

# Pharmaceutical waste: overview, management and impact of improper disposal

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**Abstract:** Pharmaceutical products are inevitable for human health. Owing to the growing need for pharmaceuticals, pharmaceutical companies introduce drugs annually into the market in addition to the large collection of existing pharmaceutical products. Households, farms, health facilities and pharmaceutical industries release pharmaceutical waste into the environment at low concentrations through routine pharmaceutical use, damage and expiry. The effects of active pharmaceutical ingredients (API) on non-target species in the environment are not known. Unwanted pharmaceuticals should be safely disposed at a reduced financial cost to mitigate public and environment health risk. Over the years, pharmaceuticals such as diclofenac and ibuprofen in trace amounts have been detected in public water systems, ground and surface water. Lack of general knowledge of how to dispose of unused pharmaceuticals leads to improper disposal resulting in accidental toxicity, rising healthcare costs, landfills pilfering/scavenging, water supply pollution, anti-microbial resistance and death. To mitigate such effects, pharmacists should raise public awareness about safe disposal practices. This review aims to examine the sources of pharmaceutical waste, disposal costs, secure disposal methods, the effects of inappropriate disposal and the role of pharmacists in the disposal. The information on the stated objectives was gathered from available sources through a comprehensive literature review. Many countries contain tons of pharmaceutical waste that are expensive to destroy. Because of improper disposal, pharmaceutical waste has been found at trace amounts in drinking and surface water. A practical, environmentally sustainable approach to pharmaceutical waste management, with policies and guidelines, as well as public awareness campaigns, are necessary to address the problem of safe waste disposal. The national drug regulatory bodies should conduct environmental risk assessment resulting from disposal of unwanted pharmaceuticals. Pharmacists should facilitate extensive training on sustainable drug use and proper pharmaceutical waste disposal at all levels to reduce the risks associated with improper disposal. Reduction of pharmaceutical waste generation at each step of a drugs lifecycle, implementing take-back options, collection at approved sites and modern technology to treat wastewater are highly recommended to reduce effects of unwanted pharmaceuticals on human health and environment.

**Keywords:** Pharmaceutical waste, sources, cost of disposal, management, impact, pharmacists.

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## I. INTRODUCTION

The pharmaceutical industry ranks among the world's wealthiest industries. Owing to a growing need for health care, use in livestock farming, horticulture and aquaculture, the industry has seen more pharmaceutical development in the last few years. With increased usage and degradation of pharmaceutical products and substances, the environment is experiencing high levels of contamination. After being burned in home furnaces, the products get disposed of as municipal waste or gaseous waste [1].

The Pharmacy and Poisons Board (PPB) defines pharmaceutical waste as waste containing medicines that are expired, contaminated, split, unused and no longer needed, including items containing or contaminated by

pharmaceuticals such as bottles, boxes, vials, ampules, gloves and masks [2]. Pharmaceutical waste generally includes expired medicine, personal medication discarded by patients, waste material inholding chemotherapeutics and excess medicine e.g. intravenous (IV) bags and syringes, containers containing hazardous pharmaceuticals and unused drugs, discarded drugs, spill cleanup equipment and contaminated absorbents and protective gear such as garments [3]. There are three categories of pharmaceutical waste; Hazardous, non-hazardous and chemo pharmaceutical waste. Hazardous waste includes the Environmental Protection Agency (EPA) coded pharmaceutical waste or pharmaceuticals that are toxic, reactive, corrosive and ignitable. These wastes have detrimental effects to the environment and human health [3-4]. There are two categories of hazardous wastes namely listed and characteristic waste. Listed wastes

contain pharmaceutical products for commercial use while characteristic wastes are controlled as they exhibit toxicity, reactivity, corrosivity and ignitability [3]. Non-Hazardous waste includes expired medicines, manufacturers sample, loose pills, damaged or contaminated patient medication, including packaging such as containers [4]. They contain components that have a low threshold of causing harm to human health and environment [4]. The PPB defines a pharmaceutical waste generator as any person whose actions or actions under his or her supervision generate pharmaceutical waste or, if that person is not identified, the person who owns or regulates the pharmaceutical waste [2].

In 1999, the World Health Organisation (WHO) developed the guidelines for safe disposal of pharmaceutical waste. The document highlights the methods of disposal, sorting category and recommended disposal methods [5]. In 2014, the WHO published the second edition of the guidelines for the effective disposal of health-care waste, which highlighted the categories, risks, policy and legislative aspects, minimization, sorting, transport storage and disposal of healthcare waste [6]. In 2015, the WHO and United Nations Children Fund (UNICEF) formed a joint program to ensure safe management of healthcare waste and provided regular updates on the same [7]. The Food and Drug Administration (FDA) requires all manufacturers to provide Environment Assessment reports (EAs) backed by scientific data prior to new drug registration. In 1998, the FDA published guidelines for environmental assessment of new drug applications. The guidelines excluded manufacturers whose pharmaceuticals had an Expected Introduction Concentration (EIC) of  $< 1$  ppb of the active pharmaceutical ingredient (API) in the water bodies from providing EAs for new drug application. Data has shown that APIs of pharmaceutical products with aquatic EIC  $< 1$  ppb have insignificant effects on the environment. These results formed the FDA exclusion criteria in the guidelines [8].

A Serbian study projected that 74,929 kg of expired drugs are released from households perennially. The study revealed that 97% of households disposed unwanted pharmaceuticals in trash bins [9]. A South Korean study done to evaluate environmental risk of pharmaceuticals in WWTPs found ibuprofen, carbamazepine, ketoprofen, gemfibrozil, acetaminophen and sulfamethoxazole present at 22.6-8330.9 ng/L, 0.4-35.0 ng/L, 55.4-888.4 ng/L, 16.16-17.1 ng/L, 7.4-12.9 ng/L, 0.1-4.2 ng/L concentrations, respectively. Carbamazepine, ketoprofen and gemfibrozil posed high risk to fish while ibuprofen and sulfamethoxazole posed high risk to green algae [10]. A German study reported that 156 pharmaceuticals were present in ground, surface

and water supply systems [11]. High concentrations of hormones in aquatic environment have caused feminization of male fish [12]. An Ethiopian study reported that 55% of the respondents were not aware of the waste management and disposal guidelines published by the government. In the study, 85% and 77% of the respondents opined that waste management policies and focal persons were unavailable. Only 13% of the facilities had a designated person or committee to handle pharmaceutical waste. Landfill and burning in open air were the most utilized methods while waste immobilization, high temperature incineration and return to manufacture were not practiced. Moreover, 89% of the facilities had not received training on pharmaceutical waste management. Only one industry possessed a wastewater treatment plant (WWTPs) other facilities discharged waste water directly into effluent system [13]. On unused opioids, the FDA has implemented take back to the Drug Enforcement Administration (DEA) options such as collection at authorized DEA sites, mail-back or biannual events. However if this method is not feasible the guidelines recommend disposal in the trash and flushing. Flushing has led to trace amounts of opioids in water supply systems. WWTPs are not designed to degrade opioids. APIs have been detected in leachate due to disposing in pharmaceutical waste in trash. The leachate from landfills enter water sources and wastewater streams posing a health risk to humans and the environment [14].

Pharmaceuticals are an important part of a health framework; therefore, sufficient stocks are required consistently. The human health and veterinary sector receive pharmaceuticals through donations and procuring. Some medicines may be damaged during transport, storage, handling, routine use, and others may expire. During disasters such as famine, war, floods, countries receive large quantities of pharmaceuticals in their supply chain [2]. When treatment guidelines change or new regimens are introduced, other regimens may become obsolete, e.g., anti-malaria drug Amodiaquine. Unwanted pharmaceuticals may arise due to poor stock control and procurement practices or irrational drug use. Over-prescription, misdiagnosis and self-medication lead to the accumulation of pharmaceuticals in the environment. Poor quality and adulterated medicine are a factor for disposal. Therefore, handling pharmaceutical waste safely must be done to promote public and environmental health as part of monitoring Sustainable Development Goal 6 [7].

### *Trends and Sources of pharmaceutical waste*

The use of pharmaceuticals is projected to increase due to an increase in population age and life-span, economic growth in developing countries, the

emergence of new clinical practices, engineering of new pharmaceuticals, intensification of agricultural practices and climate change. The United Nations (U.N.) has estimated the annual growth rate of the pharmaceutical industry as 6.5%. Furthermore, 10% of manufactured pharmaceutical products are an environmental hazard. The Product Stewardship Council announced in 2019 that one-third of the 4 billion prescription products in the United States of America (USA) had become waste. As a result of climate change, the risk of succumbing to mosquito and tick-borne diseases is projected to increase. The use of antibiotics in livestock is projected to increase by 67% by 2030 in developing countries. In Germany, due to the large aging population, the use of pharmaceuticals is expected to increase by 43% by 2045. APIs are administered globally via over-the-counter, prescription and veterinary medicines. Animals and humans excrete 30% to 90% of oral pharmaceuticals as active substances via urine and faeces. A high concentration of pharmaceuticals has been detected in rivers and industrial effluents in India, China, Korea, the USA and Israel. Moreover, in the United Kingdom (U.K.), 13% of WWTPs were found to contain high concentrations of diclofenac, propranolol, ibuprofen and ethinylestradiol [15].

There are six sources of pharmaceutical waste, namely pharmaceutical manufacturing plants, hospital, industry and municipal wastewater treatment plants (MWWTPs), waste management settings such as landfills, agriculture particularly intensive livestock and crop farming, aquaculture and septic tanks (figure 1) [16-17]. There are two main pathways of the release of pharmaceuticals, namely point source such as discharge from WWTPs and diffuse source, which encompasses of surface runoff and leaching of septic tanks to groundwater. The concentration patterns of pharmaceutical waste include continuous, seasonal and intermittent. The WWTPs have endless concentration patterns, whereas seasonal concentration patterns are linked to water flow, farming practices, temperature and allergies. Periodic concentration patterns are governed by the overflow of storm water, pandemics, rainfall and irrigation designs. The impact of disposal pharmaceutical waste depends on the following properties: toxicity, mobility, bioaccumulation and persistence. Persistence includes transformation products, metabolites, solubility and half-life. Adverse effects of toxicity may be individual, population-based, mixture and additive effects. The sinks of pharmaceutical waste include rivers, oceans, groundwater, soil, lakes and sediments [15]. Households and hospitals are the primary sources of pharmaceutical chemicals in sewer systems. Health facilities dispose IV bags and Syringes down the drain. Pharmaceutical wastes disposed in landfills enter sewer

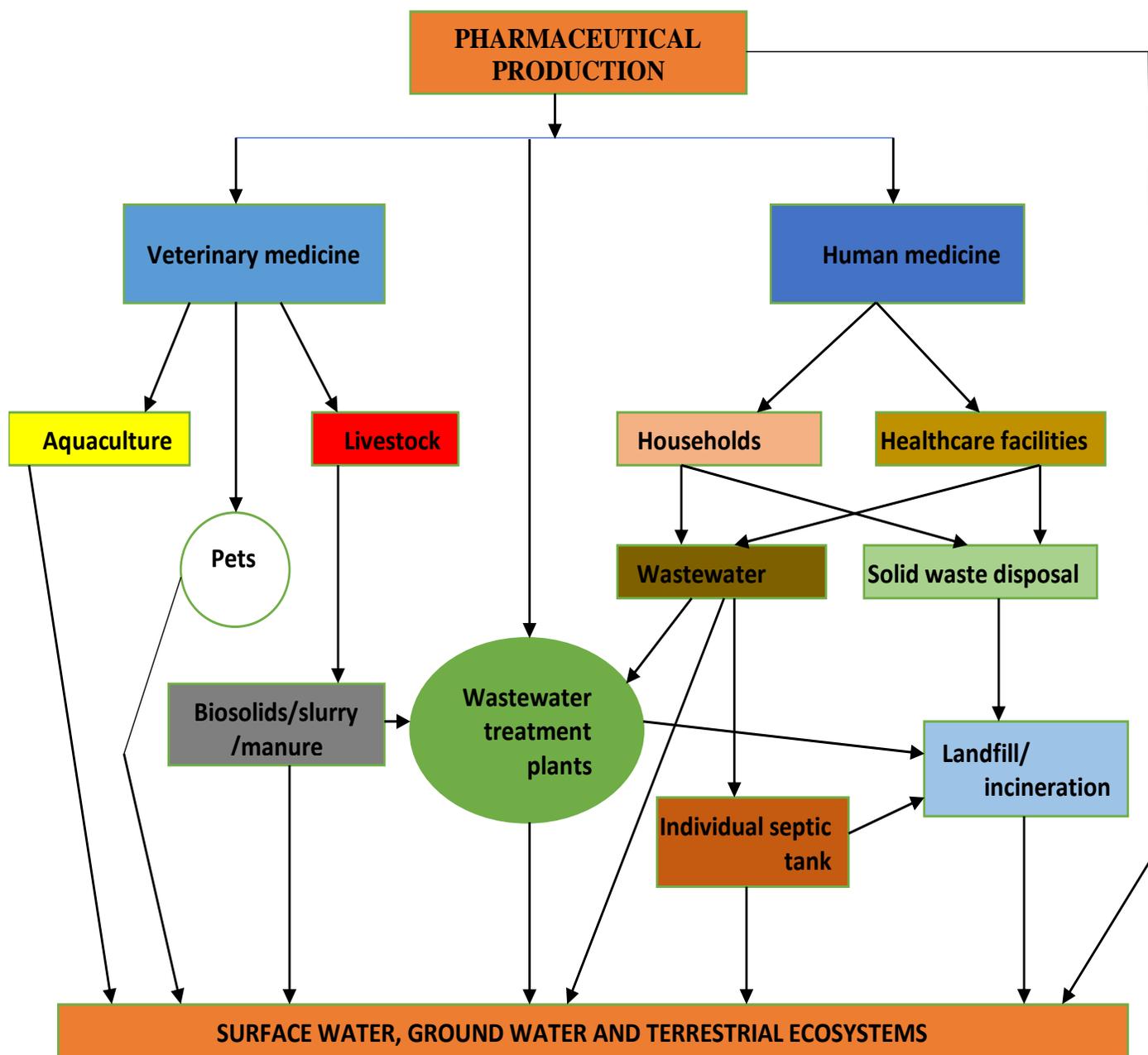
systems and groundwater through leaching [18]. A study conducted in the Baltic Sea region to evaluate pharmaceutical waste in aquatic environment found that the primary source of waste was from excreted APIs through faeces and urine from human and animals. Pharmaceuticals entered the aquatic environment through discharged effluents from MWWTPs. The MWWTPs released approximately 1800 tons of waste annually. Surprisingly, during wastewater treatment, 9 out of 118 pharmaceuticals were removed at 95% efficiency. Pharmaceuticals detected at high concentrations included analgesics, anti-inflammatory, central nervous system and cardiovascular agents [19]. A systematic review on disposal of pharmaceutical waste found that flushing and discarding pharmaceuticals in the trash bin are the main methods of disposal in households [20].

Impact and concentration of pharmaceutical waste are affected by agricultural, veterinary and medical activities, technology in the WWTPs, illicit drug use, structure of the food web, climate change, consumption rates, waste management practices, drainage, exposure history, sink type and water flow variations [15]. Several studies have described the following as passages of pharmaceutical waste in the environment [7,16-17,21].

- Release from healthcare waste
- Improper and direct disposal of expired/unused medicines in the sink or trash or through faeces or urine.
- Disposal by pharmacies
- Release from low-cost drug companies in economically developing nations like India, Pakistan, Bangladesh and China.
- Veterinary medicine or additives in animal food excreted into the soil or surface waters
- Leaching from faulty landfills
- Release from pest control drugs and molecular farming
- Disposal of medicated/euthanized animal carcasses
- Household sewage or garbage mixed with the excess drug
- Disposal of dairy waste/slurry
- Excretion from aquaculture using the medicated feed.
- Improper disposal of physician samples given for promotional purposes which end up unused or expired.

#### *Cost of disposal*

Pharmaceuticals are generally disposed of by incineration at high temperatures (above 1200 ° C). Industrialized countries such as Bosnia and Croatia, with efficient incineration facilities and excellent pollution controls, charge \$2.2-4.1 per kg. The amount of money needed for pharmaceutical waste disposal in the USA



**Figure1:** Sources and release of pharmaceuticals into the environment

ranges from \$4.4-8.2 million [5]. India is using 0.5 to 2% of its pharmaceutical revenue to dispose of pharmaceutical waste [21]. The cost of disposing of one kilogram of pharmaceutical waste in Kenya in the '90s ranged from Sh200-400. The price now ranges from Sh25-30 / kilogram. In 2017, about 65,000 kilograms of pharmaceutical waste worth Sh1.29 million was disposed at the Envirosafe Limited incinerator, Athi River. High-temperature incinerators are only available in the Kenya Medical Research and Training Institute (KEMRI) (3000°C) and Kenyatta National Hospital (KNH) (1700°C). Most healthcare facilities in Kenya have brick and motor incinerators that reach 300°C. These incinerators cannot meet the high costs of the incinerator

therefore, they are outsourced. Kenya's pharmaceutical industries lack incinerators and rely on a return to manufacture method six months before expiry [22].

A Greek study showed that 22900g of cytostatic waste were generated every day making the production rate 274.8kg annually. The generation rates translated to 140g/patient/day and 210g/bed/day. Such studies are important as they assist to plan cost of disposal and asses' environment impact of pharmaceutical waste [23].

***Measures of disposing of pharmaceutical waste recommended by the WHO***

Here are seven main steps to follow when unwanted drugs are disposed of [5]

**Decision:** The Pharmacy Company or health care facility should determine when to dispose of accumulated pharmaceutical waste.

**Approval:** The authorization to dispose of pharmaceutical waste is sought from the authorities concerned. In Kenya, disposal is carried out under the oversight of the National Environment Management Authority (NEMA) and the PPB. The waste generator should fill out the disposal form properly and pay the PPB a fee of 2,500Ksh. The PPB issues a Drug Safe Disposal Certificate upon disposal [2]. In Hong Kong, one has to apply as a chemical waste generator to the Environmental Protection Department (EPD) after which a waste generator number is given to the applicant. The charges are issued to the waste generator within a month after collection. The waste collector issues a trip ticket to the generator upon collection [24].

**Planning:** This is crucial if money, human capital, skills, time, equipment and methods of disposal are to be made available. The volume of pharmaceutical waste should be estimated at this stage and is determined in weights per quantity using 0.2 metric tons per m<sup>3</sup>.

**Developing working teams:** The disposal teams should be composed of pharmacists, pharmacist technicians and pharmaceutical warehouse staff. Conditions of the worksite, composition and volume of pharmaceutical waste determine personnel size and ratio.

**Safety and health work teams:** Protective equipment such as masks, gloves, helmets, boots, and overalls should be given to the groups handling disposal.

**Sorting:** Pharmaceuticals are available in various pharmacological and dosage forms. Different methods of disposal are needed for each of the categories and some can be safely returned to the supply chain, so it is essential to sort. Pharmaceutical waste should be separated, stored securely and labeled before disposal.

**Disposal:** There are several options for waste disposal that should be determined in terms of cost, safety, simplicity and practicability of the methods. Record: date and location of destruction, disposal method, pharmaceutical name, dosage form and amount, the value of items, reasons for disposal and name and signature of pharmacist disposing of and a witness before destruction.

**Security:** In dealing with narcotics, psychotropics and antineoplastics, strict protection and regulation must be maintained to avoid diversion during sorting, scavenging and pilfering.

### *Methods of disposing of pharmaceutical waste*

There are eight methods of disposal of pharmaceutical waste, namely, return to donor, incineration, immobilization, landfill, sewer, chemical decomposition, burning in open containers and fast-flowing watercourses [2,5,16,21].

#### *Return to donor*

Large pharmaceuticals that are challenging to dispose of, such as antineoplastics and unwanted/expired donations, should be returned to the manufacturer or donor for disposal. Cross-border transfers can be used to dispose of pharmaceutical waste. This approach involves moving hazardous waste across international boundaries. It is regulated by the Basel Convention on Transboundary Transfers of Hazardous Wastes. However, the procedures around this method take a long time to warrant transfer.

#### *Landfill*

Land filling refers to the direct disposal of untreated pharmaceutical waste in a land disposal site. A landfill is the most used disposal method. There are three categories of landfills.

#### *Open uncontrolled non-engineered dump*

It is widely practiced in developing countries. This process should not be used to dispose of untreated waste. After immobilization, it can be used as a last resort. In the event immobilization is not practicable, waste should be filled with municipal waste to avoid scavenging. Open dumps should be isolated from watercourses to avoid pollution.

#### *Engineered landfill*

The second-best method to dispose of immobilized pharmaceutical waste. The technique has features to minimize release into the aquifer.

#### *Heavy duty sanitary landfill*

These sites are well constructed, managed, over the water table and separated from watercourses. This method is most safe to dispose of waste as it offers protection of the aquifer. Waste is compacted and coated with soil to preserve the conditions for sanitary waste.

#### *Immobilization*

There are two methods of waste immobilization, namely; encapsulation and inertization.

#### *Encapsulation*

It involves immobilizing waste into a solid block within a drum. The following procedure is used; clean drums. Do not use drums that previously contained explosive materials. Cut drum lids open and bend them back.

Fill drums with solid or semi-solid waste, controlled substances, liquids, powders, or antineoplastics to 75% capacity. Fill the drum with cement, lime and water in the ratio of 15:15:5. Add a significant quantity of water to achieve consistency. Bend back and weld the lid. Place the drums at the bottom of the landfill and cover with fresh municipal waste.

#### ***Inertization***

This method is cheap and can be undertaken using unsophisticated equipment. Materials required include grinder, concrete mixture and cement, lime and water supply. It is suitable for disposing of solid or semi-solid waste, controlled substances, powders, or antineoplastics. The following procedure is used; Put on protecting clothing such as gloves and masks. Separate packaging materials such as blister packs, plastics, papers and cardboards from pharmaceuticals. Mix pharmaceutical waste, water, lime and cement in the ratio of 65%: 15%: 15%: 5% to form a homogeneous waste. Transport the waste to a landfill using a concrete mixer truck. Decant into normal urban waste or disperse into municipal waste.

#### ***Sewer***

Disposing of into drains involves releasing small quantities of diluted waste into sewers. The method is suitable when disposing of liquids, intravenous fluids and small amounts of disinfectants or antiseptics. This approach should not be used to dispose of undiluted antiseptics or disinfectants and antineoplastics.

#### ***Burning in open containers***

Should be used for disposal of small amounts of pharmaceutical waste. Pharmaceuticals disposed of by this method should not be burnt at low temperatures to avoid air pollution. It is suitable for pharmaceuticals packed in papers and cupboards. Burning materials that contain Polyvinyl chloride (PVC) should be avoided.

#### ***Chemical decomposition***

It is only feasible if chemical expertise is available and disposal by incineration is not possible. It is time consuming, tedious and chemicals used must always be available. It can be used to dispose of antineoplastics less than 50kg. Should be undertaken following manufactures' recommendations.

#### ***Incineration***

Incineration can be carried out via two methods namely; medium and novel high-temperature combustion.

#### ***Medium temperature incineration***

It can be used to dispose of solids, semi-solids, powders and controlled substances if high-temperature incinerators are unavailable or if less safe methods are available such as inadequate disposal to a landfill. The incinerator has two chambers that attain 850<sup>0</sup>C. The second chamber has a combustion retention time of 2 seconds. Pharmaceutical waste should be mixed with municipal waste in the ratio of 1:1000. Medium temperature incinerators should not be used to dispose of halogenated compounds (>1% halogenated compounds) as negligible amounts of halogen end up in combustion gases.

#### ***Novel high-temperature incineration***

This method can be used to dispose of solids, semi-solids, liquids, powders, controlled substances and antineoplastics. Such incinerators, e.g. cement kilns, operate at temperatures above 1200<sup>0</sup>C, have short gas residence time, proper emission controls, long combustion retention time, expensive and use sophisticated technology. This incinerator disintegrates all organic waste components and absorbs any toxic combustion products. They can be used to dispose of significant volumes of pharmaceutical waste in a short period of time. Pharmaceuticals should be put in small amounts (5%) in the furnace compared to fuel feed (95%). Before incineration, remove packaging materials and grind the pharmaceuticals to avoid blockage of fuel feed.

#### ***Dangers of improper disposal***

Improper habits during storage, handling and disposal pose serious consequences to the environment, economy, human and animal life. Pharmaceutical waste finds its way into rivers and lakes or leaches from landfills into aquifers. Households, healthcare facilities and pharmaceutical industries should not pour down the drain or flush into sewer systems. A study conducted to evaluate disposal practices in South and South-East Asia found that majority of liquid dosage forms were disposed through toilet and sink while solid waste was disposed in trash or bins. The disposal methods highlighted by the study had the potential to cause harmful environmental effects [25]. The following are some of the consequences of improper disposal [2,4-5,7,21-22,26-29].

- Contamination of water supplies for wildlife and domestic animals. Uncontrolled sex-drive was observed in sheep after drinking Viagra contaminated water.
- Improper disposal of opioids can lead to drug abuse as teenagers think prescription drugs are safer than other drugs.

- Accidental poisoning of children who come along improperly disposed drugs. Pills are colorful and look like candy; kids may unintentionally take medicine when the parent isn't cautious and cause overdosing.
- Potential of getting into the wrong hands of the public and pets.
- **Improper disposal affects aquatic life:** Male fish have turned inter-sex by displaying sexual characteristics due to pollution with Ethinylestradiol. Masculinization of female fish due to androgens. Analgesics have caused reduced hatching and organ damage in fish. Fluoxetine disposed of in watercourses caused frogs to hatch tadpoles with no legs and induced behavior changes, reproduction toxicity and disruption of hormones in fish. Reduced growth of aquatic plants (artemia, Daphnia) and algae due to antibiotics and antifungals. Data collected by Helsinki Commission (HELCOM) in collaboration with Baltic sea states found felodipine, carbamazepine and tramadol in blue mussels at concentrations >100 µg/kg. Sea birds e.g. Common eider were found to contain large number of these pharmaceuticals suggesting that they can be transferred in food chains [30].
- Non-biodegradable disinfectants, antineoplastics, antibiotics kill bacteria in bacteria required for sewage treatment affecting organic degradation processes, nitrification and denitrification.
- Anti-microbial resistance and development of superbugs due to misuse, overuse, use as a growth promoter in livestock and release of high quantities of antibiotics in fresh watercourses. A study conducted among professionals working in pediatric wards at Sao Paulo university hospital found that antimicrobials (22.7%) were the most disposed pharmaceuticals and sink drain was the second most utilized method of disposal. Most of the pharmaceuticals were disposed in their physical form. In addition, 48% of the disposed medicines posed human and environmental health risk [31].
- Burning pharmaceuticals at low temperatures or in open containers releases airborne toxic carbon emissions that cause pollution.
- Promotion of illegal activities, e.g. scavenging, diversion and resale of expired pharmaceuticals to the public.
- Damage to the soil. Soil cannot support plant growth and resulting plants have toxic molecules. Pharmaceutical chemicals in the soil cause phytotoxic effects on plants. 1000 µg/L of amoxicillin, an antibiotic, was observed to affect root growth in carrots and lettuce. Diclofenac, a Non-steroidal anti-inflammatory reduced viability in Hordseradish by 65% [32].
- Formulation of landfills which lead to slow decomposition of waste and leaching, leading to poisonous soil, making it hard for production.
- Infectious blood disposed of in landfills, syringes being washed up in beaches.
- Heavy use of diclofenac (Cataflam, Voltaren) in cattle caused renal failure in vultures that fed in carcasses.
- Increased healthcare costs and unnecessary waste of healthcare costs.
- Loss of reputation, fines and licensing of the waste generator.

### *Challenges of managing pharmaceuticals in the environment*

Pharmaceuticals are discharged into the environment through the manufacturing and formulation of pharmaceutical products, agriculture, patient use, improper disposal, consumption and excretion. Medicines interact with humans and animals to produce a pharmacological effect at low doses. When non-target organisms in the environment are exposed to these pharmaceuticals even at low concentrations, detrimental effects will occur, such as waterborne toxicity in micrograms per liter of the antidepressant fluoxetine has affected spawning in shellfish [33]. Pharmaceuticals are tailored to be stable to reach and interact with target molecules; therefore, they degrade very slowly. Constant use of pharmaceuticals leads to their accumulation in the environment at rates higher than their degradation rates. Medicines used in agriculture and aquaculture are released into water bodies directly or via surface runoff. WWTPs are not created to identify or remove pharmaceutical waste from water. For wildlife, exposure to pharmaceuticals is long-term as it occurs via multiple exposure routes such as freshwater bodies and terrestrial ecosystems and involves a mixture of substances [15]. Majority of health facilities have inadequate storage space for waste and cannot destroy waste according to the required standards. Developing countries lack policies, guidelines on waste management, adequate financing, human resource, space, equipment, professional expertise and time to carry out disposal [22]. A study conducted among hospitals in Basra to evaluate the environmental impact of pharmaceutical waste reported the barriers of safe waste disposal as lack of awareness, handling chemotherapeutic waste like other medical waste, lack of a systematic approach to waste management and old incinerators that operate at low temperatures i.e. < 400°C. The incinerators generate toxic emissions and ash that contains high concentration of heavy metals. The ash ends up in landfills through municipal waste presenting high health risk to the environment and transfer of diseases [34] Managing pharmaceutical waste is now a

global challenge since several countries lack take-back programs that can safely dispose waste. Public unawareness and irrational medicine use among patients contributes greatly to accumulation of pharmaceutical waste [35]. An Albanian study found the main waste management challenges were the high cost of contract with waste treatment companies, unawareness of waste laws and regulations, decreased inspection visits by the Ministry of Health and lack of motivators e.g. incentives [36]. A Nepal study revealed barriers as absence of waste management guidelines, incinerators, sanitary landfills, waste collecting trucks, burial pits and unawareness of disposal guidelines [37]. Challenges that contributed to accumulation of pharmaceutical waste in Finland include manual maintenance of expiry dates and stock levels, inconsistent information, infrequent ordering process that ordered large batches, inefficient recycling processes, inaccurate monitoring of waste [38].

#### *Mitigation options to control pharmaceutical waste in the environment*

Studies exploring the harmful effects of pharmaceuticals on the environment are constrained. During clinical trials, pharmaceutical companies focus on patient health, dosage and effectiveness, and 88% of human medicines do not have data on environmental toxicity. Countries like the Netherlands, France, Germany and Sweden have developed a strategic approach for tackling environmental, pharmaceutical waste. Mitigation options should be geared specifically to a pharmaceuticals life-cycle to achieve long-term benefits and cost-effectiveness in the following steps [15,39]:

**Cross-cutting:** The Government should prioritize high-risk APIs, develop new methods of monitoring water quality, risk assessment and modelling together with pharmaceutical and research organizations. Guidelines should be established to define the water and environmental quality standards of pharmaceuticals.

**Design:** In addition to developing a green pharmacy, pharmaceutical companies should develop customized or effective drugs and biological therapies.

**Authorization:** Until approving a prescription product, the Government should oversee regulations and determine the environmental risk. Before the market launch, pharmaceuticals with a high ecological risk should face strict conditions. The industry should offer options for risk intervention, Eco-labelling, post-approval monitoring and mitigation.

**Production:** The Government and the pharmaceutical sector should develop an environmental criterion describing effluent discharge limits, disclosure of wastewater discharge and ethical production practices.

**Consumption:** The health sector should prescribe environmentally friendly pharmaceuticals, individualized medicines and targeted delivery mechanisms while decreasing inappropriate prescribing. The industry and health sector should improve customer selection and awareness by way of Eco-labelling for self-consumption. The Government should ban high-risk pharmaceuticals such as the use of antibiotics for prophylaxis in livestock, and the use of hormones to enhance livestock growth. Good livestock handling practices, safe management and improved hygiene and diagnosis, are required in health care facilities to prevent emissions.

**Collection and disposal:** Solid waste utilities should implement anaerobic biogas fermentation and passive manure storage to improve manure management. The industries should introduce schemes for processing of unused or expired medicines. The public should be told to avoid the dumping of unused or expired drugs in toilets and sinks.

**Wastewater treatment:** WWTPs should upgrade wastewater utilities to enhance the detection of pharmaceutical traces. Use of photocatalytic-ultra-filtration membranes immobilized by sol-gel in wastewater treatment plants have shown to degrade over 40% and 30% of chlorhexidine digluconate and methylene blue, respectively [40]. A toxicological study showed that a combination of biochemical, Fenton's and ozone treatment successfully removed 90% of pantoprazole in wastewater. The integrated process is cheap, safe and consumes less energy [41]. Laccase enzyme extracted from *trametes* fungus can be used to minimise pharmaceutical chemicals in waste water. The enzyme causes degradation of pharmaceuticals such as diclofenac and ibuprofen in waste water through hydroxylation reaction [42]. Modern anaerobic technologies such as hybrid anaerobic-chemical and anaerobic-aerobic systems are useful in treating wastewater as they have low operation costs, high organic loading and produce less sludge. The systems have achieved > 90% and 97% removal of amoxicillin and sulfamerazine, respectively [43]. Modern wastewater technology e.g. electron-fenton technique decreased the concentration of ibuprofen from wastewater from 400 ppm to 6.8 ppm when operating at optimum conditions [44].

**Drinking water treatment:** Drinking water providers should incorporate water safety planning and upgrade to modern technology treatment plants. Pharmaceutical waste such as ibuprofen detected in surface and ground water is extremely stable. Conventional contaminated water treatment technologies (CCWTTs) are not able to fully degrade such waste and their application leads to formation of toxic by products. Its primary metabolite is

present after degradation and poses risk to human and aquatic life. Modern technology such as photocatalysts e.g.  $\text{Ag}_3\text{PO}_4$  and adsorbent e.g. halo site nanotubes have proven efficient in adsorption of pharmaceutical chemicals such as carbamazepine, ibuprofen, diclofenac and naproxen [45]. Collaboration between pharmaceutical and water industries should be encouraged to enhance effective water treatment.

A Serbian study showed that assessing the life-cycle of pharmaceuticals is the most effective method of controlling household generated pharmaceutical waste [9]. Waste and inventory reduction projects conducted in Minnesota, led to annual saving of \$80,000 and \$123,000 in Hennepin County Medical Centre and Falls Memorial Hospital, respectively. The projects led to a significant reduction of pharmaceutical waste by minimising excess stock, expired medicines and availing usage reports [18]. A recent study has shown that incorporating a cultural perspective i.e. understanding pharmaceutical waste disposal from a social, economical and political context can tackle the root cause of the problem by explaining reasons why certain medicines are prescribed, consumed and disposed of by specific populations. The perspective provides insights on how beliefs, perceptions and values interrelate with waste disposal practices. The study showed that cultural preferences influenced monitoring and reporting of pharmaceutical waste pollution [46].

#### ***Role of a pharmacist in managing pharmaceutical waste***

A pharmacist should be involved during the disposal of unused pharmaceuticals. Pharmacists should be aware of available disposal methods used in their area. They should prohibit disposal by open dumpsites, burning and destruction in poorly constructed/insecure landfills as these carry a public health risk. They should inform the competent authorities on the cost of disposal, the available disposal options and where to outsource disposal services [22]. Pharmacists are imperative in the pharmaceutical management cycle to ensure rational drug use to minimize the harmful environmental effects of pharmaceuticals. They should be included in the selection, acquisition, usage, delivery and policy mechanism, legislation, rules of pharmaceuticals. An Ethiopian study revealed that pharmacists have better knowledge regarding waste disposal practices compared to other cadres. In the study 29% and 32% of the respondents indicated that inappropriate storage and receiving short expiry drugs led to damage of medicines [47]. The pharmacist should flag up any extravagant or overprescribing to reduce leftovers that end up being disposed of improperly. Pharmacists should promote and track patient adherence and ensure that all prescribed drugs are used [21]. Pharmacists should supervise the

ordering of stocks by predicting how much inventory to order and how long it will last to avoid overstocking, which increases the risk of expiring medicines. Proper storage practices should be followed to prevent damage. Pharmacists should establish standard operating procedures for disposing of low quality, expired, damaged and unwanted pharmaceuticals properly. Being highly resourceful in information about drugs, pharmacists should be at the forefront of recommending the best methods of disposal for consumers in households. Physicians should undertake regular patient education, after prescribing, on appropriate means of disposal specific to each dosage type [48]. A Serbian study found that hospital staff in one out of 5 hospitals had not received training on pharmaceutical waste management. Moreover, training influenced safe waste management. The study concluded that having waste management specialists and routine training opportunities can enhance pharmaceutical waste management [49]. Healthcare facilities must designate thoroughly trained personnel who can properly handle waste during emergencies and normal operations. In the USA, personnel handling waste must undertake hazardous waste disposal training annually. Learning institutions must retain training records of individuals handling pharmaceutical waste.<sup>[50]</sup> Pharmacists should train stakeholders (prescribers, politicians) and serve as environmental watchdogs at all levels to increase public consciousness of the risks of inappropriate disposal and impact of different pharmaceutical formulations. A Palestine study found a significant relationship ( $P < 0.001$ ) between training and improvement in practice and knowledge among healthcare workers handling pharmaceutical waste. The study recommended the hospital administration to conduct healthcare worker centred training frequently.<sup>[51]</sup> A Nepal study reported a significant association between knowledge and practices of waste disposal. Knowledgeable respondents practiced safe disposal practices. In the study participating in continuous medical education and training status influenced safe waste disposal practices. This clarifies that training waste handlers is essential to achieving safe disposal practices [37].

The health ministry, drug control agency, environment ministry, waste management experts, pharmacists, and Non-Governmental Organizations (NGOs) should assess, examine, and monitor drug disposal activities. Monitoring can be achieved by creating national legislation and environmentally sustainable disposal strategies to prevent the use and release of toxic pharmaceuticals into the environment [5]. The Organization for Economic Co-operation and Development (OECD) countries such as the USA, the UK, Sweden, Korea, Germany, Switzerland and Australia

have developed and adopted environmental, pharmaceutical control policy instruments [15]. Finally, higher learning institutions should train pharmacists to work on pharmaceutical waste earlier to practice. The curriculum should be restructured to include sources and risks of pharmaceutical waste, methods of disposal / treatment / removal, ways of neutralizing pharmaceutical waste, effects of inappropriate disposal, and removal / treatment guidelines / policies. This program will provide a clear understanding of medicines' interaction with nature, which is a critical element in achieving future safe disposal practices [21].

## II. CONCLUSION

A large volume of pharmaceutical waste amasses yearly as a result of consumption, overproduction and over prescription. Numerous studies have shown the presence of trace amounts of pharmaceuticals in waterways, water supply systems and soil. Due to improper disposal, these active pharmaceutical ingredients enter the food chain and are transferred back to humans, animals and plants. Safe disposal of pharmaceutical waste is critical if public and environmental safeties are to be sustained. The critical shortcomings in pharmaceutical waste disposal are inadequate storage space, insufficient funds, weak infrastructure, and insufficient awareness among health care staff, patients and the public. All stakeholders such as the Government, pharmaceutical companies, media, healthcare workers, patients, the public and NGOs should pursue and implement safe waste management practices. Multidisciplinary cooperation and coordination at the household, healthcare and industrial levels are required to enforce safe disposal. Introduction of national guidelines, cost-effective solutions to disposal, training personnel and educating the public are crucial to achieving a reduction in pharmaceutical waste-related hazards. Legislation dealing with expired medicine needs to be developed to control the large volumes of expired pharmaceuticals which have harmful effects to the environment. To reduce stockpile accumulation, the Government should invest in public collection schemes, high-temperature incinerators with controlled emissions and fenced burial places. Regular inspection by regulatory bodies is necessary at all levels to ensure that qualified health staff handles waste and safe disposal practices and guidelines are adhered to. Pharmaceutical industries should balance the manufacturing and consumption rates of medicine to avoid expiry. Modern technology should be applied in stability tests with an aim of prolonging pharmaceutical shelf life. Take back options, collection events and approved collection sites should be implemented and popularized through awareness campaigns. During production, safe disposal instructions should be included

in the inserts or on the package to enhance public knowledge on safe disposal practices. The introduction of pharmaceutical waste management into the curriculum of the health sciences is necessary. Pharmacists are in a strong position to reduce the burden of unwanted pharmaceuticals by raising public awareness, training other health cadres, delivering patient care, tracking disposal to ensure that this is achieved in the right way. Moreover, they can assist in formulating and reforming policies for managing the use and release of high-risk pharmaceuticals into the environment. To avoid environmental pollution and the health threats, wastewater and drinking water treatment plants should upgrade technology to eliminate traces of pharmaceuticals in water. Further research should be conducted across all nations to assess the magnitude of unsafe disposal practices.

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