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PHARMACEUTICAL AND BIO-MEDICAL WASTE MANAGEMENT: COST OF DISPOSAL, TRAINING, AND REPORTING

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ABSTRACT

The pharmaceutical and biomedical waste management sector faces significant challenges stemming from the increased production and disposal of pharmaceutical products, driven by escalating healthcare demands. This research explores the complexities associated with pharmaceutical waste, which includes expired, unused, or contaminated medications as well as various materials contaminated by pharmaceuticals. The study further elucidates the regulatory landscape, particularly the Bio-medical Waste Management (BMWM) Rules of 1998 in India, which categorize and govern the disposal of biomedical waste. It highlights the environmental and public health risks posed by improper disposal practices, emphasizing the necessity for effective waste management strategies that comply with established regulations. The financial implications of waste disposal are examined, revealing that costs often exceed production expenses, leading to risky disposal practices in some regions. The research underscores the importance of budget allocation for waste management in healthcare facilities and the need for comprehensive training of healthcare workers on proper waste handling procedures. Additionally, it discusses reporting requirements and the necessity for ongoing training to enhance compliance and safety. The study concludes by advocating for improved waste management practices and the recycling of certain pharmaceutical materials, aiming to mitigate environmental impacts and protect public health.

KEYWORDS: Pharmaceutical waste, biomedical waste, Disposal cost, Training requirements, Reporting.

INTRODUCTION

The pharmaceutical sector is recognized as one of the most affluent industries globally. Driven by an escalating demand for healthcare, as well as application in livestock farming, horticulture, and aquaculture, there has been a notable surge in pharmaceutical development in recent years. However, this increased utilization, coupled with the degradation of pharmaceutical products and substances, has led to significant environmental contamination. Following incineration in residential furnaces, these products are often discarded as municipal waste or released as gaseous emissions.[1] The pharmacy and Poisons Board (PPB) characterizes pharmaceutical waste as any waste that includes medications that are expired, contaminated, broken, unused or no longer required. This definition also encompasses materials that contain or have been contaminated by pharmaceuticals, such as bottles, boxes, vials, ampoules, gloves, and masks.[2] Pharmaceutical waste typically encompasses a variety of items, including expired medications, personal prescriptions that patients have disposed of, and waste materials associated with chemotherapeutic agents. Additionally, it includes surplus medications such as intravenous (IV) bags and syringes, containers that hold hazardous pharmaceuticals, and unused drugs. Other components of pharmaceutical waste consist discarded medications, equipment used for spill clean-up, as well as contaminated absorbents and protective clothing.[3]

The Bio-medical Waste Management (BMWM) Rules of 1998 in India delineate bio-medical waste as any solid, liquid, or fluid waste, along with its container and any intermediate products, produced during the diagnosis, treatment, or immunization processes involving humans or animals, as well as in related research activities or in the production and testing of biological materials. Additionally, it encompasses animal waste originating from slaughterhouses and similar facilities. Improper disposal of various hazardous medical and dental wastes poses significant risks to environmental safety.[4] Bio-medical waste, often referred to as infectious or medical waste, encompasses materials produced during various medical activities such as diagnosis, testing, treatment, research, or the manufacturing of biological products

intended for human or animal use. This category of waste comprises items such as syringes, live vaccines, laboratory specimens, human of animal tissues, bodily fluids, sharp instruments like needles, as well as cultures and lancets.[5]

Pharmaceutical play a crucial role within the healthcare system, necessitating a consistent and adequate supply. Both the human health and veterinary sectors obtain pharmaceuticals through various means, including donations and procurement processes. However, it is important to note that some medications may sustain damage during transportation, storage, handling, or routine usage, while others may reach their expiration dates. In times of crises, such as famine, conflict, or natural disasters, nation often receive substantial shipments of pharmaceuticals to support their healthcare supply chains.[2] Bio-medical waste is produced not only within medical facilities, laboratories, and research institutions but can also arise in domestic settings, particularly through procedures such as dialysis, medication administration, and injections. Additionally, rural regions contribute to this waste through veterinary health practices involving animals.[6]

Pharmaceutical and Biomedical waste must undergo treatment and be disposed of in compliance with regulations specifically designed for biomedical waste management.[7] Pharmaceutical waste and Bio-medical waste are generally managed through disposal methods such as landfilling and incineration.[8] The management of bio-medical waste is intrinsically linked to potential impacts on both public health and environmental integrity.[9] Consequently, it is imperative that pharmaceutical waste is managed with care to enhance the well-being of the community and the environment.[10]

COST OF DISPOSAL

The expenses associated with the disposal of pharmaceuticals exceed those related to their production, leading many individuals in Asian nations to resort to burying waste materials in the ground. This practice raises significant concerns regarding environmental sustainability and the potential repercussions for future generations.[11] The expenses associated with the disposal of pharmaceutical waste through high-temperature incineration in the United States range from approximately $4.4 million to $8.2 million.[12] In India, the expenses associated with such disposal range from approximately 0.5% to 2% of the overall sales revenue.[13] Environmental risks contribute to approximately 25% of the global disease burden, with this figure rising to nearly 35% in areas like Sub-Saharan Africa.[14,15] A comprehensive research initiative examined 123,761 recorded instances of pharmaceutical concentrations in the environment across various regions worldwide.[16] The growing reliance on pharmaceuticals within both clinical and veterinary settings is clearly capable of negatively impacting the environment.[17]

Pharmaceutical waste is typically managed through incineration at elevated temperatures exceeding 1200 °C. Countries with advanced industrial capabilities, such as Bosnia and Croatia, benefit from well-established incineration systems equipped with robust pollution control measures, which result in disposal costs ranging from $2.2 to $4.1 per kilogram. In contrast, the financial requirements for the disposal of pharmaceutical waste in the United States are significantly higher, estimated to be between $4.4 and $8.2 million.[10] The expense associated with the disposal of one kilogram of pharmaceutical waste in Kenya during the 1990s was between Sh200 and Sh400. Currently, this cost has significantly decreased to a range of Sh25 to Sh30 per kilogram. In 2017, approximately 65,000 kilograms of pharmaceutical waste, valued at Sh1.29 million, were processed at the Envirosafe Limited incinerator located in Athi River. High-temperature incineration facilities are limited to the Kenya Medical Research and Training Institute (KEMRI), which operates at 3000°C, and Kenyatta National Hospital (KNH), which operates at 1700°C. The majority of healthcare institutions in Kenya utilize brick and mortar incinerators that can only achieve temperatures of up to 300°C, rendering them inadequate for the high disposal costs, thus necessitating outsourcing for waste management. Furthermore, the pharmaceutical sector in Kenya does not possess its own incineration facilities and instead resorts to a return-to-manufacture approach for products six months prior to their expiration.[18] A research study conducted in Greece revealed that the daily production of cytostatic waste amounted to 22,900 grams, resulting in an annual generation rate of 274.8 kilograms. This data indicates a per-patient waste generation rate of 140 grams per day and a per-bed rate of 210 grams per day. Such investigations are crucial as they facilitate the planning of disposal costs and the evaluation of the environmental impact associated with pharmaceutical waste.[19]

BUDGET ALLOCATION FOR BIO MEDICAL WASTE MANAGEMENT

According to Schedule III of the Bio-Medical Waste Management (BMWM) Rules, 2016, it is imperative for the State Government of Health or the Union Territory Government or Administration to allocate sufficient financial resources to government healthcare facilities for the effective management of bio-medical waste. Healthcare facilities (HCFs) should establish a specific budget for bio-medical waste management as part of their annual financial planning. This budget should encompass both recurring and non-recurring expenses anticipated by HCFs in relation to bio-medical waste management activities. Furthermore, states are encouraged to incorporate this budget into their annual Programme Implementation Plan (PIP) to secure approval and funding from the Central Government of India.[20]

TRAINING OF HEALTH CARE WORKERS

According to the Bio Medical Waste Management Rules of 2016, it is essential for all employees within healthcare facilities to receive training on the management and handling of biomedical waste.[20]

Training Need Analysis: It is essential for every healthcare worker entering the healthcare facility to complete training on Bio Medical Waste Management during their induction process. The Bio Medical Waste Rules of 2016 further require that healthcare personnel engaged in the management of bio-medical waste receive annual training. It is recommended that the committee or individual responsible for overseeing the activities related to bio-medical waste management conduct a training needs assessment for the staff, considering several key factors:

- Theoretical knowledge
- Demonstration of bio-medical waste handling techniques
- Practical implementation of these methods.

Training Schedule: According to the BMWM Rules of 2016, health care facilities are mandated to provide training on biomedical waste management activities at least once a year for all personnel, as well as whenever new staff members are introduced to the facility. It is advisable for each health care institution to develop a training calendar dedicated to the education of staff on the handling of biomedical waste, ensuring that training is delivered in accordance with the established training plan.

Trainers: In addition to professional trainers, healthcare facilities (HCFs) may extend invitations to relevant officials from the State Pollution Control Boards (SPCBs) and operators of Common Biomedical Waste Treatment Facilities (CBWTF) to participate in internal training sessions aimed at educating staff on the management of biomedical waste (BMW) within healthcare settings.

- HCFs are required to assign designated personnel and other selected staff members to participate in training programs organized by SPCBs and Pollution Control Committees (PCCs) as they become available.
- The Nodal Officer responsible for biomedical waste management within the HCF should assume the duty of delivering induction training to newly hired healthcare personnel.
- A trained healthcare worker may also assume the role of a trainer, thereby facilitating knowledge transfer within the organization.
- It is essential for HCFs to ensure that all staff involved in the handling of biomedical waste receive adequate training to promote compliance with regulatory standards and enhance safety protocols.

Training Material: The BMWM Rules of 2016 mandate the establishment of a standardized training module for delivering training within healthcare facilities. To fulfil this requirement, the provided guidelines may serve as training resources, or alternatively, any pertinent materials published by recognized authorities such as the SPCB or PCC can be utilized as training content.

Training Records: Health care facilities must ensure the meticulous maintenance of all training records related to Bio Medical Waste Management, which includes both induction and in-service training for all personnel, to demonstrate compliance with regulatory standards. It is essential that attendance records for each training session are accurately kept, with signatures from trainees that include their names and designations. Furthermore, health care facilities are required to compile and submit comprehensive details regarding the training provided for the handling of biomedical waste to the State Pollution Control Board (SPCB) or the Pollution Control Committee (PCC). These records must be included in the annual report submitted to the relevant authority, specifically the SPCB or PCC, by the deadline of June 30th each year.

The training details include

- Total Number of trainings conducted along with the date of imparting the training
- Total number of participants of each training
- Attendance Record
- Total Number of staffs trained on BMW Handling
- Total number of staffs trained on BMW handling at the time of Induction
- Total number of staffs, not undergone any sought of training on BMW Handling

Training Effectiveness: The assessment of training effectiveness can be conducted by examining the same criteria identified in the staff training needs analysis or by administering a mock test, which may be either verbal or written, following the completion of the training program.[20]

Facility Level Training Plan

The individual accountable for overseeing this initiative is the Nodal Officer, along with the Members of the BMW Management Committee and the specifically assigned personnel for each BMW generation site. To guarantee the effectiveness of waste management operations, it is essential to implement ongoing training and awareness initiatives. The primary personnel at these facilities who require regular training and heightened awareness encompass medical officers, nurses, technicians, and waste management staff.[21]

The following considerations may be incorporated in the training plan

- The training program will encompass a comprehensive examination of the fundamental aspects of BMW, including the rationale, location, content, participants, timing, and methodology, as outlined at the beginning of the manual.

- Determine the appropriate batch size and composition: training sessions may be organized by ward, with each session including doctors, nursing staff, and ward attendants from that specific ward.
- Establish a suitable timeframe for delivering the training: sessions may be scheduled to take place after regular hospital hours.
- The trainers have the authority to determine the length of the training sessions, with a recommended duration of two hours. It is essential that this time frame is adequate for raising awareness, delivering necessary information, and evaluating the trainees' understanding.
- Training should incorporate the use of flip charts or other audio-visual aids to enhance the learning experience.
- It is advisable for trainers to employ demonstration methods during the training, utilizing a collection of coloured bins, actual waste samples, and additional materials to facilitate effective learning.

Training flip chart material available with the nodal officer covers the following

- Definition and classification of biomedical waste, including examples of materials that fall within and outside this category.
- Identification of the appropriate timing, locations, and personnel responsible for the segregation of biomedical waste.
- Overview of the segregation process for biomedical waste, detailing the specific color-coded bins (Yellow, Red, Blue) and the use of puncture-proof containers.
- Strategies for the management of sharps in healthcare settings
- Approaches to prevent and address needle stick injuries
- Protocols for the management of liquid spills
- Guidelines for the use of personal protective equipment
- Recommended steps for hand hygiene as per WHO guidelines.[21]

REPORTING

According to the Bio Medical Waste Management Rules of 2016, healthcare facilities are mandated to submit an Annual Report to the State Pollution Control Board (SPCB) or the Pollution Control Committee (PCC) by June 30th each year. This report must cover the period from January to December of the previous calendar year. It is essential that the annual report is completed using the designated format outlined in Form IV, as specified by the BMW Management Rules of 2016.[20]

The annual report contains details of following

- Information regarding the occupier and healthcare facility (HCF)
- Annual waste generation quantified in kilograms
- Specifications concerning the storage, treatment, transportation, processing, and disposal facilities
- Comprehensive overview of training sessions focused on the management of biomedical waste.
- Documentation of incidents that transpired during operations.
- Analysis of emissions and effluent testing results.

The Annual Report that is submitted to the State Pollution Control Board or the Pollution Control Committee should include the following details

- Instructional sessions conducted for Health Care Workers responsible for the management of bio-medical waste.
- Documentation of the proceedings from the BMW Management Committee meetings.
- Comprehensive account of accidents that transpired over the past year, including corrective measures implemented.
- Documentation of emissions testing results for diesel generators and boilers.
- Records detailing the effluent produced by the health care facility and its specific characteristics.
- Documentation of pre-treatment processes for designated waste categories, including the quantity of recyclable waste transferred to the licensed recycler measured in kilograms per annum, where permitted by the State Pollution Control Board or Pollution Control Committee.
- Maintenance of health status records for healthcare personnel engaged in the management of biomedical waste.
- Documentation of immunization status for healthcare workers responsible for the handling of biomedical waste.

Healthcare facilities are required to publish the annual report submitted to the relevant SPCB/PCC on their respective websites.

Accident Reporting

Any incident that takes place during the management of biomedical waste within a healthcare facility poses a risk to both environmental integrity and human health, necessitating documentation by the healthcare facility (HCF).[20]

According to the Biomedical Waste Management Rules of 2016, such incidents are categorized into two distinct types:

1. Major Accidents
2. Minor Accidents

Major Accidents

Major accidents include but not limited to following;

- Overturning of the vehicle transporting bio-medical waste
- Unintentional discharge of bio-medical waste into aquatic environments
- Risk of fire incidents

- Explosions
- Waterlogging or soil erosion affecting the deep burial site, among other concerns

According to the BMWM Rules 2016, healthcare facilities are required to report any significant accidents that occur during the management of biomedical waste to the appropriate State Pollution Control Board or Pollution Control Committee. This report must include documentation of the remedial measures implemented, encompassing both corrective and preventive actions. Furthermore, it is essential that the Accident Report is submitted in writing to the relevant SPCB or PCC within 24 hours following the incident. The reporting must adhere to the format specified in Form 1 as outlined in the BMWM Rules 2016.

Minor Accidents

Minor accidents include but not limited to following

- Injuries resulting from needle punctures
- Exposure through splashes
- Contamination from the spillage of mercury or other chemicals

Minor incidents do not require immediate notification to the State Pollution Control Board or the Pollution Control Committee; however, they must be documented by the healthcare facility, which is also responsible for implementing suitable remedial measures. Additionally, the healthcare facility is obligated to provide a comprehensive report detailing both major and minor accidents, including the number of individuals impacted, the remedial actions undertaken, and any fatalities, as part of the annual report for the previous calendar year. This consolidated report must be submitted to the SPCB or PCC by June 30th each year.[23]

Other Reporting Requirements

In addition to the requirements for annual and incident reporting, each healthcare facility is obligated to notify the appropriate State Pollution Control Board (SPCB) or Pollution Control Committee (PCC) in the occurrence of specific events.

In the event that the waste collection agency or the Common Biomedical Waste Treatment Facility (CBWTF) fails to collect the waste within a 48-hour timeframe following its generation, it becomes the obligation of the Healthcare Facility (HCF) to promptly notify the appropriate State Pollution Control Board or Pollution Control Committee regarding this oversight. It is essential to notify the appropriate State Pollution Control Board or Pollution Control Committee regarding the justification for retaining waste in the facility for more than 48 hours. Additionally, healthcare facilities must detail the corrective measures implemented to prevent any negative impact on human health and the environment resulting from the stored waste.[20]

RECYCLING OF PHARMACEUTICAL WASTE

Specific liquid pharmaceuticals, such as syrups and IV solutions, can be safely disposed of by diluting with water and gradually releasing into sewers in small amounts. Similarly, well-diluted liquid pharmaceuticals or antiseptics can be disposed of in fast-flowing water bodies.

- The pharmaceutical waste management process involves:
- Segregation
- Collection
- Pre-treatment
- Intramural transportation
- Storage

The responsibility for treating and disposing of biomedical waste falls on Centralized Bio-Medical Waste Treatment Facilities (CBWTF) operators, with the exception of laboratory waste and highly infectious materials. Healthcare Facilities (HCFs) are required to pre-treat these specific waste types.[24]

Recyclable material

Various materials, including paper, textiles, packaging materials, clothing, gauze, and wooden items like pallets, can be managed through recycling, incineration, or landfill disposal. Plastic, metal, and glass items can be repurposed (e.g., glassware for laboratories, mechanical items for scrap metal), recycled (if facilities are available), or sent to a landfill. Depending on the material type and intended reuse, appropriate treatment like cleaning or disinfection may be necessary. Other miscellaneous waste can be landfilled. If recycling programs exist, materials can be segregated from pharmaceutical waste prior to landfill disposal.[25]

CONCLUSION

In conclusion, it is evident that the proper management of pharmaceutical and biomedical waste is of utmost importance for the protection of both the environment and public health. The implementation of appropriate disposal methods such as landfilling, incineration, and recycling plays a vital role in mitigating the potential environmental impact of pharmaceutical waste. Furthermore, it is imperative for healthcare facilities to allocate sufficient financial resources for bio-medical waste management and to ensure comprehensive training for all personnel involved in waste handling. Accurate reporting of incidents and accidents, along with strict adherence to regulations, is essential for maintaining the integrity of the environment and safeguarding human health. Ultimately, the effective management of pharmaceutical and biomedical waste is not only a regulatory requirement but also a moral obligation for the well-being of communities and the preservation of the environment.

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