Waste Disposition Management: An Enabler to Achieve the United Nations' SDG #3 within the Pharmaceutical Industry

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2023

Abstract

Among many industries that generate waste, the pharmaceutical industry generates significant amounts, including unused and expired drugs, contributing to environmental degradation. To support the third Sustainable Development Goal (SDG), Good Health and Well-being, and achieve environmental sustainability, new regulations are necessary to enable a strong reverse logistics program in the pharmaceutical industry. This paper critically analyzes the challenges and opportunities and proposes additional ANSI-approved American National Standards for effective disposition management programs for pharmaceutical waste.

The study examines the regulatory frameworks and laws of the pharmaceutical industry in the United States vs. international practices in managing waste and the challenges of collecting and disposing of/recycling pharmaceutical waste at the household level. It also investigates the role of regulatory frameworks in facilitating an effective disposition management program that can reduce the environmental impact of pharmaceutical waste.

The study highlights the opportunities for developing new regulations that incentivize households, pharmaceutical companies, and municipalities to adopt sustainable practices and invest in infrastructure to support environmentally friendly waste disposal methods. The study also suggests a socially responsible framework for local governments to motivate safe citizenship practices regarding pharmaceutical waste disposal.

In summary, the study highlights the need for new regulations and additional ANSI-approved American National Standards as guidance for enabling a robust pharmaceutical waste disposition management program in the American pharmaceutical industry to achieve the third SDG.

Key Words: Pharmaceutical waste, New Regulations, disposition management, waste management, recycling, standards.

1. Problem Identification

Pharmaceutical waste refers to unused, expired, or leftover medications that need to be disposed of by individuals or institutions. Adversely, 30-90% of pharmaceutical waste is flushed down the drain each year, contributing to pharmaceuticals in waterways that impacts drinking water quality [2]. Research has shown that even low levels of pharmaceuticals in drinking water can have adverse effects on human health, including endocrine disruption and developmental effects [3]. Long-term exposure to Active Pharmaceutical Ingredients (APIs) in drinking water can have negative health consequences [4].

SDG 3.9, a target under the Sustainable Development Goal (SDG) #3, "Good Health and Well-Being," aims to substantially decrease deaths and illnesses caused by **hazardous chemicals** and air, **water**, and soil pollution by 2030 [1]. The proper disposal of household pharmaceutical waste applies to SDG 3.9 because these hazardous chemicals contaminate ground and surface water sources, consequently impacting public health. Waste management initiatives can reduce the presence of APIs in waterways [5].

There are three significant public-health risks when pharmaceutical waste enters local waterways.

1. *Antibiotic Resistance*

Antibiotic resistance is a phenomenon that occurs when bacteria evolve to become resistant to antibiotics, making it more difficult or impossible to treat infections. This can happen naturally but is also accelerated by the overuse/misuse of antibiotics in human and animal medicine [6]. Antibiotic resistance is a significant problem, leading to increased mortality, extended hospital stays, and higher healthcare costs [7]. Uncontrolled antibiotic resistance may worsen with more infections becoming resistant, potentially causing increased mortality [8]. Moreover, it could raise healthcare expenses and hinder medical advancements reliant on antibiotics.

2. *Endocrine Disruption*

Research has shown that pharmaceutical exposure can lead to endocrine disruption, interfering with normal hormone function in humans and wildlife [9] [10]. Endocrine disruption can have many adverse health effects, including reproductive and developmental problems like thyroid dysfunction and cancer. For example, studies have found that exposure to estrogen-like compounds from birth control pills can cause the feminization of male fish, while exposure to antidepressant drugs can cause behavioral changes in aquatic organisms [11] [12].

3. *Neurological Development*

The presence of pharmaceutical drugs in U.S. waterways due to flushing down the drain can have negative effects on the human brain. According to a study [13], antidepressants and other psychotropic drugs can alter neurotransmitters in the brain, which can have long-term effects on the mental health of individuals who consume contaminated water.

2. Literature Review

This literature review highlights the need to prevent household pharmaceutical chemicals from entering U.S. public waterways, suggesting potential improvements to regulations by the U.S. Environmental Protection Agency (EPA) and the U.S. Food and Drug Administration (FDA), and to voluntary consensus standards.

2.1.1 European Union

The European Union has implemented various regulations to manage pharmaceutical waste [18].

The Water Framework Directive (WFD) [14] established a framework for community action in the field of water policy. This requires member-states to prevent and control water pollution from hazardous substances [14]. WFD also provides a legal framework for protecting and managing water resources, including controlling emerging pollutants [15].

The Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) [19] regulation requires chemical manufacturers and importers (including pharmaceuticals) to register and evaluate risks of their products [16].

Additionally, the European Medicines Agency (EMA) and the European Chemicals Agency (ECHA) established the Medicines Disposal Taskforce in 2008 to address the improper disposal of household pharmaceuticals. The Taskforce aimed to raise public awareness and promote the proper disposal of drugs while also advocating for the inclusion of environmental considerations in the approval process of drugs [14].

Sousa et al. [17] reviewed the environmental monitoring of organic water pollutants identified by EU guidelines. They found that several monitoring programs have been implemented to assess harmful chemicals' presence and have helped identify potential sources of pharmaceutical pollution and guide management actions to prevent contamination.

2.1.2 Brazil

In Brazil, the disposal of household pharmaceuticals is regulated by the National Health Surveillance Agency (ANVISA) [20]. Lima et al. [15] note that ANVISA's regulations require the manufacturers of drugs to develop a reverse logistics system for collecting and disposing of expired or unused medications. The Brazilian government also implemented the National Solid Waste Policy (NSWP) in 2010 to promote sustainable waste management practices [16]. Viegas et al. [17] explain that ANVISA has recently proposed regulations focusing on the sustainability-based reverse flows of drugs, emphasizing the need to incorporate environmental considerations in drug development and approval.

2.1.3 United States of America

The FDA and EPA's regulatory frameworks are vital for addressing chemical contamination in US public waterways. The FDA has issued guidelines outlining the proper handling, storage, and disposal of pharmaceutical waste, with specific manufacturer instructions [21]. Manufacturers are also required to report any environmental contamination resulting from waste disposal.

Meanwhile, the EPA regulates the discharge of pollutants into waterways, including pharmaceutical waste, by issuing permits and monitoring the discharge to meet predefined standards [22].

The regulation of active chemicals from entering waterways through household drains is governed by several frameworks, including the Clean Water Act (CWA), the Safe Drinking Water Act (SDWA), and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) [23] [24] [25] [27]. CWA is the primary federal law that regulates the discharge of pollutants into U.S. waters, including wastewater treatment plants that handle household sewage [24] [25].

The EPA is responsible for implementing the CWA and developing regulations to address pollutants that threaten water quality, including pharmaceuticals [24]. The EPA has also established a National Pollutant Discharge Elimination System (NPDES) permitting program, which regulates point source discharges of pollutants from municipal and industrial sources, including wastewater treatment plants [24] [25].

The SDWA requires public water systems to test for contaminants, including pharmaceutical compounds, and establish treatments to remove them if certain levels are exceeded. The EPA sets national standards for drinking water contaminants and guides states in implementing these standards [26].

The FDA regulates the approval of drugs for human and animal use, including antibiotics, antidepressants, and steroids, and requires testing of their environmental impacts [28] [29]. The EPA has also established a voluntary program for pharmaceutical companies to test their products for environmental impacts and develop environmental stewardship plans [30].

Pharmaceuticals in public waterways are monitored by agencies like the U.S. Geological Survey (USGS) and the EPA [23] [25]. The USGS assesses the occurrence and distribution of pharmaceuticals in U.S. waterways and groundwater [25]. Through its Unregulated Contaminant Monitoring Rule, the EPA requires public water systems to monitor for a list of contaminants, including pharmaceuticals [31].

2.2 Comparative Analysis

The European Union (EU) and Brazil demonstrate a proactive precautionary approach to regulating chemical compounds in waterways, whereas the U.S. heavily relies on reactive post-market surveillance [32] [34] [35].

In the EU, regulations such as the Water Framework Directive (WFD) and the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) Regulation reflect a precautionary approach [33]. The WFD emphasizes preventing and reducing hazardous substance release into water bodies, while REACH requires companies to assess and manage the risks associated with chemical substances [33]. These regulations prioritize risk prevention and proactive measures to protect human health and the environment.

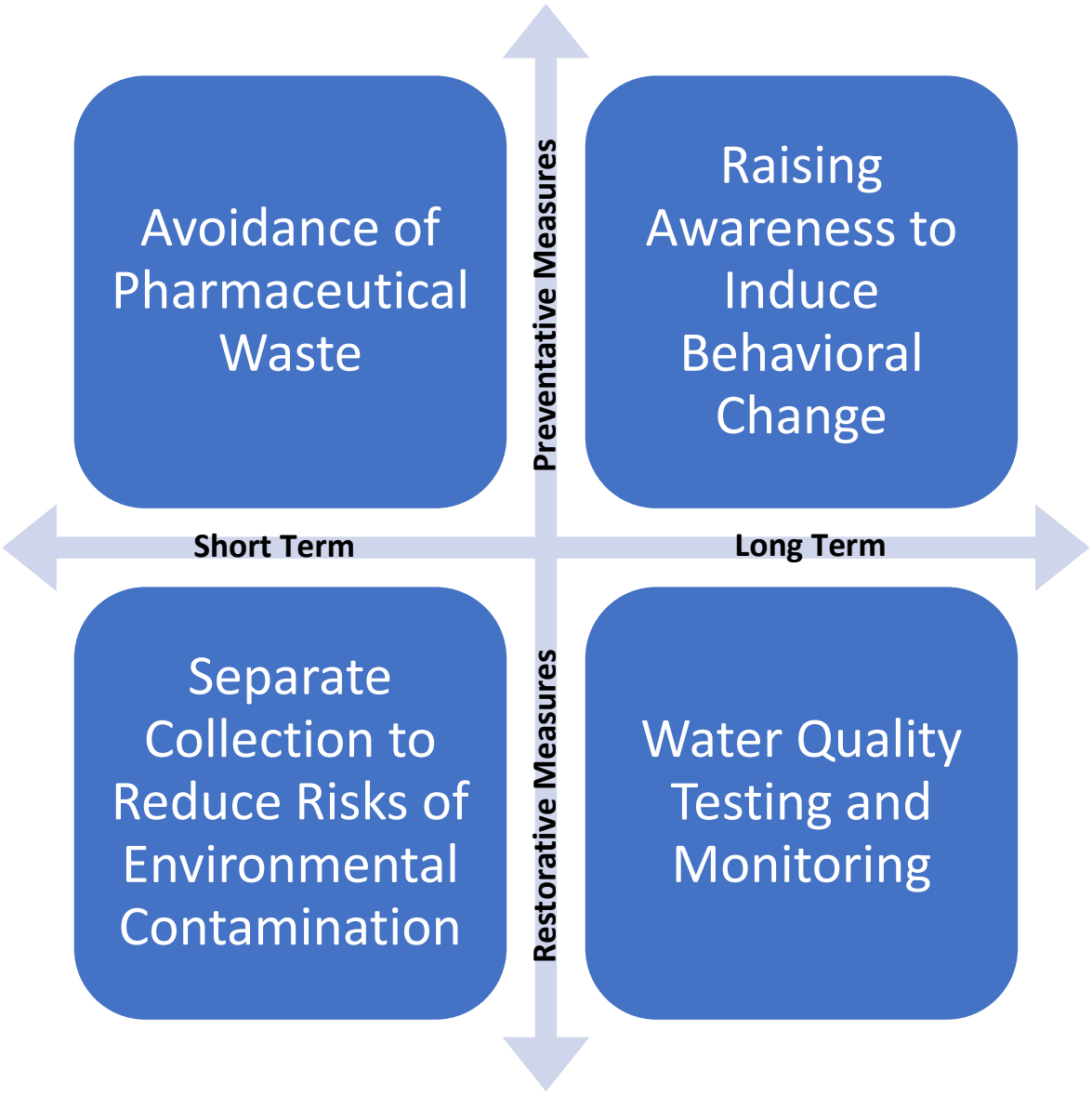
Similarly, the Brazilian Constitution establishes the right to a healthy environment, and the National Policy on the environment emphasizes preventive action and environmental protection. Brazil's regulatory framework, including laws such as the Brazilian Environmental Crimes Law and the National Water Resources Policy, focuses on preventive measures to avoid harm to water bodies and ecosystems [34].

In contrast, the U.S. leans toward post-market surveillance and monitoring of chemical compounds. The Toxic Substances Control Act (TSCA) places the burden of proof on the government to demonstrate the risks associated with chemicals [35]. Only when substantial evidence of harm emerges can regulatory action and measures be implemented.

The differing approaches reflect a divergence in regulatory philosophies [33] [34] [35]. The EU and Brazil prioritize precaution and preventive action, seeking to avoid harm by regulating substances before significant risks are identified [32] [34]. In contrast, the U.S. emphasizes post-market surveillance, responding to evidence of harm, and implementing regulatory measures as needed [35]. While both approaches have their merits, balancing the benefits of innovation and economic considerations with the potential risks to public health remains an ongoing challenge for all three regions [32] [34] [35].

3. Standards

As a part of this research, an implementation matrix was created by identifying standards that target goals based on different objectives.



3.1.1 Avoidance of Pharmaceutical Waste

Source-directed initiatives in the drug product lifecycle can prevent pharmaceutical waste from entering the waterways.

ANSI/IAPMO Z1167-2023, *Solid Waste Containment Interceptors*, is a plumbing industry standard that covers testing and performance requirements for solid waste containment interceptors' equipment.

This standard can be expanded by incorporating guidelines for designing and constructing solid waste containment interceptors to capture and effectively contain pharmaceutical waste. This may involve considerations such as the sizing and configuration of the interceptors, appropriate filtration, or adsorption mechanisms to capture pharmaceutical substances, and the materials used to construct the interceptors to ensure compatibility with pharmaceutical waste.

3.1.2 Raising Awareness to Change Customer Behavior

ANSI/NFPA 82-2019, *Incinerators and Waste and Linen Handling Systems and Equipment*, can be expanded to educate civilians on proper incineration disposal of pharmaceutical waste. This includes guidelines, outreach programs, and collaboration with public health organizations to raise awareness about environmental health risks of improper disposal.

3.1.3 Separate Collection to Reduce Risks of Environmental Contamination

Separate collection of pharmaceutical waste provides environmental benefits and reduces risks, but no specific ANSI-approved American National Standards address household drug collection (as of September 2021).

<u>New Standard:</u> Standard for Separate Collection of Unused or Expired Medicine from Households by Public Garbage Disposal Crews

1. Purpose: This standard aims to establish guidelines for the separate collection of unused or expired medicine from households by public garbage disposal crews to reduce the environmental impacts of pharmaceutical waste on waterways.

2. Scope: This standard applies to all public garbage disposal crews responsible for collecting household waste, including unused or expired medicine, and all entities involved in the transportation, storage, and disposal of such waste.

3. Requirements:

    1. Public garbage disposal crews shall provide separate containers for unused or expired medicine at designated collection sites.

    2. Collection containers shall be labeled and designed to prevent unauthorized access and spills.

    3. Collection containers shall be regularly emptied and properly disposed of at an authorized facility.

    4. Public education and outreach efforts shall be conducted to inform households of the availability of separate collection containers.

3.1.4 Water Quality Testing Policies

ANSI/AWWA G300-17, *Source Water Protection*, provides guidelines for protecting the quality of source water supplies, including surface and groundwater.

To expand this standard, a new section could be added to monitor and report active and inactive pharmaceutical ingredients in waterways. This section would require water utilities and other responsible entities to regularly test and report waterways' pharmaceutical and chemical waste

levels. Additionally, the standard could include guidelines for treating water sources contaminated with pharmaceutical and chemical waste including recommendations for treatment technologies such as activated carbon, reverse osmosis, and ozone treatment, which effectively remove pharmaceuticals from water.

ANSI/AWWA B604-18, *Granular Activated Carbon*, provides guidance and requirements for using and regenerating granular activated carbon (GAC) in water treatment processes. The standard specifies criteria for the quality and performance of GAC, including parameters such as particle size, density, and adsorption capacity.

To effectively expand ANSI/AWWA B604-18 for filtering active pharmaceutical ingredients (APIs) from waterways, several potential expansions can be considered:

1. Inclusion of API-specific testing requirements: The standard can include specific testing protocols and performance criteria for removing APIs, such as establishing allowable limits for different pharmaceutical compounds and incorporating analytical methods to assess the effectiveness of GAC in their removal.

2. Integration of monitoring and control strategies: The expanded standard can emphasize the importance of robust monitoring and control strategies to ensure the continuous and effective removal of APIs, such as implementing online monitoring systems to detect API breakthroughs and the development of protocols for GAC media replacement or regeneration based on performance indicators.

4. Conclusion

In conclusion, preventing pharmaceutical waste from entering waterways is a critical step towards achieving SDG 3.9, which aims to reduce water-borne illnesses. To effectively address this issue, it is imperative for ANSI, as the coordinator of the U.S. voluntary standards system, to play an active role in supporting standards related to pharmaceutical waste management. By

promoting comprehensive guidelines and regulations, ANSI can contribute significantly to environmental sustainability, protect water resources, and enhance public health outcomes.

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