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"REVIEW ON: REGULATORY GAPS IN PHARMACEUTICAL WASTE MANAGEMENT"

Sagar Dixit Kumar Kaushikbhai[1]*, Dr. Nidhi Chauhan[2], Mohammad Naimuddin Chauhan[1], Singh Mohit Awadhesh[1], Bala Mubassira[1]

M. Pharma (Quality Assurance), Laxminarayan Dev College of Pharmacy, Bholav, Bharuch – 392015, India.

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Corresponding Author: Sagar Dixit Kumar Kaushikbhai

Address: M. Pharma (Quality Assurance), Laxminarayan Dev College of Pharmacy, Bholav, Bharuch – 392015, India. **DOI:** http://doi.org/10.5281/zenodo.22261842,

ABSTRACT

Introduction: Due to environmental contamination, antimicrobial resistance, and public health hazards brought on by inappropriate disposal methods, pharmaceutical waste management is becoming a major global concern. **Methodology:** India, Malaysia, Bhutan, France, Spain, and other nations' pharmaceutical waste management systems and legal frameworks are compared in this study. The examination focuses on funding channels, public awareness campaigns, disposal techniques, government engagement, and collection systems. **Results:** Enforcement, infrastructure, monitoring, and public engagement were found to have significant regulatory deficiencies, particularly in developing nations. In **conclusion**, effective pharmaceutical waste management and environmental protection depend on strengthening regulations, enhancing infrastructure, raising public awareness, and implementing sustainable disposal methods.

KEYWORDS: pharmaceutical waste management, regulatory gaps, environmental pollution, sustainable waste disposal, regulatory compliance, environmental sustainability.

INTRODUCTION[1]

Pharmaceuticals pose significant dangers to ecosystems and public health, which has led to worldwide concern over the presence of pharmaceuticals in the environment [1,2]. Similar to the rise in the use of pharmaceuticals around the world, there has also been a substantial

increase in the use of pharmaceuticals over the last several decades [1,3]. In many areas, there is an increased discharge of larger amounts of pharmaceutical compounds such as trimethoprim, sulfamethoxazole, and oxytetracycline into surface waters because of the use of outdated wastewater treatment systems.[1,4]

Pharmaceuticals enter the environment through many different sources: production, usage, and improper disposal. Sources of pharmaceuticals include household, industrial, healthcare facility, and agricultural activities. In addition to entering domestic wastewater through human excretion, pharmaceuticals can enter domestic wastewater if an individual disposes of unused pharmaceuticals in a sink, toilet, or household refuse.[1,5] Landfills containing pharmaceuticals can leach into the soil and groundwater. Because typical municipal wastewater treatment plants are not engineered specifically for the removal of these types of contaminants, pharmaceutical residues can eventually be released to surface water, soil, groundwater, and ultimately to drinking water supplies.[1,6,7]

Environmental exposure to drugs can negatively impact the environment by affecting hormones and promoting antimicrobial resistance.[1,6,8,9] For example, Diclofenac has caused a high percentage of vulture mortality.[1,10] Additionally, endocrine-disrupting chemicals can alter the hormonal systems of aquatic animals, creating anomalies and impairing their reproduction.[1,11] Antimicrobial agents are used broadly among humans, animals, and agriculture. This broad use generates significant amounts of pharmaceutical waste in the environment, allowing for the potential proliferation of antibiotic-resistant organisms.[1,12] Additionally, some pharmaceutical pollutants which are lipophilic, are located in wastewater plants, and are not readily degraded.[1,14] The lipophilic nature of these compounds enables, via bioaccumulation, accumulation in living organisms.[1,13]

POTENTIAL SOURCES OF PHARMACEUTICAL WASTE[15]

A. Healthcare Facilities

Produce Many Different Types of Pharmaceutical Waste, Including Hospitals, clinics and pharmacies generate a large-Amount of pharmaceutical wastes through failure to use medications properly (e.g., unused medications); through not using medications correctly (e.g., leftover medication); and through the inappropriate use of medical equipment or supplies (e.g., IV bags, syringes, needles). Hospitals, clinics and pharmacies also generate large amounts of sharps waste (e.g., needles and lancets) due to providing patient care within their facilities. Proper management of pharmaceutical waste in hospitals, clinics and

pharmacies is important for: preventing cross contamination; protecting the health and safety of health care workers; and minimizing environmental impacts.[15,16]

B. Pharmaceutical Manufacturing:

Pharmaceutical Manufacturers also produce significant amounts of pharmaceutical wastes by producing pharmaceutical products; producing defective production runs; producing expired chemicals; generating equipment wastes; and failing to use/retain manufacturing raw materials. These wastes may contain active pharmaceutical ingredients (APIs) and other chemicals that may pose a hazard to the health and safety of humans and/or the environment. Pharmaceutical manufacturers must follow strict waste-management plans in order to ensure the proper handling, treatment and disposal of wastes that contain hazardous materials in accordance with applicable regulations.

C. Research Laboratories and Institutions:

Pharmaceutical waste can also arise from research conducted within academic institutions and laboratories, including both preclinical and clinical research, drug development, and research conducted for educational purposes that produces pharmaceutical products, resulting in pharmaceutical waste such as unused or expired pharmaceuticals or chemical laboratory reagents and experimental samples. Furthermore, pharmaceutical waste can occur in laboratories conducting animal experiments due to the presence of pharmacological agents in the biological materials produced through animal testing.

To reduce the risk associated with these pharmaceutical waste streams, appropriate segregation and proper disposal processes must be developed and utilized to ensure the protection of the environment.

D. Household Disposal of Pharmaceuticals:

Inappropriate disposal of pharmaceuticals at the household level is an additional source of pharmaceutical waste that ultimately enters the environment. Some patients will dispose of their unused/expires medications, whether prescription drugs or over-the-counter products by throwing them in the trash or flushing them down the toilet/sink. This allows for medications to enter landfills or potentially contaminate ground water and, in turn, ultimately contaminate local water supply systems.

Public education programs increasing awareness of safe disposal of medications and promoting availability of pharmaceutical drop-off programs is needed to decrease inappropriate.[15,17]

E. Veterinary Facilities:

Another type of pharmaceutical waste generated through veterinary medical care is from the use of currently unneeded or expired veterinary pharmaceuticals, as well as ancillary medical supplies associated with treating animals. Safe management and disposal of veterinary pharmaceutical wastes is necessary to provide protection to the environment and public health. Thus, disposal of veterinary pharmaceutical wastes should adhere to the same regulations as those required in managing human healthcare wastes.

F. Returns and Exchanges, Pharmacy:

Pharmacies, distributors, and wholesalers may have large quantities (e.g., surplus) of pharmaceutical (non-consuming) inventory, as well as some products that have expired. Many manufacturers or reverse distributors allow you to return these items to return to their place of purchase for proper disposal (e.g., destruction or reprocessing). It is critical that pharmaceutical return and exchange systems are effectively managed so that returned medicines are not mixed with typical waste materials and cause contamination of the surrounding environment.

Types of Waste Materials[18]

1. Biomedical Waste:

Biomedical waste includes any solid or liquid waste generated by the diagnosis and treatment of human or animal patients as well as research associated with the diagnosis/treatment and production/testing of biological materials. It is estimated that 85% of the waste generated by hospitals is non-hazardous; 10% is infectious; and 5% contains hazardous chemicals (e.g., formaldehyde and methyl chloride) but is not infectious. The transmission of infectious diseases (e.g., HIV/AIDS, Hepatitis B, and Hepatitis C) cannot occur due to hazardous healthcare waste. Contaminated syringes and needles present the greatest potential to transmit disease among the various healthcare waste materials.[18,19]

Historically hospital waste has usually just been thrown away instead of being managed correctly. When this type of waste is not disposed of properly it may create a hazard to the environment when mixed with municipal solid waste along with being disposed of

improperly in uncontrolled or illegal disposal sites. Such sites include uncontrolled land next to slum areas and residential districts. These practices can cause significant environmental pollution along with having serious public health consequences for such diseases as HIV/AIDS, Hepatitis, Plague, and Cholera. Healthcare waste presents a greater challenge than most waste because of the many pathogenic micro-organisms and hazardous substances found in the waste.[18,20]

1. Summary of Types of Health Care Waste (Summary by WHO):

The World Health Organisation (WHO) has identified three different types of waste in health care. The classification of these three types of wastes is largely dependent upon the material making up the waste and the level of risk associated with the waste.

a. Household Waste:

Household waste refers to solid materials that are neither radioactive, harmful due to chemicals, nor infectious. General healthcare waste is typically referred to as household waste in terms of similarities to regular waste created in the home or municipality. Common examples of household waste include, but are not limited to:

Food, Cartons, Paper, Plastics, Glass

When properly managed, household waste presents little to no risk to public health.

b. Biomedical Waste:

Biomedical waste is also known as special waste, hazardous healthcare waste, or healthcare risk waste because of the potential presence of infectious agents or hazardous materials in the waste. In most cases, biomedical waste can be subdivided into the following categories.

1. Infectious Waste

Infectious waste consists of items that are suspected of containing living pathogenic microorganisms (those that can cause disease).

Examples include:

Isolation ward waste, Microbial cultures or stocks, Contaminated tissues, Bandages and swabs, Materials that have been soaked in blood or body fluids

2. Anatomical waste

Anatomical waste refers to human parts/tissue that still look like humans (i.e., body parts) that do not need to stay on a patient after an operation was done on that area of their body. This type of waste comes from surgical procedures, autopsies and medical procedures.

Some examples of anatomical waste are:
Human tissue/organs, Body Parts, Blood and Other Body Fluids

3. Sharps waste

Sharps waste refers to things that can cut you/puncture your skin or put you at risk for getting an infectious disease.

Some examples of sharps waste are:
Needles, Syringes, Scalpels, Other surgical blades, Broken Glass

4. Pharmaceutical waste

Pharmaceutical waste is medication/drug, it can be anything from expired to unused to spilt but it will NOT have any medical or drug use left from them.
Some examples of Pharmaceutical Waste are:
Expired Medicines, Vaccines, Drug Containers

5. Genotoxic Waste

Genotoxic Waste contains chemicals that could harm your DNA/Genetic material (which is your DNA). The main sources of Genotoxic Waste are Drugs Used in Chemotherapy/Treatment for Cancer.

Some examples of Genotoxic Waste are:
Chemotherapy/Cytotoxic Drugs, Materials contaminated with chemotherapies /cytotoxic drugs

6. Chemical Waste

Chemical waste includes any chemicals that have been used and thrown away due to either medical or laboratory work.

Examples of chemical waste are:
Laboratory reagents, Film developing chemicals, Solvents, Outdated disinfectant solution, Organic chemicals like formaldehyde and phenol-based cleaners

7. Heavy Metal Waste

Heavy metal waste is waste that contains toxic metals that can pollute water or land.

Examples of heavy metal waste are:

Batteries, Broken thermometers (containing mercury), Blood pressure cuffs or monitors, Compressed containers (including aerosols and gas cylinders) containing Anaesthetic- gases such as nitrous oxide, halothane, enflurane, or ethylene oxide.

8. Radioactive Waste

Radioactive waste refers to waste that comes from medical procedures where radioactive materials were used (diagnosis/therapy).

Examples of radioactive waste are:

Unused radioactive liquids, Waste produced by patients who received treatment/testing from radioactive materials.[18,21]

Various organizations are responsible for the monitoring and controlling of pharmaceutical waste management to protect the environment and the health of the public.

Leading Authorities Regulating Agencies

1. Environmental Protection Agency (EPA):

regulates hazardous waste management and protection of the environment

2. U.S. Department of Transportation (DOT):

responsible for the safe transportation of hazardous materials including pharmaceuticals.

3. Drug Enforcement Administration (DEA):

regulates the proper disposal of controlled substances.

4. Occupational Safety and Health Administration (OSHA):

ensures the safety of workers from exposure to hazardous materials at work.

5. State Environmental Protection Agencies:

implement state environmental laws.

6. State Board of Pharmacies:

regulate the storage and disposal of medications, as well as other pharmacy practice issues.

7. Publicly Owned Treatment Works (POTW):

municipal wastewater management facilities that are responsible for providing treatment for wastewater that includes pharmaceutical residue.

The Resource Conservation and Recovery Act (RCRA) is the regulatory foundation for managing solid and hazardous waste in the United States. RCRA was enacted in 1976 to provide the framework for handling, treating, storing, and disposing of hazardous waste.

Several years ago, the Environmental Protection Agency (EPA) and state environmental inspectors discovered that healthcare facilities were not fully compliant with RCRA regulations when managing hazardous waste. Many pharmaceutical products and their formulations are classified as hazardous waste under RCRA criteria.

As a result of these increased regulatory requirements, healthcare facilities are required to:

1. Identify hazardous pharmaceutical waste
2. Properly segregate and contain the waste
3. Correctly label and store the waste
4. Safely transport the waste
5. Dispose of the waste in accordance with regulatory guidelines

With increased regulatory scrutiny, The Joint Commission and other accrediting agencies have incorporated pharmaceutical waste management practices into their accreditation and survey process.[18,22]

Biomedical Waste Management Regulations (1998)

The Biomedical Waste Management Regulations (BWMR) of 1998 establish the guidelines for how biomedical wastes must be managed in India. The rules have been amended twice since their initial publication in 2000 to strengthen the management system. The primary purpose of the BWMR is to prevent the improper disposal of biomedical waste by establishing a separation of biomedical waste from other types of municipal waste, along with the appropriate methods for collecting, containing, treating, and disposing of various types of biomedical waste.

In addition to requiring the separation of biomedical waste from other waste types, the BWMR classify 10 different types of biomedical waste and prescribe processes for collecting, storing, treating, and disposing of each waste type in a manner that will protect the health and safety of both individuals and the environment.

Summary of India's Regulations for Biomedical Waste (BWMR) 1998

The Ministry of Environment and Forests Establishes the BWMR. Below is a summary of the most salient features of the BWMR:

1. Biomedical Waste Defined

Biomedical waste is defined in consideration of the following:

Diagnosis or the generation of a disease in the human or animal population;

Treatment or immunization of the human or animal population;

Biological or scientific research for the use of products in biological production; and

Creation and/or testing of biological products.

2. Who Must Comply with the Biomedical Waste Regulatory Requirements?

All individuals or organizations that are involved with the management of biomedical waste are subject to the same regulatory requirements. This includes any individual or organization that generates biomedical waste; collects biomedical waste; receives biomedical waste; stores biomedical waste; transports biomedical waste; or treats, disposes of, or in any way handles biomedical waste.

3. Responsibilities of the Healthcare Facility Operator

The operator of a healthcare facility (such as hospitals, nursing homes, clinics, dispensaries, veterinary facilities, animal research facilities, and blood banks) is responsible for the safe and appropriate management of biomedical waste generated by their business operations. The operator or business must use proper procedures and methods for treating and disposing of solid and infectious waste in accordance with the governing regulations and without causing harm to human health or the environment.

4. Regulatory Authority

In the event of a violation of the Biomedical Waste Management Regulations, two (2) government entities are responsible for establishing, monitoring, and enforcing compliance:

the SPCB in each of the individual states; and

the Pollution Control Committee in each of the Union Territories.

Each of the above agencies will ensure that the relevant healthcare businesses comply with the Biomedical Waste Management Regulations.

5. Permit Requirements

Health care facility operators and owners (occupiers) managing biomedical waste from 1,000 patients or more each month must first obtain permission from the relevant local governmental entity.

6. Record Keeping

Occupiers (Operators) are required to maintain records on:

Biomedical waste generated at their facility, Biomedical waste received and picked up from (collected from) their facility, Biomedical waste stored, transported, treated, and disposed of

These records must be available for inspection by the appropriate regulatory entity, and such entity has the right to review and verify them as it regularly inspects the facility.

7. Reporting Accidents

The operator of a healthcare facility must notify the appropriate local authority of the occurrence of any accident or incident involving biomedical waste during handling, treatment, transportation, and/or disposal.

8. Yearly Reporting

Each occupier must submit a yearly report of:

The types of biomedical wastes generated, The total amount of biomedical waste generated

The method(s) of treating and disposing of biomedical wastes generated at their facility

9. Common Disposal and Incineration Facilities

Public authorities within the local geographical area shall create common facilities for the treatment and disposal of biomedical waste, (e.g., incineration, recycling, etc.). Operators of healthcare facilities are required to follow the Biomedical Waste Rules when using these common facilities.

10. Segregation, Packaging, Transportation and Storage

Biomedical waste must not be disposed of with general municipal waste and must therefore be:

Segregated into containers / bags that are color-coded, properly packaged according to the laws and regulations, transported in vehicles that are authorized for the purpose

Unprocessed biomedical waste can only be stored for 48 hours or less unless otherwise approved by the regulatory agency.

11. Standards for Treatment and Disposal

The Biomedical Waste Rules contain standards for various methods of treatment and disposal of biomedical waste, including:

Burial at considerable depth, Autoclaving, Incineration, Microwaving, Liquid waste treatment and discharge.

These standards are meant to ensure the safe management of biomedical waste to protect humans and the environment.[18,23]

PHARMACEUTICAL WASTE

The majority of pharmaceutical waste produced in healthcare facilities comes from the handling of pharmaceuticals for medical purposes, including drug preparation, administration, and disposal. Pharmaceutical waste is generated through various methods during medical procedures that require pharmaceuticals, such as using syringes or IV systems for drug preparation. In many cases, the preparation, administration, and the disposal of medications can all produce waste from the leftover/contaminated materials used in the preparation of those medications.

Some examples include:

a. Medications that have passed their expiration dates
b. Patients' medications that are disposed of during the course of treatment
c. Used medical supplies that contain drugs or drug residues from syringe
d. Use and disposal of IV bags, IV tubing, and IV Vials
e. Waste contaminated with chemotherapeutic drugs
f. Opened medication containers that are no longer usable
g. Empty containers for acutely hazardous (P-listed) drugs
h. Used or partially used medications (medications that were dispensed prior to the patient's visit)
i. Contaminated clothing, spill clean-up supplies, and absorbent materials used to clean up drug spills

To properly manage the disposal of pharmaceutical wastes to reduce environmental impacts and health risks, you must adhere to strict guidelines.

Pharmaceutical Waste can be categorized into three types of waste:

1. Hazardous Waste

Waste that contains chemical substances or pharmaceuticals that can be harmful to human health and/or the environment.

2. Non-Hazardous Waste

Waste that does not meet hazardous waste criteria, but still needs disposing of properly.

3. Chemotherapy Waste

Waste produced from cytotoxic drugs used in treating certain cancers, such as chemotherapy and related materials that have been exposed to these drugs.

2. Pharmaceutical Hazardous Waste

Hazardous pharmaceutical waste can be found in many different forms, and may include liquids, solids, contained gases and sludges. The hazards posed to human health and the environment by any of these materials must be properly managed. Hazardous waste is generally classified in two major categories:

a. Listed Hazardous Waste & Container
b. Characteristic Hazardous Waste & Container

The listed hazardous waste materials are those specifically referenced in the four hazardous waste listings contained within the Resource Conservation and Recovery Act (RCRA):

F-List: waste from non-specific industrial sources

K-List: waste from specific industrial sources

P-List: acutely hazardous commercial chemical products

U-List: toxic commercial chemical products

Both the P and U lists contain many medications classified as pharmaceutical waste; consequently, both lists contain a large number of pharmaceuticals that should be managed through hazardous waste disposal regulations.

Associated Characteristic Hazardous Waste

Characteristic hazardous waste has been regulated due to exhibiting one or more of the following characteristics that are hazardous in nature:

Toxicity (poisonous), Corrosivity (able to corrode or eat away), Reactivity (able to chemically react with another substance), Ignitability or flammable (the ability to catch fire)

If a waste exhibits any of these characteristics, it must be treated according to hazardous waste regulations.

Solid Waste

Solid waste is defined as a waste material that does not have a listing under hazardous waste and does not exhibit any of the above-mentioned characteristics associated with hazardous materials. However, solid wastes must still be disposed of in accordance with state or municipal law (including laws concerning the management of regulated medical wastes).[18,24]

Listed Hazardous Waste

2.1 P-listed Pharmaceutical Waste

P-listed wastes consist of commercial chemical products that have been classified as acutely hazardous under the Resource Conservation and Recovery Act (RCRA).

The toxicity of a drug/chemical plays an important role in determining whether or not it will gain P-list status; the amount needed to kill 50% of animals through oral ingestion (i.e., the median lethal dose or LD50) is the basis for classifying pharmaceutical compounds as P-listed.

While each substance is assessed according to its own individual characteristics, typically, substances qualify as P-listed when their oral LD50 is 50 mg/kg or less.

For the purposes of assessing toxicity, the LD50 of a toxin is defined as the dosage at which 50% of animals exposed to the toxin die following a single exposure (e.g., a single dose). Thus, toxins with low LD50s are very toxic and can lead to serious health problems or death, even at a low dosage level. This is why the safe handling, storage, and disposal of P-listed pharmaceuticals requires; extremely careful protocols due to their extreme toxicity.

How to Manage P-Listed Pharmaceutical Waste

Pharmaceutical Waste Must be Managed as Hazardous Waste if There are Two Conditions:

A pharmaceutical contains only a p-list chemical constituent and is no longer able to be utilized for its intended use.

It is within these conditions that the Waste is Managed in Accordance with RCRA.

P-Listed Waste: Empty Containers:

According to 40 CFR Part 261.7 (b)(3)

A container, which previously contained p-listed hazardous waste is only considered empty when:

i. The container has been Triple rinsed; or,
ii. The Rinsete is handled and disposed of as hazardous waste.

(Healthcare facilities cannot typically triple rinse containers.) Therefore, all containers in the above-mentioned waste category (for example: vials, IV bags, etc.) will usually need to be handled/disposed of according to hazardous waste regulations even though they may not contain product at the time of disposal.

Additionally, some jurisdictions do not view empty warfarin stock bottles or unit-dose packaging as hazardous waste. These jurisdictions use a less strict definition of used for solid dosage forms (tablets, capsule, etc.).

2.2 Pharmaceutical Waste Regulated as a U-Listed Hazardous Waste

The U-LIST contains a greater variety of medications than the P-LIST. A medication will fall under the regulation of U-listed hazardous waste only if the U-listed chemical is the only active ingredient in the drug.

If the medication has more than one active ingredient and the U-listed drug is not the only one present, the chemical can still be disposed of properly but will not be classified as hazardous waste.

Some of the chemicals on the U-LIST have been included because they are toxic to people or the environment.

Pharmaceutical waste with U-listed chemicals must be categorized as hazardous waste if:
The medication contains a single active ingredient that is included on the U-LIST.
The medication has not been used for its intended purpose.

U-listed Waste Containers E.R.C. 261.7. B1.

A container that was previously used to store R.C.R.A. waste shall be considered as being "R.C.R.A. empty" only if it meets both of the following two conditions:

All materials that can be removed from the container using typical practices (for instance, liquids should be removed from a container with a syringe.) must have been completely removed from the container.

The container does not have more than 3 % of its original mass still in the container.

If either of the above two requirements do not apply, then the empty container must be managed as hazardous waste.

Any residue that is removed from the empty container also must be managed and disposed of in compliance with applicable regulations pertaining to hazardous waste.[18,25]

CHARACTERISTICS OF WASTE

The EPA defines four major attributes that classify hazardous waste. These attributes are utilized to help the regulatory agencies decide if a waste should be treated as hazardous. The four attributes include:

1. Ignitability (D001)
2. Corrosivity (D002)
3. Reactivity (D003)
4. Toxicity (D-code designation unique to the chemical).

1. Ignitability (D001: 40 CFR 261.21)

The purpose of the ignitable characteristic is to identify any waste characteristics that will: create a fire hazard when being stored, transported or disposed of, increase the intensity of a fire.

There are many different combinations of ways that a particular pharmaceutical formulation (product) can be ignitable in nature. Most of the hazardous wastes generated and managed in a pharmacy environment will typically be flammable or combustible materials (meaning they are capable of igniting). Because of the ignitable nature of the waste, it creates a significant challenge for management in a pharmacy and healthcare setting.

Ignitable wastes can generally be defined as material that ignites readily or can easily ignite in everyday situations.

2. Corrosivity - D002

Corrosive materials are generally defined as liquids that:
Are acidic, have a level of Acidity at 2.0 or below (the pH scale) or
Are basic, have an alkalinity at 12.5 or above (the pH scale).

These types of materials can harm metal items, damage other substances, and cause burning of the skin if handled incorrectly.

Some examples of corrosive materials include:
glacial acetic acid (an acid; a pH $\leq$ 2.0)
potassium hydroxide or sodium hydroxide (bases; a pH $\geq$12.5)

The majority of hospital/pharmacy generated corrosive materials are created during the compounding of products or the preparation of chemical formulations for use in the pharmacy.

3. Reactivity – D003

(40 CFR Part 261.23 Requirements for Reactive Wastes)

Definition:
Reactive wastes are those that are not stable under ambient conditions and can undergo hazardous chemical reactions.

Potential Types of Reactive Wastes:
Reactive wastes have the potential to:
Explode upon heating or compression, generate hazardous smoke, fume or vapor from chemical reaction, React violently when in contact with water or other materials.

Example:

Cline test tablets that are used to determine sugar in urine are classified as reactive waste.

A pure nitro glycerine is considered a highly reactive material; however, nitro glycerine is usually found in medications as a very small amount of the total medication, therefore it is stable. Medications containing nitro glycerine do not meet the criteria as reactive waste under federal and many state regulations.

4. Toxicity: Multiple D Codes

(Per 40 CFR Part 261.24) Toxic waste is any type of waste material containing hazardous organics or heavy metals that could create a hazard to human health or our environment.

Some examples of toxic heavy metals are: Chromium, Lead, Mercury, Cadmium

Under the Resource Conservation and Recovery Act (RCRA), over forty chemicals are considered toxic because they have leaching concentrations over a set limit.

If a waste material contains these chemicals over the regulatory limit, it needs to be managed and disposed of as a hazardous waste.[18,25,26]

3. NON-HAZARDOUS PHARMACEUTICAL WASTE

Pharmaceuticals that are not hazardous are those which do not have enough hazardous characteristics to be deemed as such. However, this doesn't mean that there aren't any hazardous constituents in the waste stream. The hazardous constituents that are in the waste stream are at a level deemed as not posing a risk to the environment or human health.

Classification of waste as not hazardous can also change over time. A substance added to or removed from the waste stream can change the characteristics of that waste stream such that it can affect the way it's treated and handled once disposed of.

Pharmaceutically Inert Materials:

The following medical products are examples of inert pharmaceuticals (not actively used in the treatment of disease): Sodium Chloride, Dextrose

Although these two examples will be used by healthcare workers and provide no pharmacologic activity to the patient, they still have to be evaluated to determine if hazardous characteristics are present at the time of disposal.

When used, these products may be contaminated (e.g., saline) or mixed with other chemicals, making it necessary to evaluate the products for hazardous characteristics and, if so, dispose as hazardous.

4. Waste from Chemotherapy

There are two major types of waste produced while undergoing chemotherapy.

1. **Trace Chemotherapy Waste**
2. **Bulk Chemotherapy Waste**

1. Trace Chemotherapy Waste

Trace chemotherapy waste is not regulated by federal regulations, which by reason of the Resource Conservation and Recovery Act (RCRA) does not define a lower concentration limit that separates trace chemotherapy contaminated substances from bulk, P-listed or U-listed hazardous substances. Most state regulators do not define trace chemotherapy waste sufficiently and virtually lack any regulations or definitions regarding trace chemotherapy based on the concept of separating trace chemotherapy wastes first reported in a research paper published by pharmacy staff from the National Institute of Health in 1984 applying RCRA to antineoplastics (drugs used in the treatment of malignant tumours).

Some regulations established by California's Medical Waste Management Act and Wisconsin's Medical Waste Rules provide a definition for trace chemotherapy waste and require the disposal of such waste via incineration at a licensed medical waste treatment facility or through alternative approved methods. All equipment that has potentially been exposed to trace chemotherapy should be disposed of as trace chemotherapy waste.

Examples of items to be managed as trace chemotherapy waste include:
“RCRA Empty” vials, syringes, IV bags and tubing
Gowns, gloves, wipes and supplies utilized to routinely prepare, administer and/or handle chemotherapy

Cleaning wipes and cleaning/disinfecting supplies routinely used inside biological safety cabinets or glove boxes

Material is considered to be trace waste unless it includes a hazardous material such as an alcohol, phenol or a regulated chemical.

2. Bulk Chemotherapy Waste

Chemotherapy waste that is discarded as bulk waste generally consists of chemotherapy products that have significant residual amounts, including:

Partially utilized or unused chemotherapy products
Chemotherapy drugs that were spilled
Containers with large residual amounts of chemotherapy products

The Resource Conservation and Recovery Act (RCRA) list 8 chemotherapy drugs as hazardous waste (U-listed drugs) and 1 chemotherapy drug as hazardous waste (P-listed drugs).

In the past, it has been commonplace for companies to dispose of listed chemotherapy drug waste into trace chemotherapy waste containers illegally. This practice is illegal and incorrect for two reasons:
Trace chemotherapy waste is generally incinerated in RMW (regulated medical waste) incinerators.

RMW incinerators are subject to less stringent emissions and permitting requirements than hazardous waste incinerators.

Thus, bulk P-listed and bulk U-listed chemotherapy drug waste must be managed and disposed of as hazardous waste versus trace chemotherapy waste.[18]

The aim of the study:
Examining and contrasting the policies and legal systems of a few chosen nations with relation to the gathering and disposal of unwanted and expired medications is the goal of this study. It aims to determine the main players in these processes and evaluate how well the current systems are working to reduce environmental risks. The results could be used as a basis for creating models of environmentally conscious policy.

Methodology:
The present study consists of using legal regulations, official guidelines, and other related governmental initiatives to collect and transported/dispose of Pharmaceutical Waste in each country.

The current information is compiled through peer-reviewed scientific literature, international organization reports, and official government placement data sources. Each of these sources provided quality data regarding the Pharmaceutical Waste Management Practicing Worldwide by analysing the available data they contained for each country.

Country Case Studies:

Table 1. Key Characteristics of Pharmaceutical Waste Management Based on Country Case Studies.[1,15,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41]

Country	System and Organizations Involved	State/Government Involvement	Collection Methods	Funding and Financial Mechanisms	Processing and Disposal	Public Campaigns and Awareness Initiatives
India	Central Pollution Control Board (CPCB), State Pollution Control Boards (SPCBs), CDSCO	Strong legal framework under Biomedical Waste Management Rules, but weak enforcement in some areas	Segregation at source (hospitals, clinics), collection via CBWTFs	Government + private operators; user fees in some states	Incineration, autoclaving, microwaving, deep burial, landfilling	Limited public awareness; training gaps among healthcare workers
Malaysia	Environmental Quality Act (Act 127), Scheduled Waste Regulations	Strong federal regulation for industrial and healthcare waste; weak control for household waste	Collection from healthcare facilities and industries; no proper system for household pharmaceutical waste	Government regulated; industry compliance-based	Controlled disposal from generation to final stage under regulations	Limited awareness; major gap in household pharmaceutical waste education
Bhutan	Ministry of Health, National Environment Commission (NEC), hospitals (e.g., JDWNRH)	Centralized government-led healthcare system	Collection mainly through hospitals and Basic Health Units (BHUs)	Fully government-funded (public healthcare system)	Incineration at hospital level; limited advanced treatment facilities	Basic awareness programs; limited nationwide campaigns
France	Cyclamed (non-profit organization)	Supported by government, special return points in rural areas	Collection via pharmacies and public drop-off bins	Funded by the pharmaceutical industry	Transport and disposal strictly follow national regulations	Educational campaigns and widespread placement of collection bins
Spain	SIGRE (non-profit organization)	Local government cooperation	Pharmacy based containers and roadside collection sites	Funded by pharmaceutical manufacturer s	Specialized recycling centre's process the collected waste	Environmental education and awareness actions
Hungary	Recyclomed (non-profit initiative)	State supported; local authorities involved	Collection via pharmacies and designated bins for expired medicines	Industry financed	Destruction compliant with national regulations	Campaigns on safe disposal of expired pharmaceuticals

Finland	Local municipalities coordinate the system	Public and socio-economic involvement through municipalities	Mobile collection units; operational across all regions	Publicly funded, minor contributions from local governments	Project-based transportation and environment ally safe disposal	Public awareness campaigns adapted to regional needs
Romania	Pharmacies bear full responsibility	A legal framework exists, but limited enforcement for producers	Only through pharmacies; no broader public collection infrastructure	Financed by individual pharmacies	Limited oversight of disposal effectiveness	Emphasis on developing a national system for expired medicine management
Italy	Assinde[24] and pharmaceutical associations	Formal agreements with the Ministry of Environment	Container based systems in pharmacies, public drop-off services	Industry funded; supported by local governments	Includes intermediate storage facilities and regulated destruction	Official campaigns and local initiatives by municipalities
Netherlands	KNMP (Royal Dutch Pharmacists Association), local authorities	Government policies on post-consumer pharmaceutical waste	Collection points in pharmacies and public areas	Joint funding from national and local governments	Waste is processed in compliance with environment al regulations	Educational campaigns in pharmacies; awareness through KNMP platforms
United Kingdom	Eco-Pharm (project-based systems)	National-level government involvement	Public and pharmacy-based collection points	Primarily financed through the public health sector (NHS)	NHS managed recycling and safe disposal schemes	Global environment al awareness campaigns; thematic initiatives
Sweden	Svenska Apoteksförenn gen (Swedish Pharmacy Association)	Sector-specific regulations at the local level	Sector-specific regulations at the local level	Financed by local administrations	Waste is recycled or destroyed in regulated facilities	Environmental education through varied outreach activities
Greece	Pharmacy Association of Greece	State supported	Public collection containers for unused medicines	Financed by pharmacies	Controlled disposal through designated collection points	Eco awareness campaigns and public information services
Bulgaria	EKO-Pharma (infrastructure-based system)	State and municipal engagement	Collection containers are placed in pharmacies	Local government funding	Controlled disposal and supervised transportation	Public awareness efforts and subsidization of the pharmacy network
Portugal	VALORMED (pharmaceutic-a l sector initiative)	Government and pharmaceutical supply chain cooperation	Collection in pharmacies via designated containers	VALORMED ’s operational budget covers the system	Medicines are gathered and transported to licensed treatment facilities	National media campaigns and public education strategies

Czech Republic	Česka lékárnická komora (Czech Pharmacy Chamber)	Government involvement and regulatory oversight	Pharmacy and roadside collection points	Government financed with partial industry support	Branded as "Medicine Waste Collection" with clear disposal processes	Information al programs targeted at raising public awareness

Many notable differences and trends on a comparative basis can be observed in the pharmaceutical waste management systems within the areas of organizational structure, government engagement, collection methodology, financial aspects, waste management methods, and education/public awareness.

There are typically five types of models for managing pharmaceutical waste: Model of Centralized, Regulated and Coordinated, Public-Private Collaboration Model, Decentralized, Environmentally Sustainable Model, Large-Scale Biomedical Waste Management Model, Healthcare Waste Management Model. These classifications encompass five examples in order to illustrate varying methods of the pharmaceutical waste management of five countries.

Model of Centralized, Regulated and Coordinated – France: This model has a comprehensive take-back system for nationally regulated pharmaceutical disposal, and the waste-disposal-system is supported and funded by pharmaceutical industry revenues.

Public-Private Collaboration Model – Spain: Spain has a well-organized SIGRE organization with participating pharmacies that make their use of eco-friendly packaging a major part of the registered pharmacy. (i.e. a pharmacy may act as an Echara as part of a SIGRE pharmacy).

Decentralized, Environmentally Sustainable Model – Finland: – Finland has implemented waste management solutions that utilize municipal waste collection and provide mobile return options for communities that lack access to the collection services.

Large-Scale Biomedical Waste Management Model – India: – India has a series of CBWTF networks that implement mandated biomedical waste segregation across the nation, providing consistent biomedical waste processing capability within their countries.

Healthcare Waste Management Model – Bhutan: – Bhutan has a waste management strategy that encourages the three Rs (Reduce, Reuse, and Recycle) for the environmental

impact of its government-assisted initiatives through the incorporation of sustainable development principles.

PHARMACEUTICAL WASTE TREATMENT AND DISPOSAL

1. Incineration

One approach is through incineration, which occurs when you carry out a thermal process on the solid organic waste to change their physical state from solid to either gas or detritus. Waste materials created in solid waste disposal (residue) and solid waste water disposal (residue) may be treated using this technique as well. The solid waste will be reduced in quantity (volume) by converting it to 20 – 30% of the volume at the time of initial generation through this process.

Incineration and other high-temperature methods of treating waste are sometimes referred to as "thermal treatment" processes. Ash, gas, and heat are produced as waste materials undergo burning and are converted into steam. Incineration is used by both small and large companies to dispose of all forms of waste (gaseous, liquid and solid).There are alternatives for the safe disposal of many hazardous materials (including biological waste from hospitals) through incineration.

Incineration is considered a controversial method of waste disposal because of its potential to release harmful gases into the atmosphere. Victims of ill health should not be subjected to incineration.

Waste types that cannot be safely incinerated include: pressurized gas containers, high volumes of reactive chemical wastes, waste treated with halogenated chemicals, halogenated plastics such as PVC, cadmium or mercury containing waste (e.g., expired mercury batteries, broken thermometer) and radiographic waste. Incinerators must be designed according to the proposed CPCB regulations. This includes the use of dual chamber design and a scrubber as air pollution control equipment. Ash generated by incineration will need to be disposed of in a safe landfill.

Incinerators need highly qualified operators and are usually associated with extremely high capital and operating expenses.

2. Autoclaving

During the process of autoclaving, saturated steam comes into direct contact with the biomedical waste (BMW) within a pressure vessel, under conditions of sufficient temperature and duration to destroy any microorganisms. The Biomedical Waste Rules establish minimum standards for safe disinfection as required by law; and included in those standards are the recommended minimum temperature, pressure, and residence time of an autoclave. Animal, hazardous chemicals, pharmaceutical, and human anatomical wastes cannot be processed in the autoclave. BMW must be shredded to appropriate dimensions before they can be processed, and periodic disassembly of machines will be necessary. The resulting waste from autoclaved BMW can be landfilled with municipal waste. There is also liquid waste generated from the autoclave that must be disposed of in accordance with the applicable waste regulations. An autoclave must have qualified personnel to operate it, reasonable initial capital investment, and reasonable ongoing operational expenses.

3. Microwaving

The production of heat through conduction destroys the infectious agent in the BMW when the microwaves from the appliance pass over the BMW. The waves cause the water in the waste to vibrate, which also creates heat. Ultraviolet rays can also be used to treat the waste; however, both methods will require that the BMW be humidified and shredded prior to being placed in the microwave.

Although microwaves can be used to treat waste, they generally should not be used to treat large metal parts, medical waste containing human or animal waste, and chemical or pharmaceutical waste. Treatment of waste in the microwave creates the potential for municipal solid waste at the location where the waste is treated.

One of the primary advantages of this microwave treatment system is that it requires neither steam nor very much electricity. Two disadvantages are that it requires skilled operators to work the equipment and that shredders tend to malfunction regularly. The upfront costs of this technology are somewhat moderate; however, the ongoing costs are also moderately priced.

4. Chemical disinfection

Chemical disinfection is the most effective method for disinfecting liquid waste, including blood, urine, stools, and sewage from healthcare facilities. Pathogens present in the biological

medical waste (BMW) are killed or inactivated through the addition of a strong oxidant such as chlorine and its compounds, ammonium salts, aldehydes, or phenolic compounds. In addition to disinfecting liquid waste, microbiological cultures may also be disinfected by using chemical disinfectants. In general, the disinfection of BMW through chemical disinfectants is reliant on several factors, including the type and amount of chemical disinfectant used, as well as the amount of time and extent of contact between the chemical disinfectant and the BMW. Users should wear protective clothing around chemical disinfectants because they can have hazardous (specifically toxic) properties. Chemical disinfectants should not be discharged into surface water and large amounts should not be allowed to enter into the sewer system.

5. Deep burial

The regulations about Biomedical Waste indicate that animal and human body parts must be disposed of in rural areas (i.e., outside metropolitan cities of less than 500,000 populations) by using deep burial. This means that the preparing location for the deep burial must include excavating a pit or trench to a depth of at least 2 meters and that the site must have adequate drainage, be located on stable soil, have no manmade structures or shallow wells within close proximity, and is not at risk of being contaminated by surface waters.

The BMW should be inserted into the pit until it is half full, and lime must cover the BMW all around it.

Every time the BMW is put into the pit, the BMW's waste must be covered in 10cm of dirt or a sufficient amount of dirt will cause the waste to decompose.

6. Secure land filling

Solid biomedical waste (BMW) containing cytotoxic drugs, solid chemical waste and incinerated ash must be disposed of at a secured landfill in accordance with the Biomedical Waste Rules. Landfilling refers to burying the waste; this method of disposal is still prevalent in many nations throughout the world today. Most landfills are developed in old abandoned or unused quarries, mining excavations or borrow pits. A well-designed and operated landfill is the most economical and most hygienically safe method of managing waste. Older, poorly constructed, and poorly managed landfills tend to be more environmentally damaging, as they often result in wind-blown litter, attract various types of vermin, and produce a liquid leachate. One of the other commons by services of a landfill is gas caused by the anaerobic

decomposition of organic materials, with carbon dioxide and methane being the predominant gases. Methane promotes the greenhouse effect and affects plant growth on the surface, in addition to creating Odor problems. While landfill design has advanced to include methods of containing leachate, such as using clay to provide a continuous barrier between the ground and the landfill, or by using plastic liner material, the method of covering deposited refuse with soil to help deter vermin (such as mice or rats) and compacting refuse to increase density and stability continues to be used today.

Landfill gas will be extracted from many landfills by the use of landfill gas extraction systems, such as perforated pipe systems, that can either burn or flare off the gas to provide energy.

7. Waste immobilization: encapsulation

Encapsulation refers to placing the drugs into a solid block that is located inside a metal or plastic drum that can be filled with a maximum of 25% full solids. It is important that these drums be free of contaminants from prior use and should never have been filled with explosive or hazardous materials. After the drugs are inside the drum, they are then filled to 100% of volume capacity by excess material that may be bituminous, sand, plastic foam, or cement and/or a mixture of lime and cement.

Prior to filling the drum, it is important to take precautions when performing this operation to avoid facial and hand injuries by using a sharp utility knife to cut the lid of drums open at the top and bending the lid back. After approximately 75% of the available volume is filled with a mixture of drugs, water and lime cement will be added in a weight ratio of 15:15:5, and then the remaining space will be filled with additional bi-condensation material. In certain situations, it may take more than a normal amount of water to produce an acceptable liquid consistency. The lids of the steel drums should then be bent back and sealed, preferably using spot-welding or seam-welding. At the bottom of the landfill, the sealed drums can be topped off with new municipal solid waste. Pallets could be used to transport the drums, and pallets could be transported by way of a pallet transport vehicle.

8. Waste immobilization: Inertization

Inertization is another method of encapsulating pharmaceuticals and is a process that begins with removing all of the paper, cardboard, and plastic packaging materials associated with each of the drugs, including the removal of all of the pills from their blister packets. After

that, a homogenous paste will be created that contains ground-up pharmaceuticals that have been mixed with a combination of water, cement, and lime.

As there might be a risk of dust, protective equipment in the form of masks and clothing are needed to protect the workers. Once this is done, the paste is then transported to a landfill in the liquid state via concrete mixer trucks and deposited into municipal garbage for disposal. Then as the paste dries, it becomes dispersed with the municipal solid waste. This process requires only a few tools and is relatively inexpensive. The most important tools needed for the process are concrete mixers, stocks of cement, lime, and water, and a grinder/roller for breaking down the medications.

9. Sewer

It is possible to mix various types of liquid medications (like syrups) and IV fluids with water so that they can be gradually flushed into the sewer at low concentrations. The low concentration means that their effect on public health or the environment will not be significant. Well-diluted liquid medications or saline solutions that are well-diluted can also be flushed using Very fast Moving surface water. If the sewer system is in bad condition (such as due to damage from war), it is best to contact a hydrogeologist or sanitary engineer.

Managing pharmaceutical waste requires five steps:

1) Developing a Pharmacy Waste Management Plan;
2) Identifying hazardous vs non-hazardous waste;
3) Implementing Best Management Practices;
4) Determining Generator Classification; and
5) Complying with Transportation & Disposal Regulations.

CONCLUSION

In summary, pharmaceutical waste remains one of the biggest threats to both global environmental and public health. There are many differences between how different countries manage pharmaceutical waste. For example, some countries have developed their waste management systems that are very regulated and monitored well; they also have considerable public awareness regarding proper disposal and how to discard pharmaceuticals; they have more advanced treatment technologies; and, they have appropriate government participation. In contrast, developing countries struggle to manage pharmaceutical waste because they lack adequate infrastructure, funding, proper segregation, trained staff, and public engagement.

According to the report, poor pharmaceutical disposal practices can lead to toxicity in waterways, increased resistance to antibiotics, damaged environment, and significant risk to public health. While pharmaceutical disposal regulations and guidance have been established in many countries, implementation, auditing systems, documentation, and collaboration between the healthcare sector and regulatory agencies continue to have major gaps. Digital tracking solutions, standardization of audit records, EPRs and sustainable waste treatment practices offer significant opportunities for the enhancement of waste traceability and compliance.

An integrated approach between government agencies, the healthcare industry, waste disposal companies, and public awareness campaigns Produces the greatest success for a sustainable approach to managing pharmaceutical waste. This means that to eliminate pharmaceutical pollution and ensure long-term environmental sustainability and public safety, we need to develop regulations, promote international agreements on what constitutes acceptable standards, invest in the infrastructure for waste disposal, and encourage environmentally friendly disposal of pharmaceutical waste.

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