

Drug Disposal Regulations: Current Status in United States and Europe

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Abstract

Improper disposal of unused or expired medicines leads to serious personal and environmental health hazards. Recent research in United States suggests that the nation’s water supply is contaminated with trace pharmaceuticals that affect a negative environmental and public health impact. Incorrect medication disposal methods (e.g. flushing medications down the toilet or drain) are a significant factor contributing to the presence of medication compounds in the aquatic environment. More than 150 different pharmaceutical substances and metabolites have been found in various water bodies in Europe, including drinking water supplies. The improper drug disposal also leads to drug abuse and diversion of expired medicines into the market. National and State disposal regulations in US and EU are existing for the disposal of unused drugs. As per Government Accountability Office Report, only 3% of eligible pharmacies and other entities voluntarily participate as Drug Enforcement Administration authorized collectors of unused prescription Drugs. The Stake holders cited cost and uncertainty over proper implementation as main reasons. They prefer to participate in other medicine- take back programs. In Europe, the directives do not provide any guidelines on implementation of schemes & there are significant differences between Member States. Therefore detailed information regarding the implementation and efficiency of collection schemes for unused pharmaceuticals throughout Europe is highly scattered and deficient for comparison.

Key words: Drug disposal, unused medicines, expired medicines, medication disposal, drug abuse

INTRODUCTION

The world pharmaceutical market can exceed \$1.5 trillion by 2023 growing at a 3-6% compound annual growth rate over the next five years. The compound annual growth of US pharmaceutical is 4-7%. In Europe, cost-containment measures and less growth from new products contribute to slower growth of 1-4%, compared to the 4.7% compound annual growth seen over the past five years. The return of pharmaceuticals in the industry is worth \$2.5 billion.¹ Some of the common reasons for returns faced by the industry are expiry and damages, product returns due to wrong shipments, counterfeits, and product recalls. In addition to industrial returns, there is house hold unused medicines which needs to be disposed. Hence the drug disposal methods include both individual and industry oriented.²

Incorrect medication disposal methods (e.g. flushing medications down the toilet or drain) are a significant factor contributing to the presence of medicated compounds in the aquatic environment. Recent research in United States suggested that the nation’s water supply is contaminated with trace pharmaceuticals that affect a negative environmental and public health impact. If the medicine disposal practices are improper, the health of the exposed population is at high risk. In Europe, input of pharmaceutical residues via domestic waste water is estimated to be 80%. Detectable quantities of one or more chemicals were found in 80% samples of 139 susceptible streams in 30 states of US. The objective of this study is to provide an insight about the current regulations for safe disposal of drug/ medications in US and Europe.³

There benefits with the proper disposal of pharmaceutical drug products include:

- 1. Minimize Diversion**
- 2. Environmental Protection:** According to a study, over \$5 billion worth of drugs in unopened

packages are placed into the garbage annually. Products returned through proper channels are kept out of landfills and reduces potential contamination of land and water from unapproved disposal methods

- 3. Decrease Drug Abuse:** When unused and expired medications are removed promptly from the marketplace, the supply of drugs with the potential for abuse is reduced
- 4. Safety and Security:** Effective return of pharmaceutical drug products helps keep them off the streets, contributing to safer neighbourhoods.

DISCUSSION

I. Disposal regulations in United States

NATIONAL REGULATIONS	STATE REGULATIONS
<p>Secure and Responsible Drug Disposal Act of 2010 The "Secure and Responsible Drug Disposal Act of 2010" was proposed to amend the "Controlled Substances Act" created in 1970 which prohibits the disposal of controlled substances unless a member of law enforcement has authorization from the Drug Enforcement Administration (DEA) to directly receive and dispose of the controlled substance. This prevents drug take-back programs for members of the public, which in turn can lead to the potential</p>	<p>1) Alameda County Safe Drug Disposal Ordinance Alameda County was the first county in the United States to make the manufacturer pay for safe disposal of pharmaceutical waste. This ordinance required companies that manufacture drugs sold and distributed in Alameda County must operate and pay for a "Product Stewardship Program". Examples of these programs include a drug kiosk or mail-back program and volunteer collectors, such as law enforcement and</p>

<p>misuse of these drugs. Misuse of prescription medications has been a growing epidemic. The Secure and Responsible Drug Disposal Act of 2010, regulates distribution, importation, manufacture, possession, and use of controlled substances. Under this amendment, the DEA was given authority to create regulations and propose new options for proper medication disposal. These regulations include medication take-back programs, medication mail-back programs, and collection receptacles for medication disposal. Prior to the passage of this amendment, the Controlled Substances Act (CSA) did not supply a means for patients to discard controlled substances (e.g. unused prescription medications); pharmacies and medical facilities were legally not allowed to accept controlled substances for disposal. As a result, many individuals employed incorrect medication disposal methods, such as discarding medications in the garbage or flushing them down the toilet. The DEA's Final Rule on 9 October 2014 effectively implemented the Secure and Responsible Drug Disposal Act of 2010. Under this regulation, pharmacies and healthcare facilities have the option to register as designated collection sites for any unwanted medications. As of February 2016, options for proper medication disposal have been established in multiple community locations and pharmacies across the US with 882 DEA registrants labeled as designated collectors. The studies have</p>	<p>pharmacies. Due to this program, 8 other counties in California adopted similar programs, including San Mateo, Santa Barbara, Santa Clara, Marin, Los Angeles, Santa Cruz, Sonoma, Contra Costa, San Luis Obispo, and Tehama Counties.</p> <p>2) California State Board of Pharmacy In California, entities including pharmacies in retail and hospital settings may host drug take-back programs as long as they follow requirements under Article 9.1 of Division 17 of Title 16 of the California Code of Regulations. These pharmacies are required to register with the DEA and notify the Board of Pharmacy and DEA within 30 days of starting or stopping a program. These pharmacies must have collection receptacles located in authorized locations and have liners that are certified to meet American Society for Testing Materials (ASTM) standards. The pharmacies must also follow protocols like accepting prescription drugs to be sent back to an authorized DEA destruction site and no employee can be part of the program if they have a history with controlled substance-related felonies. The pharmacy may not sort, count, or review the unwanted prescription medications once collected and they are required to report tampering of any receptacles to the Board of Pharmacy within 14 days. These pharmaceutical take-back programs only take prescription medications.</p> <p>3) California Senate Bill 212 On September 30, 2018, California passed Senate</p>	<p>suggested public interest in these programs as well as the potential of these programs to reduce non-medical use of prescription medications and the environmental impact of improper medication disposal.⁵</p>	<p>Bill 212: Solid waste: pharmaceutical and sharps waste stewardship. Similar to the Alameda County Ordinance, this is a statewide drug and needle program funded by manufacturers or distributors. The bill requires that these entities create their own stewardship program or be part of a stewardship program, which will be approved by CalRecycle. The bill mandates a minimum of 5 collection sites per county or if the county is larger it requires 1 per 50,000 people. They also require retail pharmacies to serve as an "authorized collector." Authorized collectors serve their counties in one location or 15% of store locations in the county, depending which is greater. The bill began in January 2019, and would require CalRecycle to adopt regulations for the administration of the bill's provisions, with an effective date of no later than January 1, 2021.</p>
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Several states have legislation that authorizes and guides proper drug disposal programs for consumers such as Maine (ME Statutes 22 604), Ohio (OH HB 93), and Washington (WA HB 2600). Some states have legislation that prohibits health care institutions from flushing unused medications into public wastewater as in Illinois (IL SB 1919). Other states provide public guidelines and educational materials about proper drug disposal such as Connecticut (CT-Medicine disposal), Florida (FL-Unwanted medications), New York (NY-Proper drug disposal), and New Jersey (NJ DEP-Medication disposal).⁸ The DEA has two drug take-back events each year- April and October. These Take Back Days are part of a mission to create safe medication disposal sites, prevent drug diversion or transfer of the prescribed drug for illicit use, and provide education for the public. In April 2017, the 13th National Drug Take Back Day included 5,498 collection sites across the country and 450 tons unused or expired prescription medicines were collected. Additionally, The National Association of Drug Diversion Investigators (NADDI) sponsors a website to locate Rx Drug Drop Boxes for safe medication disposal outside of National Prescription Drug Take-Back Days.

The April 2018 event collected 474.5 tons of unused medications, preventing these drugs from entering landfills and waterways. Recently, some companies have begun offering alternate disposal options targeted at consumers and long-term care. These products promise safe disposal and claim to use proprietary processes that change the composition of drugs, rendering them chemically harmless and allowing for trash disposal. However, few dispute these claims and note that these methods do not meet the DEA's standards for destruction of controlled substances⁹

An ideal collection scheme must be,

- ✓ Easy to use and accessible
- ✓ Funded by pharmaceutical industry
- ✓ Free of charge to public
- ✓ Safe for public health
- ✓ Responsible for chemical deactivation of Pharmaceutical waste⁶

Proper drug disposal programs accept expired, unwanted, or unused medicines from designated users and dispose of them responsibly. Programs can use in-person drop-offs, mail-in efforts or permanent secure collection receptacles and can be administered by state or local governments, municipal trash and recycling services, pharmacies, hospitals, clinics, or community organizations partnered with law enforcement. A 2014 amendment to the federal CSA allows the US DEA to register authorized collectors of controlled substances, allowing collection of pharmaceutical controlled and non-controlled substances, but not illicit drugs.⁷

II. Disposal Regulations in European Union (EU)

Unused pharmaceuticals and residues, from prescription and over-the-counter medicines, are reported to be found in surface water, groundwater and seawater worldwide. This creates major health and environmental problems which will worsen in the future due to the expected increase in the use of pharmaceuticals. Studies conducted show that more than 150 different pharmaceutical substances and metabolites have been found in various water bodies in Europe, including in drinking water supplies. The metabolite of a blood lipid regulator medicine, 1, 2, 3-Clofibric acid was the first pharmaceutical residue found in sewage effluent more than 20 years ago.

The European Parliament enacted a Directive regarding the disposal practices of medicinal products in 2001. Directive 2001/83/EC stated that the outer packaging of medications needed to include special disposal precautions. In 2004, the EU put out another directive that further clarified the 2001 directive and called for establishment of medication collection schemes and information regarding specific collection protocols for the state or country be placed on the packaging. Directive 2004/27/EC (relating to medicinal product for human use) obligates Member States to implement appropriate collection schemes for unused pharmaceutical products.¹⁰

A. Drug Take back Schemes in European Countries

A survey was conducted by European Federation of Pharmaceutical Industry Association (EFPIA) in 22 countries and found that 19 countries have schemes for

proper collection and disposal of medicines. Most schemes are managed by local pharmacies and majority is incinerated. The survey result shows the following.

- Most EU Member States now have systems in place to collect unused & expired medicines.
- There is a broad diversity in the scope, operation, funding and costs of these schemes.
- Costs of the schemes range from €400 to €4000 per ton of material destroyed.
- A total of 19,000 tons of medicines (including packaging) was recovered in 2006 from eight countries. 13,000 tons alone came from France.¹¹

The member states vary in disposal practices. Belgium has a National system of waste collection with the participation of pharmacies, pharmaceutical wholesalers and pharmaceutical industry. Pharmaceutical wholesalers are responsible for the cost of collection, removal, transportation to disposal sites. Pharmaceutical industry is responsible for the cost of incinerating the pharmaceutical waste.

According to Hungarian Legislation, Pharmaceutical industry is responsible for the establishment and operation of Disposal System. But they are allowed to transfer this responsibility to Pharmaceutical distributors or to collection agency. The cost of collection system is fully supported by the Pharmaceutical Industry. In Italy, collection is managed at local level by Municipality. The payment is done from the waste tax paid by the citizens. According to Lithuanian national legislation, pharmaceutical waste must be collected separately and treated in accordance with the waste management regulation. But, the current regulation does not cover household pharmaceutical waste and its legal responsibility. At the same time, all community pharmacies are obliged by law to accept unused and expired medicines and transfer them to a licensed pharmaceutical waste management company every three months (Farmacijos statymas nustato 2006/6/22 d. No. X-709, Official Gazette, 2006, Number: 78-3056). The legislation states that the government is responsible for the financing of the system but the role of the different institutions are not clearly defined. Pharmacies are currently responsible for paying for the disposal of collected medicines and for any communication campaigns on the topic. In practice, this means that pharmacies do not communicate widely about their obligation to take back unused pharmaceuticals and sometimes refuse to accept them because of the costs of communication and disposal. Portugal has a national collection system for unused pharmaceuticals (Human and veterinary medicines) called SIGREM – Sistema Integrado de Recolha de Embalagens e Medicamentos fora de uso. This system was implemented by the Portuguese Government in 2001 (Decreto Lei n.º 366-A/97, changed by Decreto-Lei n.º 162/2000, and by Decreto-Lei n.º 92/2006 and by Portaria n.º 29-B/98, de 15 de Janeiro), and is managed by Valormed (www.valormed.pt), a not-for-profit society created by the pharmaceutical industry (APIFARMA – Associação Portuguesa da Indústria Farmacêutica), pharmaceutical distributors (Associação de Grossistas de Produtos Químicos e

Farmacêuticos) and the national pharmacies association (ANF – Associação Nacional das Farmácias).

Pharmacies in the United Kingdom are obliged to take back and sort unwanted and/or unused medicines brought by patients and return these to the National Health Service SI 2014/349. This system only covers household waste. On certain occasions, besides the collections in pharmacies, local collection events are also organized by the NHS. The main aim of the system is to provide an easy

method for disposal of unwanted human medicines, while reducing environmental risk and accidental poisoning. No information regarding disposal is available in Bulgaria and Cyprus.¹²

The details of collection methods, funding agency of EU member states are given in the Table I

Table 1 : Medicine Disposal Schemes in European Countries¹³

Sl. No.	COUNTRY	COVERAGE	FINANCIAL SUPPORT	DISPOSAL SCHEMES
1.	Italy	National	Local government	Associazione Indennizzo Resi (Ass Inde)
2.	France	National	Pharmaceutical industry groups	Cyclamed
3.	Sweden	National	National Government	Community Pharmacy/Municipal collection centers
4.	Finland	National	Local government	Community Pharmacy/Municipal collection centers
5.	United Kingdom	National	Local government	Community Pharmacy/Municipal collection centers
6.	Germany	Only to certain areas	Local government	Community Pharmacy
7.	Bulgaria			No information
8.	Romania	National	Pharmacies	Community Pharmacy collection
9.	Hungary	National	Pharmaceutical industry groups	Community Pharmacy
10.	Croatia	National	Pharmaceutical industry groups	Community Pharmacy, Health centers, Recycling centers
11.	Cyprus			No information
12.	Greece	National	Government, Pharmaceutical industry groups	Community Pharmacy collection
13.	Spain	National	Pharmaceutical industry groups	SIGRE Collection scheme
14.	Portugal	National	Pharmaceutical Industry groups	Valormed- National scheme
15.	Ireland	National	Health safety executive/ Pharmacies	Community Pharmacy
16.	Denmark	National	Local government	Community Pharmacy
17.	Estonia	National	Pharmacies	Pharmacies, Collection centers free of charge
18.	Iceland	National		Community Pharmacy
19.	Poland	National	Local government	Community Pharmacy/Municipal collection centers
20.	Netherland	National	Local government	
21.	Latvia	National	Pharmacies	Community pharmacy/hazardous waste collection sites
22.	Lithuania	National	Pharmacies	Unused medicines from citizens free of charge
23.	Austria	National	Local Government, Pharmacies	Community Pharmacy, Communal recycling centers
24.	Czech Republic	National	Local government	Community Pharmacy
25.	Slovakia	National	National Government	Community Pharmacy
26.	Slovenia	National	Local government	Community Pharmacy
27.	Switzerland	National	National Government	Community Pharmacy, designated centers
28.	Belgium	National	Pharmaceutical industry groups	Community Pharmacy
29.	Luxembourg	National	National Government	Pharmacies, Household waste disposal sites

Hurdles in the Compliance of Disposal Regulations

According to a new analysis from the Government Accountability Office (GAO), about 4 million Americans reported misusing prescriptions in the prior month, and deaths related to opioid abuse are skyrocketing. Currently, there are three approaches to disposing of unused prescription drugs that are sanctioned by the DEA- special disposal bins installed at pharmacies or other registered entities, mail-back programs and take-back events. The problem, the GAO report noted, is that despite thousands of pharmacies, drug makers and distributors, narcotic treatment programs, and hospitals and clinics that are nominally eligible to serve as drug take-back sites, only 3% nationally register to do so. The reasons cited are the cost of purchasing, installing, and managing prescription drug disposal bins; uncertainties over complying with DEA regulations; and the availability of other drug collection efforts.¹⁴

In the United States, the Product Stewardship Institute focuses on setting up take-back programs that are funded by "Extended Producer Responsibility" (EPR) legislation. This mandates manufacturers to pay for the safe disposal of consumer products, such as batteries or paint, at the end of their useful life. There is no federal legislation pending in Congress that would implement Drug-Take-Back programs funded by EPR, but there are 20 such laws for drugs in the U.S. including two statewide laws in Massachusetts and Vermont.¹⁵

Cost is the biggest obstacle for take back programs. Most companies will not engage in expensive take-back initiatives. Walgreens has the largest drug take-back program in the U.S. Walgreens recently accepted funding from a handful of pharmaceutical and health care companies, including Pfizer, to expand the program to an additional 900 locations. Each take-back event costs approximately \$2,000, which does not include drug disposal costs; typically covered by either the DEA or local police. It is reported that medication take-back programs "secure only a small fraction of opioids available for non-medical use and remain in rudimentary stages of implementation" and that the highest rate of patient use of FDA-recommended disposal methods was just 9%.¹⁶

Directive 2004/27/EC (relating to medicinal product for human use) introduces an obligation for Member States to implement appropriate collection schemes for unused pharmaceutical products. But it does not provide any guideline on implementation of schemes & there is significant differences between Member States. A clear information regarding the implementation and efficiency of collection schemes for unused pharmaceuticals throughout Europe is highly scattered and deficient to conduct a comparison between countries and types of schemes have been implemented in the Member States. A strong regulatory framework, which can make a major contribution to environmental protection is required. The key aspects to be considered include

▶ Enforcing of disposal of pharmaceuticals in a right way.

- ▶ EU collection schemes for expired and unused pharmaceuticals must be harmonized.
- ▶ Accountability of the pharmaceutical industry must be increased.
- ▶ Transparency regarding the results of collection schemes implemented in different Member States and enforcing compliance must be increased.
- ▶ Reporting should be harmonized at EU level, so data is comparable between countries.
- ▶ ERA (Environmental Risk Assessments) for all new & old drugs.
- ▶ The adoption of a disposal code for pharmaceutical packaging about the correct disposal of pharmaceuticals and Chemical deactivation.¹⁷

CONCLUSION

Monitoring and detection of Pharmaceutical impact to environment has to be done in priority. As per Government Accountability Office Report, only 3% of eligible pharmacies and other entities voluntarily participate as DEA authorized collectors of unused prescription Drugs. The Stake holders cited cost and uncertainty over proper implementation as main reasons. They prefer to participate in other medicine-take back programs. In Europe, the Directive does not provide any guidelines on implementation of schemes & there are significant differences between Member States. A clear information on the implementation and efficiency of collection schemes for unused pharmaceuticals throughout Europe is highly scattered and deficient. Hence in both countries compliance of disposal regulations still remains a challenge.

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