

An Exploratory Study of Offence Prevalence in Retail Pharmacies in Malaysia

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ABSTRACT

The Pharmacy Enforcement Division (PED) as an enforcement agency is responsible for ensuring that all pharmacy premises with Type A license holders adhere to the rules and regulations enforced. Despite routine inspection and warning letters issued by the PED, Drug Enforcement Officers (DEO) still find offences being committed during subsequent inspections. Offences committed affect the renewal of their licenses, and eventually, their business operations. Nevertheless, there is limited study on the trends of common offences committed by Type A license holders in retail pharmacies in Malaysia.

INTRODUCTION

The Pharmacy Enforcement Division (PED) plays an important role in ensuring that pharmaceuticals, traditional medicines and cosmetics available in the market are genuine, in terms of product registration and cosmetic notification.¹ It also acts to ensure that the link between supply and marketing, and the advertising of the products (including medical services) and their usage, are managed and comply with the provisions of existing legislations. This is performed via enforcement and prevention activities, control of licensing, monitoring, and consumer awareness activities to reduce the demand for unsafe or hazardous products.² In Malaysia, there are five acts currently being enforced by authorities related to the medicines and advertisement: Poisons Act 1952 (PA 1952), Sale of Drugs Act 1952 (SODA 1952), Registration of Pharmacists Act 1951 (ROPA 1951), Medicines (Advertisement and Sale) Act 1956 (MASA 1956), and Dangerous Drugs Act 1952 (DDA 1952).

One of the monitoring activities carried out is conducting inspection on the pharmacy

¹ *Pharmacy Enforcement Division*. (n.d.). Pharmaceutical Services Programme. Retrieved June 21, 2022, from <https://www.pharmacy.gov.my/v2/en/content/pharmacy-enforcement-division.html>

² *Pharmacy Enforcement Division*. (n.d.). Pharmaceutical Services Programme. Retrieved June 21, 2022, from <https://www.pharmacy.gov.my/v2/en/content/pharmacy-enforcement-division.html>

premises of Type A license holders. Type A licences are issued under the Poisons Act 1952 to a registered pharmacist to import, store, and generally deal with poison by wholesale and retail, by wholesale only, or by retail only³. Drug Enforcement Officers (DEO) appointed under the Poisons Act 1952 conduct routine inspections to ensure compliance with the laws enforced. During these inspections, they observe for any non-compliance of laws enforced related to the supplying, recording, labelling and storage of controlled medicines and any specific requirements related to the license. The results of the inspection must be satisfactory before they can proceed with license renewal procedures for the following year. For remedial action, any non-compliance encountered is followed by the issuance of a warning letter, and the license holder is obliged to make corrections so that all the legal requirements are fulfilled.

Despite these efforts, DEO still found offences being committed during subsequent inspections. Offences committed affect the renewal of the licenses, and eventually, the business operations. According to a study conducted by Pharmaceutical Services Division, Kedah State Health Department⁴, 42.3% of License A holders were issued warning letters as compared to other license holders. From this figure, one third were repeated offences committed in the following year, although inspections were carried out routinely. However, this study does not critically analyse on the particular type of offence committed for all of Malaysia. A more specific approach that addresses the issue specifically is crucial. Nevertheless, there is limited analysis on the trends of common offences committed by licensed retail pharmacies in Malaysia.

Therefore, this study aims to explore the prevalence of offences in retail pharmacies so that the most common offences can be identified, and eventually, a more specific approach can be developed. The results of this study are important to the PED, as it could lead to proper planning for the most effective method to enforce the law, with the ultimate goal of increasing compliance among retail pharmacists.

³ Poisons Act 1952 (Malaysia), S26

⁴ Aimi bt Ishak A, Noraishah bt Abu Bakar, et. al. (2019) *A Cross Sectional Study: Prevalence of Repeated Offences by Licensed Premises under Pharmaceutical Services Division, Kedah* [Unpublished manuscript].

GENERAL OBJECTIVE

To explore the prevalence of offences in retail pharmacies.

SPECIFIC OBJECTIVES

1. To identify the prevalence of offences in retail pharmacies
2. To categorize the type of common offences in retail pharmacies
3. To make recommendations to increase the compliance to the law enforced

METHODOLOGY

STUDY TYPE AND DESIGN

This is a quantitative cross sectional retrospective study that analyzed the types of offences recorded in the warning letters issued in 2018-2019 to all licensed retail pharmacists in Malaysia. All licensed retail pharmacies that have been issued with warning letters in the years 2018 and 2019 were included in this study. Premises with Type A Licenses for wholesale only were excluded from this study.

Once the premises were identified, all the information about them (location, type of business, and type of license), and types of offences stated in the warning letters, were collected and recorded to identify common offence trends.

SAMPLE SIZE

No sample size calculation was involved. All the pharmacy premises of Type A license holders that have been issued with warning letters in the years 2018 and 2019 were recruited in this study. Premises with Type A Licenses for wholesale only were excluded from the study.

STUDY INSTRUMENT

In this research, all the warning letters issued in the years 2018-2019 were extracted from a centralized system, My.Pharma-C managed by PED. The data extracted includes location,

type of license, type of business, and types of offences. All these data were then recorded in a spreadsheet.

STATISTICAL ANALYSIS

The data collected was entered into a spreadsheet for subsequent data analysis. The numerical data was presented in mean and standard deviation if it was normally distributed. Otherwise, the median and inter-quartile range were analyzed. Categorical data was presented in frequency and percentage.

RESULTS

Table 1: Demographics of retail pharmacies issued with warning letters in 2018-2019

	Number of Premises (n=397)	
	n	(%)
State		
Selangor	181	(45.59)
Kedah	41	(10.33)
Johor	38	(9.57)
Perak	31	(7.81)
Negeri Sembilan	28	(7.05)
WPKL	23	(5.79)
Pulau Pinang	21	(5.29)
Sarawak	18	(4.53)
Terengganu	6	(1.51)
Perlis	4	(1.01)
Melaka	3	(0.76)
Pahang	3	(0.76)
Type of License		
Retail	363	(91.44)
Wholesale & Retail	34	(8.56)
Type of Business		
Sdn Bhd	303	(76.32)
Enterprise	92	(23.17)
Bhd	1	(0.25)
PLT	1	(0.25)
Number of offences per premise		
1	198	(49.87)
2	91	(22.92)
3	62	(15.62)

4	29	(7.30)
5	11	(2.77)
>5	6	(1.51)

Repeated offences (n= 32)

Selangor	19
Kedah	6
Negeri Sembilan	2
Perak	2
Perlis	2
Sarawak	1

Table 1 shows the demographics data of retail pharmacies being issued with warning letters in 2018-2019. A total of 397 retail pharmacies were issued warning letters in 2018-2019. Out of 397 premises, 32 premises were issued warning letters for both 2018 and 2019. Warning letters were issued mostly in premises in Selangor (45.59%). Analysis reveals that the number of premises with Type A licenses [Retail only] (91.44%) was the highest being issued warning letters as compared to premises with Type A Licenses [Wholesale & retail only]. In terms of ownership, retail pharmacies with a “Private Limited Company” module had the highest percentage (76.32%) as compared to others. Generally, almost half of the retail pharmacies (49.87%) committed at least one offence only throughout 2018-2019.

Table 2: Offences by Pharmacy Premises in 2018-2019 based on Acts and Regulations

Acts & Regulations	Number of Offences (n=779)	
	n	(%)
Poisons Act 1952	553	(70.99)
Poisons Regulations 1952	153	(19.64)
Poisons (Psychotropic Substances) Regulations 1989	34	(4.36)
Control of Drugs & Cosmetics Regulation 1984	22	(2.82)
Medicines (Advertisement & Sale) Act 1956	15	(1.93)
Registration of Pharmacists Act 1951	2	(0.26)

From 379 premises being issued warning letters, 779 offences were identified. Analysis reveals that the common Acts and Regulations being infringed by retail pharmacies in

Malaysia are Poisons Act 1952 (70.99%), Poisons Regulations 1952 (19.64%), Poisons (Psychotropic Substances) Regulations 1989 (4.36%), Control of Drugs & Cosmetics Regulation 1984 (2.82%), Medicines (Advertisement & Sale) Act 1956 (1.93%), and Registration of Pharmacists Act 1951 (0.26%). Based on Table 2, most of the offences identified (94.99%) were from the Poisons Act 1952 and its Regulations.

Table 3: Common offences by Pharmacy Premises in 2018-2019

Variables	Number of offences (n= 689)	
	n	(%)
Prescription	179	(25.98)
S21(1) AR52	65	
S21(2) AR52	46	
S21(4) AR52	67	
S21(5) AR52	1	
Terms & Conditions of the License	168	(24.39)
S13(b) AR52	168	
Prescription book	153	(22.21)
S24 AR52	153	
Storage	119	(17.27)
P6 PR52	119	
Labelling	36	(5.23)
P9 PR52	8	
P11(1) PR52	1	
P12 PR52	27	
Psychotropic Substances	34	(4.94)
P11(1) PR(BP)89	2	
P11(2) PR(BP)89	1	
P11(4) PR(BP)89	6	
P22(b) PR(BP)89	17	

P23 PR(BP)89	3
P24 PR(BP)89	5

From Table 3, out of 779 offences identified, most (n=689) can be categorized into six types of common offences, which are involving prescriptions (25.98%), Terms & Conditions of the License (24.39%), Prescription book (22.21%), Storage (17.27%), Labelling of Controlled medicines (5.23%), and Psychotropic Substances (4.94%). Further analysis shows that the highest common offence in the prescription category is regarding the endorsement of the prescriptions by license holders. The least common offence identified in this study was the governance of psychotropic substances category, which is generally related to the register of the psychotropic substances and prescription requirements for psychotropic substances.

DISCUSSION

In this study, the six most common offences pharmacy premises were categorized from the 779 offences identified via warning letters issued in 2018-2019. Most of the offences identified involved prescriptions of the manual recording procedure, which is much more time-consuming and increases pharmacist workload, such as endorsements on the prescriptions, recording for the 15 controlled substances which are listed in the Type A license terms and conditions, prescription books, dispensed medicine labelling and the supply register of psychotropic substances. By enforcing the Poisons Act (Amendment) 2022, these common offences related to manual recording procedures can be minimized by introducing electronic recording and prescription among community pharmacies. This is supported by the study of Cicola & Peres⁵, which demonstrated that using electronic means provides benefits in terms of timing, precision, and reliability in the management and care work process in health services. However, further research needs to be conducted to review the effectiveness of the Act in terms of electronic recording and prescription.

Besides that, most of the offences (94.99%) were from the Poisons Act 1952 and its Regulations. Although frequent dialogues with license holders and annual inspections conducted before the renewal of licenses each year, license holders still do not pay attention to what is being enforced in regulating dispensed medicines. This condition is similar to the study conducted by the Pharmaceutical Services Division, Kedah State Health Department⁶. Therefore, strict action such as scheduled forensic assessments should be conducted for license holder to allow only the fit and proper personnel to hold this license.

Lastly, the most common offences by pharmacy premises are related to prescription offences such as incomplete prescription, endorsement on prescription, dispensing without the prescription or no prescription being shown during the inspection. Although the dispensing of psychotropic substances requires the prescription to be kept for a period of at least two (2) years⁷, there is not a requirement for the other dispensed medicines scheduled in the Poisons Act 1952 to be kept for verification purposes during DEO inspection. This can create

⁵ Cicola, E. A., & Peres, H. H. C. (2019). Electronic and manual registration of Manchester System: reliability, accuracy, and time evaluation. *Revista Latino-Americana de Enfermagem*, 27.

⁶ Aimi bt Ishak A, Noraishah bt Abu Bakar, et. al. (2019) *A Cross Sectional Study: Prevalence of Repeated Offences by Licensed Premises under Pharmaceutical Services Division, Kedah* [Unpublished manuscript].

⁷ Poisons (Psychotropic Substances) Regulations 1989 (Malaysia), R11(7)

a lacuna for license holders to avoid adherence to prescription requirements by not keeping the prescription for inspection purposes, which can increase the burden for DEO to prove illegal transactions. Hence, the current legislation should be amended in order to fill in the gap from being misused by license holders.

CONCLUSION

This study managed to explore the prevalence of offenses committed by licensed retail pharmacies in Malaysia. Overall, the six (6) most common offences identified in this study are related to prescription (25.98%), compliance to terms & conditions of the license (24.39%), prescription books (22.21%), storage (17.27%), labelling of controlled medicines (5.23%) and the psychotropic substances (4.94%). From the result showed, there is a need to formulate a more strategic approach and stricter actions to increase the adherence of the license holder thus increasing the quality of services by retail pharmacies

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