Regulatory Gaps in Pharmaceutical Waste Management: A Case Study of Malaysia

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DOI: https://dx.doi.org/10.47772/IJRISS.2024.8100066

Received: 04 October 2024; Accepted: 07 October 2024; Published: 04 November 2024

ABSTRACT

Recent scientific studies emphasise the detrimental effects of pharmaceutical residues, such as antibiotics and endocrine disruptors, on aquatic ecosystems, biodiversity, and human health. Improper disposal of pharmaceutical waste poses several risks, including the development of antimicrobial resistance and hormonal imbalances. This paper reviews Malaysia's federal regulations on pollution and waste management to identify gaps in addressing pharmaceutical pollutants. A content analysis approach was employed, involving transcribing, reading, coding, categorizing, and identifying themes within the textual data. Recurring themes were then used to highlight gaps and opportunities for improving pharmaceutical waste management within the existing legal framework. The study discovered that while the current legal framework effectively manages pharmaceutical waste from point sources like healthcare facilities and manufacturing sites, there is a significant regulatory gap concerning household pharmaceutical waste. Such waste is neither regulated under environmental pollution laws nor included in hazardous or solid waste management regimes, posing a considerable risk to the country's environment. The study recommends adopting extended producer responsibility to improve household pharmaceutical waste management and highlights the potential role of solid waste legislation in achieving this goal. By prioritizing pharmaceutical waste regulation and adopting proactive environmental protection measures, Malaysia can safeguard public health, ensure a cleaner ecosystem, and strengthen its commitment to sustainable environmental management. The study also noted that many developed nations have already integrated pharmaceutical markers into their water quality monitoring standards. Therefore, Malaysia should begin monitoring emerging pharmaceutical pollutants as well. Updating the National Water Quality Index to include pharmaceutical residues will further enhance efforts to protect the environment.

Keywords: emerging pollutant, regulation, hazardous waste, waste disposal, environmental law

INTRODUCTION

The presence of pharmaceuticals in the environment has become a global concern due to the significant risks they pose to ecosystems and public health (Rogowska and Zimmermann, 2022). Reflecting the upward trend in global pharmaceutical consumption, recent decades have seen a corresponding increase in demand for pharmaceuticals in Asian countries, driven by population growth and improved living standards in the region (World Health Organization, 2004). This has led to the release of more pharmaceutical compounds, such as oxytetracycline, trimethoprim, and sulfamethoxazole, into surface waters in the region (Hashim et al., 2016), primarily due to the relatively less advanced technology used in wastewater treatment.

Pharmaceuticals can enter the environment during production, use, or through the improper disposal of unused medications from various sources, including healthcare facilities, industry, agriculture, and households. In households, these substances may be introduced through human excretion or by disposing of medications in toilets, sinks, or waste bins (Ariffin and Zakili, 2019). Pharmaceuticals in landfills can contaminate soil and groundwater through leachates. Since conventional wastewater treatment plants are not designed to remove these contaminants, residues can end up in surface water, land, and even tap water (WHO 2012; Huerta-Fontela et al. 2011).

Pharmaceuticals can cause endocrine disruption, have toxic effects, and contribute to the development of

antimicrobial resistance (Verlicchi and Zambello 2015; WHO 2012; Aus der Beek et al. 2016). For instance, Diclofenac has been linked to extremely high mortality rates among vulture species (Oaks et. al, 2004). Additionally, pharmaceuticals containing endocrine-disrupting substances affect the hormonal balance of aquatic animals, interfering with their reproduction and causing deformities (Kern 2011). The accumulation of pharmaceutical residues in the environment also promotes the development of antimicrobial-resistant organisms, a phenomenon driven by the widespread use of antimicrobial medicines in humans, animals, and plant agriculture (World Health Organization 2015). Moreover, some pharmaceutical contaminants with non-degradable lipophilic compounds accumulate in sedimentation sludge (Sokac et al. 2017). A study by Praveena et al. (2018) further demonstrated that such lipophilic pharmaceuticals tend to bioaccumulate in living organisms.

A study by Hanafiah et al. (2023) and Praveena et al. (2018) highlights that pharmaceuticals such as antibiotics and endocrine disruptors have also been detected in Malaysia's surface waters. The country's conventional wastewater treatment plants are not designed to remove pharmaceutical residues. The real risks posed by pharmaceutical waste in the environment make this issue an increasing concern that warrants attention from a legal perspective.

MATERIALS AND METHOD

Located in Southeast Asia, Malaysia is a federation of 13 individual states and three federal territories. This study is qualitative and involves content analysis. According to Erlingsson and Brysiewicz (2017), content analysis aims to systematically transform a large amount of text into a highly structured and concise summary of key results. The process of abstraction of data in each step of the analysis involves transcribing, reading and rereading, coding, categorising, and determining themes (Erlingsson and Brysiewicz, 2017). This technique can be used to examine the nature and frequency of types of legal phenomena or concepts within legal cases or policy documents (Webley, 2010). Following Erlingsson and Brysiewicz (2017) guide on content analysis, this study analysed textual material comprising Malaysia's federal environmental legislation. Relevant federal legislation was gathered from a Malaysian legal database, the Current Law Journal. The key documents reviewed are listed in Table 1 below.

Table 1: Key Malaysian Environmental Legislation and Policy Related to Pharmaceutical Waste Management

Legislation/Policy Title	Description and Scope
Environmental Quality Act 1974 (Act 127)	● Parent Legislation ● Prevention, abatement, control of pollution from residues or wastes, and enhancement of the environment. ● Applicable to the whole of Malaysia
Environmental Quality (Scheduled Waste) Regulation 2005	● Secondary legislation to Act 127 ● Control scheduled waste including pharmaceutical waste from generation until its disposal to protect the environment. ● Applicable to the whole country and any scheduled waste generator.
Environmental Quality (Industrial Effluent) Regulation 2009	● Secondary legislation to Act 127 ● Control the release of effluent into the environment including stipulating the parameters and value limits of such discharges. ● Applicable to the whole country and any premises that discharge effluent into Malaysia's environment (except for certain premises specified by the Regulations)
Environmental Solid Waste and Public Cleansing Management Act 2007 (Act 672)	● Parent Legislation ● Ensure uniformity of law and policy in the management of controlled solid waste and public cleansing to maintain proper sanitation. ● Applicable to Malaysian states which have adopted the Federal legislation

Applying the content analysis approach, these documents were analysed manually using Microsoft Word whereby related provisions and information on pharmaceutical disposal were identified, categorised, and coded. All the data that had been coded were then arranged and categorised based on similarities or the connection of each data. Once all the data were categorised, the researchers identified recurring themes and undertook interpretation structurally – by examining different parts making up the relevant environmental legislative or policy document to discover gaps and potential in the existing legislation to manage pharmaceutical waste in Malaysia.

RESULTS

This section presents the results of the analysis based on three themes: pharmaceutical waste under pollution control laws, hazardous waste law, and solid waste legislation.

Pollution Control Laws and Pharmaceutical Wastes

Under the EQA, Malaysia has explicit prohibitions on polluting the soil, inland waters, or Malaysian waters. However, the prohibition is not applicable if the discharges do not contravene the acceptable conditions. Acceptable conditions refer to standards that set the maximum concentration of specific parameters per unit of waste discharged into the environment from industrial premises. Release of discharges more than the acceptable conditions requires a licence. Therefore, the prohibition is qualified because polluting is not unlawful if a licence has been obtained.

While it is tempting to argue that pharmaceutical waste is a pollutant, the legal definition is not straightforward. Whether or not the EQA prohibitions on pollution can be used to control the depositing of pharmaceutical waste into the environment depends on whether it falls within the definition of a 'pollutant' or 'environmentally hazardous substance' or 'waste' under the EQA. The EQA defines these terms by relating them to something that can cause pollution.[1] Therefore, the subsequent question will be what is 'pollution' under the EQA? The Act defines 'pollution' as "an act or process, whether natural or artificial, resulting in the introduction of any pollutant into the environment in contravention of the acceptable conditions…".[2] Based on this definition, the legal concept of 'pollution' in the EQA is limited to actions that release pollutants into the environment in amounts exceeding the emission or effluent standards set as acceptable conditions. Therefore, the discharge or disposal of pharmaceutical residues is only prohibited if it exceeds these acceptable limits.

The acceptable conditions for the discharge of effluents from any manufacturing processes into Malaysia's environment are specified by the *Environmental Quality (Industrial Effluent) Regulations 2009* (EQIER). A closer look at the listed parameters shows that none of the parameters directly targets pharmaceutical contaminants specifically. However, the EQIER promotes the adoption of Best Management Practices (BMP) for the discharge of industrial effluents containing certain parameters. It calls for the industry to adopt any practical measures to prevent or reduce the discharge of the listed parameters, which include endocrine disruptors. Many pharmaceutical residues, particularly those related to hormones or hormone-mimicking compounds, act as endocrine disruptors, affecting wildlife and potentially humans by disrupting hormonal balance.

Furthermore, the BMPs also apply to pesticides, fungicides, herbicides, rodenticides, fumigants, or other biocides. These chemicals may also indirectly address pharmaceutical residues in the environment because they often overlap with pharmaceutical pollutants, especially in agricultural runoff or areas where pharmaceuticals are used in combination with such biocides. Nevertheless, the sufficiency of these indirect parameters to protect the environment from unwanted pharmaceutical residues is questionable. The BMP is too vague to be enforced. For example, which endocrine disruptor should be reduced by premises may differ from one to another. This raises questions about what BMP measures to adopt. These legal uncertainties in turn affect implementation by the regulated parties and hinder effective implementation and enforcement.

[1] Environmental Quality Act 1974 (Act 127), Section 2.
[2] Ibid. The acceptable conditions are specified in various regulations made under section 21

As for household pharmaceutical waste (HPW), they cannot be considered pollutants, environmentally hazardous substances, or waste under current Malaysian pollution control laws, as the EQIER specifically stipulates that it applies only to industrial premises. Therefore, no parameters for acceptable conditions have been set for households that could be breached for pollution to occur. Furthermore, the relatively small amount of pharmaceutical waste that individual households generate respectively is generally not considered hazardous. However, this approach overlooks the overall impact of HPW release on the environment.

Hazardous Waste Regulations and Pharmaceutical Wastes

Malaysia's environmental law is very strict when it comes to hazardous waste. The EQA prohibits the disposal of any listed hazardous wastes on land or into Malaysian waters except at prescribed premises only.[3] Prescribed premises comprise off-site storage, treatment, and recovery facilities, apart from scheduled waste incinerators, land treatment facilities, and secure landfills. Disposal of such wastes at other places requires prior written approval of the Director General of the Environment. Import or export of any hazardous waste in or out of Malaysia including transiting of hazardous wastes also subject to similar prohibition and approval. Failure to observe this requirement is punishable with mandatory imprisonment for a term not exceeding 5 years and a hefty fine of not less than RM100,000 and not exceeding RM10 million.

The EQA prohibition applies to all hazardous waste which are listed as scheduled waste under the EQA regulations, namely the *Environmental Quality (Scheduled Wastes) Regulations 2005* (EQSWR). There are five main broad categories of scheduled wastes under the Regulations, as shown in Table 2, each category has many subcategories.

Table 2. Categories of Scheduled Waste

Code	Category Description
SW1	Metal and metal-bearing wastes
SW2	Wastes containing principally inorganic constituents which may contain metals and organic materials
SW3	Wastes containing principally organic constituents which may contain metals and inorganic materials
SW4	Wastes which may contain either inorganic or organic constituents
SW5	Other wastes

Pharmaceutical waste can be categorised into a few relevant subcategories under category SW4 for wastes that may contain either inorganic or organic constituents, as shown in Table 3. The EQSWR stipulates the legal obligations of waste generators and the requirements for managing scheduled waste at the premises of waste generators, including transportation, treatment, recycling, recovery, and final disposal. These wastes are typically disposed of in scheduled waste incinerators.

Table 3. Subcategories of Scheduled Waste Associated with Pharmaceutical Waste

Code	Subcategory Description
SW403	Discarded drugs containing psychotropic substances or containing substances that are toxic, harmful, carcinogenic, mutagenic, or teratogenic
SW 404	Pathogenic wastes, clinical wastes, or quarantined materials
SW421	A mixture of scheduled wastes
SW422	A mixture of scheduled and non-scheduled wastes

[3] EQA, section 34B.

The EQSWR does not specify the source of scheduled waste, nor is its definition determined by the 'polluting' element. Additionally, the definition of scheduled waste does not set any minimum or maximum quantities for waste to be considered hazardous. The regulations also define a 'waste generator' as anyone who generates scheduled waste. Given these factors, it could be argued that pharmaceutical waste from households may fall under the broad scope of the EQSWR. However, despite the potential applicability of the EQSWR to manage household pharmaceutical waste, the regulations and their current implementation primarily focus on controlling waste from industrial generators and healthcare premises.

Solid Waste Regulations and Pharmaceutical Wastes

Solid waste management in Malaysia is regulated by the *Solid Waste and Public Cleansing Management Act 2007* (Act 672) ("the SWPCA"). The SWPCA is comprehensive in coverage addressing the collection and disposal of solid waste from commercial centers, public sites, construction sites, households, industrial zones, and institutions, such as schools and universities. These wastes are known as controlled solid waste. Due to the division of powers between Federal and State Governments, the SWPCA only applies in Malaysian states which have accepted it. To increase the recycling rate and improve the management of solid waste in the country, the legislation makes it mandatory for Malaysians to separate their waste at the source, including household waste (Mangsor and Low, 2023). Accordingly, the SWPCA regulates the establishment of solid waste management facilities for the handling, storage, separation, transport, transfer, processing, recycling, treatment, and disposal of solid waste.

The SWPCA interprets solid waste as including "any substance required to be disposed of as being broken, worn out, contaminated or otherwise spoiled" as well as "any other material that according to this Act or any other written law is required by the authority to be disposed of".[4] Such solid waste does not include scheduled wastes as prescribed under the EQA. Therefore, pharmaceutical waste from healthcare facilities or production premises is not covered by the SWPCA. However, pharmaceuticals from households may fall under the ambit of the SWPCA because unwanted medications from a household could be considered 'required to be disposed of' even if they are not broken, worn out, contaminated, or spoiled. The key factor here is whether the medication is required to be disposed of by some authority or regulation, such as a health or environmental law. Nevertheless, there is currently no regulation to manage household pharmaceutical waste under the SWPCA.

Additionally, the SWPCA mentions 'special solid waste,' which refers to any kind of controlled solid waste, including household solid waste, that may be deemed dangerous to public health and requires special provisions for handling. The SWPCA also includes provisions allowing the Minister to require manufacturers to operate a 'product take-back' system or implement the 'extended producer responsibility' (EPR) concept. These provisions offer a potential framework for regulating HPW in Malaysia through the EPR concept, which could include a medicine take-back program if Malaysia chooses to adopt that approach.

DISCUSSION

Malaysia's federal legislative framework on pollution control does not address pollutants or waste released by households, including their cumulative environmental impact. The laws also do not govern the quality of environmental media like rivers as they set no emission value or standard for such water bodies. Additionally, the various legal prohibitions on causing pollution do not address emerging pollutants, such as pharmaceutical residues (Othman and Ariffin, 2019). This regulatory gap has significant consequences, rendering technological or procedural barriers, as well as existing legal parameters aimed at controlling pollution, ineffective in addressing pharmaceutical waste.

Amending the EQA and its regulations to include pharmaceutical residues in pollution prohibitions is crucial for preventing further pharmaceutical waste from entering our ecosystem, particularly water bodies. This can be achieved by adding specific chemical markers or compounds, such as Diclofenac, Carbamazepine, and ethinylestradiol, as parameters in acceptable conditions under the EQA regulations. Alternatively, if the country is not yet ready for binding legal requirements, Malaysia could begin by monitoring compounds commonly

[4] SWPCA, Section 2.

associated with pharmaceuticals found in water bodies through the National Water Quality Index (WQI). The existing WQI has been in place for more than 25 years and only employs seven parameters which are general indicators of water quality and pollution levels but do not target or detect the presence of pharmaceuticals.[5] Studies on the analysis of the occurrence, detection, and assessment of pharmaceutical compounds in Malaysian rivers have focused on certain common pharmaceutical compounds (Al-Odaini et al. 2013). Further studies can help the authority to prioritise which pharmaceuticals should be included in the WQI to ensure monitoring.

Several other developed countries have also taken steps to include pharmaceutical markers in legislation or regulatory frameworks concerning water quality and pollution control. The European Union (EU), Canada, and Australia are taking steps to monitor pharmaceuticals in water due to their environmental risks, though direct regulations are limited. The EU, for instance, tracks pharmaceuticals like Diclofenac and hormones under the Water Framework Directive Watch List and sets concentration limits through the Environmental Quality Standards (EQS) Directive (European Commission, 2020). The EQS sets concentration thresholds for specific pollutant levels in environmental media, below which no harmful effects occur. These standards consider local environmental conditions and dilution at discharge points, regardless of their source or distribution method (Inglezakis et. al., 2016). Meanwhile, Canada prioritises pharmaceuticals like ethinylestradiol for monitoring under its environmental legislation (Government of Canada, 2017), while Australia assesses pharmaceuticals like Carbamazepine and estradiol under its water management strategy (Department of Climate Change, Energy, the Environment and Water, 2019). Despite the lack of direct regulations, these countries are incorporating pharmaceuticals into their water management strategies to address potential environmental and health impacts.

Additionally, in the U.S., the Environmental Protection Agency is required to periodically develop a list of contaminants that are not regulated but may pose a health risk. This list is called the Drinking Water Contaminant Candidate List (National Research Council 2001 (USEPA 2018). Something like the candidate contaminant list in the US can be set up to prioritise the pollutants of concern in Malaysia, which should be further evaluated in terms of their occurrence and toxicity. Those that top the list can then be included in the Water Quality Index for periodical monitoring by the environmental agency. Subsequently, pollutants that are found to occur widely can then be included in the regulatory standards for water pollution control.

Concerning pharmaceutical waste from households, the EQIER does not cover such HPW as the regulations and existing enforcement focus on industrial premises and healthcare facilities. Besides, there is also an ambiguity on the applicability of the scheduled waste regime to HPW (Ariffin and Zakili 2019). For now, the SWPCA offers a better legal basis for the management of HPW. The existing separation at source regulated by the Act may be extended to pharmaceutical wastes from residential premises. The SWPCA has a few general provisions that can be developed to deal with HPW as special controlled waste and through the EPR concept. Like in many countries, the collection and management of HPW may start as voluntary schemes for households. The EPR places the responsibility on producers to manage their products, which have come to the end of life (Inglezakis and Moustakas 2015).[6] Generally, under such a voluntary programme, householders must sort and segregate the HPW, store it, and then transfer it to a collection site. Therefore, the implementation of EPR in Malaysia could potentially be governed by the SWPCA.

CONCLUSION

In conclusion, Malaysia's current federal legislative framework on pollution control presents significant gaps, particularly in addressing household pollutants and their cumulative environmental impacts. The discovery of active pharmaceutical ingredients in Malaysian rivers should have attracted both public and governmental scrutiny of pharmaceutical waste management practices due to their potential adverse effects on human health and the environment. Since pharmaceuticals enter the ecosystem through various waste streams involving multiple public and private sectors, as well as households, it is crucial to recognize that several existing

[5] The Biochemical Oxygen Demand (BOD), Chemical Oxygen Demand (COD), Suspended Solids (SS), Ammoniacal Nitrogen (NH3-N), Dissolved Oxygen (DO), pH, and Total Suspended Solid (TSS).

[6] Examples of EPR legislation include the EU WEEE Directive and the associated Restriction of Hazardous Substances, and the Japanese Home Appliance Recycling Law 2001.

regulations are relevant to addressing this issue. Unfortunately, regulations often neglect emerging pollutants like pharmaceuticals due to insufficient data on their occurrence and associated risks.

This neglect is evident from the current study's findings, which identified a lack of acceptable conditions set for the release of pharmaceutical residues and the absence of emission value for such pollutants in environmental media. While the EQSWR imposes conditions on the disposal, transport, and receipt of hazardous waste, these regulations do not apply to the disposal of wastes from domestic households or place any obligations on householders. Thus, more insights and data related to the disposal of pharmaceuticals and their environmental impact are needed in the Malaysian context.

To address these concerns, it is imperative to amend existing laws to incorporate pharmaceutical compounds into pollution prohibitions and monitoring frameworks. Adding new parameters related to pharmaceutical waste to the WQI will ensure regular monitoring and allow authorities to impose regulatory effluent standards on pharmaceutical waste discharges and drinking water standards when necessary. Moreover, a more comprehensive participation from pharmaceutical industry players, including producers, supported by regulations applying the Extended Producer Responsibility (EPR) principle, should be considered.

Learning from the regulatory approaches of developed countries such as the European Union, Canada, and Australia can provide valuable insights into integrating pharmaceuticals into water quality legislation. By prioritising the regulation of household pharmaceutical waste and fostering a proactive approach to environmental protection, Malaysia can safeguard public health and ensure a cleaner and safer ecosystem for future generations. These steps are essential for reinforcing Malaysia's commitment to sustainable environmental management and addressing the pressing risks posed by pharmaceutical pollutants.

ACKNOWLEDGEMENTS

The author would like to acknowledge that this research did not receive any financial support or grants.

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Data Availability Statement

The datasets analysed during the current study are available from the corresponding author upon reasonable request.