road Transport and Highways in ensuring safe and effective transport of waste, role of Occupational Safety and Health Administration in protecting the safety of workers from hazards associated with waste management is also highlighted. Furthermore, we inquire the Biomedical Waste Rules 2016, a significant regulatory framework in India, and analyze its effect on the management of healthcare waste. By understanding the adaptability and interaction of these regulatory bodies, we can appreciate the complexity of waste management and importance of appropriate regulatory governance.

KEYWORDS: Waste Management, Pharmaceutical Waste, Regulatory Body, Environmental Protection Agency, Biomedical Waste Rules.

REGULATORY BODY

Regulatory body is a government authority responsible for exercising regulatory control over various domains of human activity by exerting a licensing power. Roles and responsibilities of regulatory authority includes.

- Keep tracking of the everchanging legislation, amendments in existing rules and regulations.
- Draft, issue, and revise standards
- Conduct inspection, audits and reviews
- Ensure companies comply with regulations and laws
- Promotes facilitation of fair trade
- Issue, review and revision of standards

Regulatory bodies of waste management include:[1]

1. Environmental Protection Agency
2. Department of Transportation
3. Drug Enforcement Administration
4. Occupational Safety and Health Administration
5. State Environment Agency
6. Biomedical Waste Management Rules 2016

Environmental Protection Agency

Fig 1: Environmental Protection Agency.[2]

Environmental protection Agency (EPA) is a United States government agency which undertakes the function of environmental protection. Their mission is to protect human health and environment. Environmental Protection Agency works to ensure that the people have clean air, land and water, federal laws protecting health and environment are enforced accurately, all communities of the society is provided access to accurate information which is

sufficient to participate in various health management programs, cleaning up of contaminated lands and toxic sites as well as review safety of chemicals available in the marketplace.[2]

Indian regulatory body of EPA- The Ministry of Environment, Forest and Climate Change (MoEFCC)

Fig 2: Ministry of Environment, Forest and Climate Change[3]

The Ministry of Environment, Forest and Climate Change (MoEFCC) is a nodal agency of Central Government of India for the planning, promotion, coordination and to oversee the implementation of environmental and forestry policies and programs of India. **MoEFCC** also serves as a nodal agency in India for United nations Environment Program (UNEP), South Asia Co-operative Environment Program (SACEP), International Centre for Integrated Mountain Development (ICIMOD). They also act as a nodal agency for the follow-up of the Unites Nations Conference on Environment Facility (UNCED). Issues relating to multilateral bodies such as the Commission on Sustainable development (CSD), Global Environment Facility (GEF) and of regional bodies like Economic and Social Council for Asia and Pacific (ESCAP)and South Asian Association for Regional Cooperation (SAARC) on matters pertaining to the environment bestow upon the shoulders of this agency.[3]

Major objectives of this ministry include.

- Survey and conservation of flora, fauna, forests and wildlife.
- Prevent and control pollution
- Afforestation
- Regeneration of degraded areas
- Conservation of environment and
- Ensuring animal welfare

DEPARTMENT OF TRANSPORTATION

Department of Transportation/Unites States Department of Transportation (USDOT Or DOT) is an executive department of the U.S federal government headed by the secretary of transportation, who reports directly to the president of United States. Department of Transportation holds an unavoidable role in ensuring the safety and security of transportation of biomedical waste. Even though the overall responsibility of biomedical waste management lies within the shoulders of EPA and their subordinates, DOT specifically focuses on the transportation wing of the process. [4] Here's how DOT contributes.

1. By enforcing Hazardous Material Transportation Act (HMTA)
2. Conduct training for personnel involved in transportation
3. Enforcing safety regulations
4. Conduct inspections of vehicles transporting hazardous materials
5. Enforcement actions to those who violates HMTA
6. Collaboration with other agencies
7. Provide guidance and resources to shippers and transportation

DOT plays an integral role in minimising risk associated with biomedical waste transportation by enforcing these regulations. It is the responsibility of DOT to ensure that the waste materials reach treatment/disposal facilities safely, securely and in a way, which protects the public and environment from potential hazards.

Fig 3: Department of Transportation.[5]

INDIAN REGULATORY BODY- MINISTRY OF ROAD TRANSPORT AND HIGHWAYS

Fig 4: Ministry of Road Transport and Highways.[5]

Ministry of Road Transport and highways is an independent organisation under Central Government entrusted with the task of formulating and administering policies for Road Transport, National Highways and Transport Research in consultation with other central Ministries/Departments with an objective of increased efficiency of the road transport system in the country. The ministry comprises of two wings.

a) Roads wing
b) Transport wing

Roads Wing: Roads wing is concerned with development and maintenance of National Highways in the country. They are entrusted with the responsibility of planning, development and maintenance of National Highways in the country, provide technical and financial support to State governments for the development of state roads, inter-state connectivity roads, evolution of standards and specifications for roads and bridges in the country.

Transport Wing: The main responsibilities of transport wing include legislation of motor vehicle, motor vehicle Act, 1988, taxation of motor vehicles, insurance of motor vehicles, administration of Road Transport Corporations Act,1950, promotion of transport co-operatives in the field of motor transport as well as evolution of road safety standards in the form of National Policy on Road Safety by preparing and implementing the annual Road Safety Plan.

Vision

Their vision is to achieve a sustainable, safe, efficient and internationally comparable quality of general road infrastructure as well as National Highways Infrastructure to attain enhanced connectivity, rapid mobility to a level which hastens socio-economic development.

Mission

Ministry of Road Transport and Highways works with a mission of developing National Highways (NHs) Network in the country into a network of roads having international standards for continuous flow of traffic having enhances safety features. They aim in achieving enhanced connectivity for remote and isolated areas, including North-East Region, Left Wing Extremism, Tribal areas etc. They evolve various policies and procedures for efficient and safe transportation of Road Network, safer fuel efficient and cleaner automobiles in alignment with international standards and facilitate their implementation. They strive to improve the road safety scenario in the country, promotes facilitation of online services as well as strengthening the public transport system.[5]

DRUG ENFORCEMENT ADMINISTRATION

Drug Enforcement Administration regulates controlled substances, monitors their manufacturers, distributors and providers to prevent the misuse of potentially dangerous or illegal substances. They are also authorized for the delivery of harsh penalties for non-compliance. In order to remain compliant with the regulations of pharmaceutical waste disposal requires constant diligence and meticulous documentation for reporting to be accurate. Waste management solutions are provided by Clean Earth's comprehensive controlled substance management program which helps to avoid and reduce costly violations. To irradicate violations and fines, waste should be properly segregated, destroyed and every step should be documented from identification through disposal activity and reported to relevant regulatory bodies. Complete regulatory compliance requires regular monitoring and auditing in order to avoid costly oversights.[6]

INDIAN REGULATORY BODY-CENTRAL DRUGS STANDARD CONTROL ORGANISDATION

CDSCO is the main regulatory authority of India for the regulation of pharmaceuticals and medical devices. The Drugs Controller of India (DCGI) is responsible for the regulation of these products. DCGI is advised by DTAB and DCC. CDSCO is divided into zonal offices which performs pre- and post-licensing inspections, post-market surveillance and drug recalls when required. Manufacturing organisations who work with CDSCO must appoint an Authorized Indian Representative (AIR) to represent them in every transaction with the organisation. As of February 1, 2023, Dr. Rajeev Singh Raghuvanshi is the DCGI.[7]

Fig 5: Central Drugs Standard Control Organisation.[7]

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

OSHA has designed certain guidelines for biohazard waste disposal in order to protect all industries residing in the country as well as workers in medical care and related waste environments and industries from diseases or injury that might occur due to biological, hazardous and infectious waste.

OSHA focuses to reduce and prevent injuries and illness relates to workers. The commencement of OSHA occurred in an environment where safety practices and regulations in the workplace were not just limited to the healthcare industry. Evey year serous accidents and deaths were reported more and more. It was observed that the reports of disabling injuries had increased by 20% and almost 14,000 died at their jobs every year, due to this reason representatives began drafting a new bill known as OSHA by the late 1960s.

Three Primary Components of the Act

- The Occupational Safety and Health Administration (OSHA) to determine and enforce workplace safety and health standards;
- The Occupational Safety and Health Review Commission (OSHRC) – an independent agency that adjudicated enforcement actions challenged by employers;
- The National Institute for Occupational Safety and Health (NIOSH), which was formed to conduct research on occupational safety and health.[8]

OSHA in Healthcare Waste Management

Health and safety of workers being the prime concern, OSHA's regulations play a vital role in healthcare environment. Initially, OSHA's biohazard waste guidelines centered on specific hazards such as physical injury caused by transportation, slips and falls. Gradually the focus continued to grow in order to evolve exposures to potentially dangerous drugs such as chemotherapy drugs, radiation hazards. As technology advanced over time, risk assessment

began to consider those included to exposure to MRI magnetic fields etc. OSHA introduces the dangers of biological hazard in the Bloodborne Pathogen Standard in 1991.

Risks in Healthcare

Injuries caused by needlestick and sharps posed a significant risk to healthcare workers, not only doctors, nurses and surgical staff but also janitor, housekeeping staff and even the patients and their families. According to OSHA, approximately 55,00,000 healthcare workers and related occupations are at high risk of exposure to bloodborne pathogens, including HIV, hepatitis B and C, and others. Nursing staff are most frequently poked and are exposed to hazards due to sharps which commonly occurs in patient rooms, operating rooms, and during waste management process.

Indian regulatory body- Biomedical Waste Management Rules 2016[9]

Biomedical Waste Management Rules 2016 were introduced by the Ministry of Environment Forests & Climate Change in March 2016. Amendments of the rules were made in 16.03.2018, 10.05.2019 and 19.02.2019. These revised rules focus on enhancing environmentally sustainable management of biomedical waste, efficient collection, segregation, processing, treatment and disposal. It requires non-bedded clinics to obtain one-time authorization from State Pollution Control Board.

APPLICABILITY OF BMW RULES, 2016

These rules are applicable to those who generate, collect, receive, store, transport, treat, dispose, or handle biomedical waste in any form from hospitals, nursing homes, clinics, dispensaries, veterinary institutions, animal houses, blood banks, clinical establishments, AYUSH hospitals, research institutions, health camps, first aid rooms of schools, forensic laboratories and research labs etc.

The following categories are exempted from Biomedical Waste Management Rules as they are governed by separate regulations including radioactive wastes, lead acetate batteries, hazardous wastes, E-waste under hazardous microorganisms, genetically engineered microorganisms and cells.

BARCODE SYSTEM FOR TRACKING BMW

An important concept inn all types of waste is the reduction of waste and resource recovery. Recyclable materials from bio medical waste can be recovered scientifically without any

impact on environment. There are instances where valuable materials are being recovered through unscientific ways by scrap vendors. This is to ensure that the complete waste collected are treated and disposed after the recovery of recyclable materials. Barcode/QR code system is introduced as per the Rule and implemented by healthcare units in cooperation with common facility in order to ensure that secondary handling, pilferage of recyclables, scattering or spillage by animals doesn't occur during handling of waste.

COMMON TREATMENT FACILITIES IN KERALA[11]

As per BMW Rule, treatment facilities are not encouraged if the service of CBMWTF is available within a distance of 75km.

1. M/s IMAGE, Palakkad: 55.8 TPD capacity IMAGE, IMA State Head Quarters, Anayara PO TVM-695029
2. M/s KEIL, Ernakulam: 16 TPD (w.e.f. April 2021) Common TSDF Project, Ambalamedu, Kochi-682303

Difference between Biomedical Waste Rules 1998 and 2016[9]

BMW 1998	BMW rules,2016
Application These camps and such healthcare-related activities not covered under BMW 1998 rules	The realm of the rules has been expanded to include vaccination camps. blood donation camps, surgical camps, or any other health care activity
Duties of occupier Pretreatment of the laboratory waste, blood bags etc. was not required	Pretreatment of laboratory waste, microbiological waste, blood samples, and blood bags
Use of chlorinated plastic bags, gloves, blood bags were mentioned	Phase-out the use of chlorinated plastic bags, gloves, and blood bags within 2 years
Liquid waste not to be separated at source and ETP is not mandatory	Liquid waste to be separated at source by pretreatment and ETP is required
Training and immunization for compulsory	Provide training to all HCWs in BMW rules and handling and immunize all HCWs against hepatitis B and tetanus
No barcoding system was in place	Establish a bar code system for bags or containers containing BMW for disposal
Reporting of accidents not specified and mentioned	Report all major accidents
Duties of the operator of a CBMWTF No such recommendation was in place No such records were maintained	To establish barcoding and GPS of BMW waste carrying vehicle within 1 year
No such records were maintained	Maintain a logbook of each cycle of treatment with all details such as time, date, weight, duration, and hours of treatment
CBMWTF Every HCFs shall set up a requisite BMW	No occupier shall establish on their site a BMW treatment and disposal plant, if a CBWTF is

treatment facility or ensure requisite treatment at a CBMWT	available within 75km of the HCF If no CBWTF not available, the occupier should establish a BMW treatment and disposal plant after taking prior permission from authority
	from authority
Segregation, packaging, transportation, and storage of BMW, classified into 10 categories based on treatment options If untreated BMW should be stored beyond 48 h, authorization	BMW classified into 4 categories based on treatment options if untreated human anatomical waste, animal anatomical waste, soiled waste, and biotechnology waste should be stored beyond 48 h, no authorization needed.
Treatment and disposal of waste Chemical treatment with 1% hypochlorite	Chemical treatment with at least 10% hypochlorite having 30% residual chlorine for 20 min or any other equivalent chemical reagent that should demonstrate log 4 reduction efficiency for microorganisms
Cytotoxic drugs disposal in secured landfills	Cytotoxic waste and items contaminated with cytotoxic waste should be returned to manufacturer or CBMWTF for incinerator at 1200° C or encapsulation or plasma pyrolysis at 1200° C
All drugs discarded in black bags	All drugs including expired antibiotics should be sent back to manufacturer or to incinerator
All infected metal, plastic, and glass waste to be put in blue bag and then sent for autoclaving, microwaving, and incinerator	The BMW waste to be segregated-plastics in red bag, sharps in whit container (after mutilation), and glass articles in cardboard box with blue marking, then sent to authorized recycler
	After proper treatment of plastics and
Authorization All HCFs treating 1000 or more patients/month need to obtain authorization from SPCB	One-time authorization for non-bedded HCFs and for bedded HCFs, the validity of authorization should be coordinated with consent order
Standards for emission from incinerators Permissible limit for SPM-150 mg/Nm³ Residence time in secondary chamber of incinerator at least 1s Standards for dioxin and furans - not defined Monitoring of implementation	Permissible limit for SPM-50 mg/Nm³ Residence time in secondary chamber of incinerator 2 Standards for dioxin and furans- 0.1 ng TEQ/Nm³
Not defined Not defined Not defined	Ministry of environment, forest and climate change should review the implementation of the rules in the country once a year SPCB of each state shall constitute district level monitoring committee under the chairpersonship of district collector or district magistrate or additional district magistrate to monitor the compliance of the above BMW rules. The district level monitoring committee shall submit its report once every 6 months to the SPCB

Difference in schedule for biomedical waste of 1998 and 2016

Schedule I	Categories of waste	Color code and type of waste with treatment and disposal
Schedule II	Color/code type of waste, waste category. treatment option	Standard for treatment of disposal of BMW (Autoclaving/ Microwaving/deep burial/dry heat sterilization/chemical disinfection)
Schedule III	Label of BMW category/bags	List of prescribed authorities and their duties
Schedule IV	Label for transport of BMW	Part A label for container/bag Part B - label for transport of BMW bag/container
Schedule V	Standard for treatment and disposal of BMW	Added to schedule II
Schedule VI	List of prescribed authorities and their duties	Added to schedule III

Different forms with biomedical waste 2016

Forms	Use of the Form
F1	Accident reporting
F2	Application for authorization or renewal of authorization (submitted by occupier of HCWs of CBMWTFS
F3	Authorization (for operating, facility) for generation, collection, reception, treatment, storage, transport, disposal
F4	Annual report
F5	Application for filing "appeal" against order passed by the prescribed authority

CATEGORIES OF BIOMEDICAL WASTE

CATEGORY NUMBER	WASTE DESCRIPTION	NAME OF WASTES
Category No.1	Human Anatomical waste	Blood, removed tumour, placenta, surgically removed body parts excreta
Category No.2	Animal wastes	Animal Body Parts
Category No.3	Microbiology and biotechnological wastes	Culture media, vaccine waste, regents.
Category No.4	Waste sharps	Needles, syringes, scalpels, glass bits, broken ampoules.
Category No.5	Discarded medicines and cytotoxic drugs	Discarded medicines, cartons.
Category No.6	Soiled waste	Solid cotton dressings, plaster casts, solid beddings, linen, gloves, masks,
Category No.7	Solid waste	IV sets, tubes, catheters.
Category No.8	Liquid waste	Bleaching powder solution, household phenyl solution.
Category No.9	Incinerated ash	
Category No.10	Chemical used in incineration	Bleaching powder, DDT.

COLURS OF BIOMEDICAL WASTE

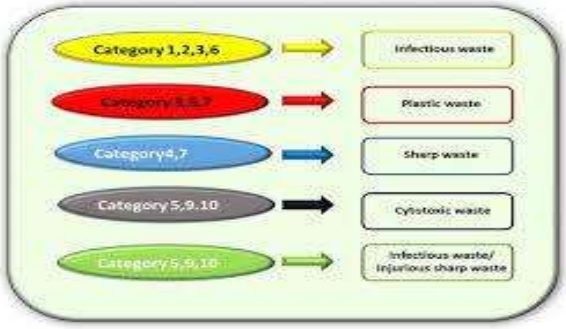

Fig 5: Colours of biomedical Waste.[10]

FEATURES OF BIOMEDICAL WASTE RULES 2016

- The applicability of scope of biomedical waste rules has been expanded including various health camps such as blood donation camp, vaccination camps, surgical camps etc.
- Duties of occupier of a HCF has been revised. Occupier holds the administrative control over the HCF generating BMW.
- The responsibility of the operator of CBMWTF has increased which helps in assisting the training of collection of HCW.
- There should be barcoding system established for handling of BMW.
- For improved segregation, packaging, transportation, and storage of biomedical waste, waste have been classified into four categories based on colour code-type of waste and treatment options. If the waste needs to be stored for more than 48 hours, the occupier should take all adequate measures to ensure that the waste is not adversely affect environment and human health.
- Health care facility should not install on-site BMW treatment and disposal facilities is there is a treatment facility available within the distance of 25kms.
- If there are no CBMWTF available, the occupier should setup required facilities such as autoclave, microwave, shredder after taking prior authorization from respective authority.

CONCLUSION

Pharmaceutical waste results from various activities of healthcare facilities, manufacturers and most common cause of pharmaceutical wastes are spills, half-used bottles, IV equipment with residual medicine on it etc. Pharmaceutical waste is quite hazardous and can result in serious health issue if not disposed properly. In order to ensure safe and effective treatment, management and disposal of pharmaceutical waste various territorial regulatory bodies are introduced. The major regulatory bodies involved in biomedical waste management includes

Environmental Protection Agency (EPA), Department of Transportation (DOT), Drug Enforcement Administration (DEA), Occupational Safety and Health Administration (OSHA), Local Publicly Owned Treatment Works (POTW) and their Indian bodies such as The Ministry of Environment, Forest and Climate Change (MoEFCC), Ministry of Road Transport and Highways, Central Drugs Control Standard Organisation (CDSCO), Biomedical Waste Rules 2016, State Pollution Control Agency etc. These regulatory bodies have developed various guidelines and policies which ensure that the waste management processes are carried out in such a way that minimises impact to human health and environment.

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