https://doi.org/10.31351/vol33iss2pp86-91

Compliance Towards the Malaysian Laws on Poisons and Sale of Drugs: a Retrospective Observational Study in The State of Sarawak

Luqman Nulhakim bin Said [*,1], Loo Shing Chyi[1], Benodict Apok anak Talin[1], Cannilia Kerine[1], Lily Siao[1], Lu Sing Ling[1], Wan Aziyani Yazmin binti Wan Yeit[1] and Tan Sin Min[1]

[1]Sarawak Pharmacy Enforcement Branch, Sarawak State Health Department, Malaysia

[*]**Corresponding author**

Received 28/3/2023, Accepted 30/5/2023, Published 27/6/2024

Abstract

Compliance with the laws and regulations on the sale and supply of medicine ensures that it is conducted safely and professionally.

This study identified the compliance rate of community pharmacists and general practitioners in the state of Sarawak towards the Malaysian Laws on Poisons and Sale of Drugs and review the effect of the enforcement actions taken by the Sarawak Pharmacy Enforcement Branch.

This was a retrospective observational study where the data were extracted retrospectively from the annual inspection reports on community pharmacists and general practitioners conducted by the Sarawak Pharmacy Enforcement Branch from 2016 to 2020. Data were extracted using a self-developed data collection tool by trained enforcement officers. Overall, 50 criteria were examined but 24 more criteria were also examined for community pharmacists.

The compliance rate of community pharmacists has improved slightly from 58.6% in 2016 to 61.1% in 2020. In the meantime, the rate of compliance among general practitioners went from 35.9% in 2016 to 71.2% in 2020, which is a big jump. The recording provisions on the supply of substances containing codeine, dextromethorphan, ephedrine, and pseudoephedrine (12.3%–24.1%) and the prescription book (7.7%–27.6%) were the most common non-compliance recorded for all the 5 years among community pharmacists and general practitioners, respectively. Enforcement action (issuance of warning letters) was found to induce a major (79.5%) improvement in the compliance rate.

Community pharmacists and general practitioners' compliance rate have improved throughout the years. The highest non-compliance rate was towards the recording provision on the supply of medicine. Constant assessment of the compliance rate, as well as the effectiveness of enforcement actions, must be done regularly.

Keywords:Community pharmacists, General Practitioners, Malaysian Laws on Poisons and Sale of Drugs, Compliance.

Introduction

The World Health Organisation defines the rational use of medicine as "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community."[(1)] Globally, countries have placed the rational use of medicine as one of the major priorities in healthcare with the best care for patients being its main focus.

All healthcare professionals have the professional obligations to deliver the best practices by practising rational use of medicine. In ensuring that rational use of medicine is practised, enforcement and regulatory activities around medicines are strengthened.[(2)] The existing laws of Malaysia with regards to medicines is the Malaysian Laws on Poisons and Sale of Drugs. The laws include the Poisons Act 1952 (Act 366) & Regulations, Sales of Drugs Act 1952 (Act 368) & Regulations, Registration of Pharmacists Act 1951(Act 371) & Regulations and Medicines (Advertisement and Sale) Act 1956 (Act 290) & Regulations.[(3)] These laws and regulations placed legal obligations towards healthcare professionals to abide to the aforementioned laws. Compliance towards the laws and guidelines are very important as it ensures that the stakeholders are playing their parts. In Malaysia, Malaysian Laws on Poisons and Sale of Drugs and other specific guidelines with regards to medicines exist and become the references for the best standard of practice. By practising the best standard of practice, positive

health outcomes can be achieved. For example, dispensed medicine labels are required by law to include specific information to guide patients on how to take their medicine once they are home and advertisements on medicine are prohibited from advertising it as cure to chronic diseases to protect the general public.[3]

Sarawak Pharmacy Enforcement Branch has been conducting inspections on community pharmacists and general practitioners regularly. The inspections focused on their compliance towards the Malaysian Laws on Poisons and Sale of Drugs. Additionally, the compliance of community pharmacists towards the Community Pharmacy Benchmarking Guidelines 2016 are also assessed. The requirements based on the laws and guidelines are included in a checklist for Sarawak Pharmacy Enforcement Branch officers to assess during inspections. The findings of the inspections are then reported. All forms of noncompliance are documented in the report, which will then be forwarded to the superiors in Sarawak Pharmacy Enforcement Branch.

Sarawak Pharmacy Enforcement Branch has only assessed the compliance of community pharmacists and general practitioners based on the inspection reports from 2012-2014 previously. The findings were published in 2017 and has shown that the compliance rate of community pharmacists and general practitioners were around 50% and many forms of noncompliance were reported.[5] However, changes to policies have been seen and the Community Pharmacy Benchmarking Guidelines had only been formulated in 2016. Hence, the findings from the previous study may not reflect the current practices of community pharmacists and general practitioners.

Many contemporary studies on the matters of compliance towards the laws and guidelines on medicines and the effectiveness of actions taken by enforcement and regulatory bodies are published in recent years, especially from developing countries. However, Malaysia has been left behind in this regard. The previous two studies on the subject of compliance of community pharmacists and general practitioners in Malaysia may not reflect the current situation.

Therefore, this study will fill the void in literature and the practical one and will serve as a contemporary study reporting the compliance rate of community pharmacists and general practitioners, the prevalence of noncompliance & the effectiveness of enforcement actions taken by Sarawak Pharmacy Enforcement Branch. These findings will help policy makers grasp the current practices of community pharmacists and general practitioners.

Methods

This study was a retrospective observational study, in which annual inspection reports by the Sarawak Pharmacy Enforcement Branch on community pharmacists and general practitioners from January 1, 2016 until December 31, 2020 were reviewed. Noncompliance with the Malaysian laws on poisons and the sale of drugs, as well as the enforcement actions taken, were analysed.

The study involved community pharmacists who practised in community pharmacies in Sarawak and general practitioners who practised in private medical clinics in Sarawak from January 1, 2016 until December 31, 2020. The sample size was calculated based on the prevalence of noncompliance with the Malaysian Laws on Poisons and Sale of Drugs among community pharmacists and general practitioners reported by Ting et al. in 2017. [5] Naing L et al. used sample size calculators for prevalence with a study confidence interval of 95%, a normal distribution, and a 5% margin of error with the known amount of population was used. [6] The sample sizes calculated were 147 community pharmacists and 174 general practitioners. Universal sampling was employed, in which all annual inspection reports from 2016 to 2020 were included. Inspection reports that were not done annually and those without details on enforcement actions were excluded.

The study involved community pharmacists who practised in community pharmacies in Sarawak and general practitioners who practised in private medical clinics in Sarawak from January 1, 2016 until December 31, 2020. The sample size was calculated based on the prevalence of noncompliance with the Malaysian Laws on Poisons and Sale of Drugs among community pharmacists and general practitioners reported by Ting et al. in 2017. [5] Naing L et al. used sample size calculators for prevalence with a study confidence interval of 95%, a normal distribution, and a 5% margin of error with the known amount of population was used. [6] The sample sizes calculated were 147 community pharmacists and 174 general practitioners. Universal sampling was employed, in which all annual inspection reports from 2016 to 2020 were included. Inspection reports that were not done annually and those without details on enforcement actions were excluded.

Data collection forms were developed. The data collected were the details of the noncompliance and enforcement actions taken at all levels. Data were entered into Microsoft Excel by the research team members and subsequently validated by the Principal Investigator. The validated data were subsequently imported into SPSS version 21.0. Descriptive statistics in numbers and percentages are used to present the findings.

Compliant community pharmacists and general practitioners were defined as those who did not commit any noncompliance. The compliance rate was calculated based on the year of inspection

and was defined as Annual Compliance Rate. It was calculated based on the following formula:

$$\textbf{Annual Compliance Ratea} = \frac{\textbf{Number of compliant CP/GP in the particular year}}{\textbf{Number of CP/GP inspected in the particular year}}.$$

Annual Compliance Rate are presented in percentages. Independent t-test was used to statistically analyse the comparison. The prevalence of noncompliance committed by community pharmacists and the effective enforcement actions was also calculated. Effective enforcement actions were calculated based on the following formula:

$$\textbf{Effective Enforcement Action} = \frac{\textbf{Number of improvement after enforcement actions}}{\textbf{Number of enforcement actions taken}}$$

Results

From 2016 to 2020, 203 community pharmacists and 156 general practitioners had their annual inspection reports included. Table 1 shows the annual compliance rate with the prevalence of noncompliance with specific acts and regulations enforced.

Table 1. Annual compliance rate with the prevalence of noncompliance with specific acts and regulations enforced

		Frequency, n (%)									
Act & Regulation Enforced	Description of Non-Compliance	2016		2017		2018		2019		2020	
		CP (n= 203)	GP (n= 156)	CP (n= 203)	GP (n= 156)	CP (n= 203)	GP (n= 156)	CP (n= 203)	GP (n= 156)	CP (n= 203)	GP (n= 156)
Poisons Act 1952											
Section 24(1)	Non-compliance towards the recording of Prescription Book	27 (13.3)	43 (27.6)	19 (9.4)	23 (14.7)	16 (7.9)	17 (11.0)	15 (7.4)	12 (7.7)	25 (12.3)	15 (9.7)
Section 26 (4) Condition 6	Storage not abiding to the storage condition as specified on label	1 (0.5)	4 (2.6)	1 (0.5)	1 (0.6)	2 (1.0)	2 (1.3)	1 (0.5)	3 (1.9)	2 (1.0)	7 (4.4)
Poisons Regulations 1952											
Regulation 6 (d)	Poisons not kept in a room or cupboard under lock and key set apart for the keeping of poisons	15 (7.4)	1 (0.6)	16 (7.9)	1 (0.6)	6 (3.0)	2 (1.3)	9 (4.4)	2 (1.3)	14 (7.0)	5 (3.2)
Poisons (Psychotropic Substances) Regulations 1988											
Regulation 19	Non-compliance towards the recording of Psychotropic Substances Records for purpose of medical, dental or animal treatment	1 (0.5)	30 (19.2)	0 (0.0)	9 (5.8)	0 (0.0)	9 (5.8)	0 (0.0)	2 (1.3)	0 (0.0)	8 (5.1)

Continued table (1).

Regulation 22 (b)	Not recording the details required sychotropic Substances Records for purpose of medical, dental or animal treatment	1 (0.5)	9 (5.8)	0 (0.0)	6 (3.9)	0 (0.0)	5 (3.2)	0 (0.0)	2 (1.3)	0 (0.0)	4 (2.6)
Regulation 22 (c)	Cancellation, obliteration or alteration of Psychotropic Substances Records for purpose of medical, dental or animal treatment	1 (0.5)	26 (16.7)	0 (0.0)	21 (13.5)	2 (1.0)	8 (5.1)	0 (0.0)	12 (7.7)	0 (0.0)	10 (6.4)
Control of Drugs and Cosmetics Regulations 1984											
Regulation 7B (b)	Repackaging of medicine from original packaging	1 (0.5)	6 (3.9)	1 (0.5)	7 (4.5)	4 (2.0)	7 (4.5)	1 (0.5)	9 (5.8)	3 (1.5)	6 (3.9)
Medicines (Advertisement & Sale) Act 1956											
Section 4 (B)	Unapproved advertisement of medicines	11 (5.4)	1 (0.6)	1 (0.5)	2 (1.3)	0 (0.0)	0 (0.0)	23 (11.3)	3 (1.9)	7 (3.5)	1 (0.6)

The rate of compliance among community pharmacists went from 58.6% in 2016 to 61.1% in 2020, which is a small improvement. On the other hand, the rate of compliance among general practitioners went from 35.9% in 2016 to 71.2% in 2020. The lowest compliance rates for both community pharmacists and general practitioners were recorded in 2016, which were 58.6% and 35.9%, respectively. There is a significant difference in the compliance rate between community pharmacists and general practitioners in 2016 ($p = 0.000$).

The highest noncompliance rate recorded annually among community pharmacists was noncompliance with Section 26(4) of the Poisons Act 1952, specifically the terms and conditions subjected to community pharmacists. The term and condition were Condition 2, which was on the keeping of records on the supply of substances containing codeine, dextromethorphan, ephedrine, and pseudoephedrine. The highest noncompliance rate was recorded in 2016 (24.1%). 45.9% of the noncompliance with this term and condition was on the recording of the current stock of the substances.

In terms of general practitioners, the highest annual noncompliance rate from 2016 to 2020 was the noncompliance against Section 24(1) of the Poisons Act 1952, which is a noncompliance towards the keeping of prescription book records. The highest noncompliance rate against this provision was recorded in 2016 (27.6%), while the lowest was in 2020 (9.6%). The noncompliance was mainly due to not recording the address of the patient in the prescription book records (69.6%), which is one of the requirements under this section. Compliance with this provision has shown improvement throughout the years, although it has remained the highest noncompliance rate recorded annually. However, there is a significant difference ($p = 0.000$) between the noncompliance rate in 2016 and 2020.

Table 2 shows the enforcement actions taken by the Sarawak Pharmacy Enforcement Branch both during and after inspection. Warning letters seem to be the most effective enforcement action, as the improvement after sending warning letters was at 79.6%. The term "electronic commerce" refers to the sale of electronic goods. However, for community pharmacists, reminder letters showed the highest improvement at 81.5%, while warning letters were the second highest at 75.3%. Noncompliance has shown to provide the lowest improvement at 55.1%, which was 55.4% in community pharmacists and 54.6% in general practitioners.

Table 2. The enforcement actions taken by the Sarawak Pharmacy Enforcement Branch both during and after inspection

Enforcement Actions Taken	CP	GP	Total	CP	Percentage Improvement (CP)	GP	Percentage Improvement (GP)	Total	Percentage Improvement (Total)
Verbal Reminder	130	83	213	93	71.54%	61	73.49%	154	72.30%
Noncompliance Form	531	346	877	294	55.37%	189	54.62%	483	55.07%
Reminder Letter	54	59	113	44	81.48%	42	71.19%	86	76.11%
Warning Letter	89	45	134	67	75.28%	40	88.89%	107	79.85%
Follow-up Inspection	69	37	106	46	66.67%	19	51.35%	65	61.32%

Discussion

Overall Compliance

The lowest compliance rates for both community pharmacists and general practitioners were recorded in 2016, which were 58.6% and 35.9%, respectively. This is an improvement in the compliance rate among community pharmacists, which was reported to be 50.0% in 2014. [5] However, this is a drop in compliance rate among general practitioners, which was 51.0% in 2014. [5] There is a significant difference in the compliance rate between community pharmacists and general practitioners in 2016 ($p = 0.000$).

In 2016, the main areas of noncompliance among general practitioners were the recording of prescription books (27.6%), the recording of psychotropic substances (19.2%), and the labelling of dispensed medicine (16.0%). However, this has largely improved throughout the years through constant engagement with the general practitioners and reminders during inspections.

Records on the supply of Preparations containing Codeine, Dextromethorpan, Ephedrine or Pseudoephedrine

Community pharmacists were found to be most noncompliant with Condition 2, added under Section 26(4) of the Poisons Act 1952. Section 26(4) allows the licencing officer to add any terms and conditions not inconsistent with the act. Condition 2 adds the provision to the record on the supply of any capsule or tablet preparations containing codeine, dextromethorphan, ephedrine, or pseudoephedrine in a book and its maintenance, or, if using a computer, a copy printed into a bound book. This was consistent with the findings by Ting et al. [5] This added condition was enforced with the view of controlling its sales and reducing the potential for diversion. In fact, it has been shown that mandatory recording for such substances in community pharmacies is a promising method for addressing such worries. [8] The Sarawak Pharmacy Enforcement Branch has taken additional steps in addressing these worries with regular audits on the sales and supply of such substances throughout the years. These audits, as well as regular surveillance, can hopefully improve compliance.

Records on Prescription Book

General practitioners recorded the highest number of noncompliance with the recording provision of the prescription book, which is a provision under Section 24(1) of the Poisons Act 1952. The details that are required to be recorded in the prescription book are as follows: (i) date of supply; (ii) name and quantity of medicine supplied; (iii) name of patient or recipient, in cases relating to animal treatment; and (iv) name and address of the person who supplied the medicine. [3] More than half (58.2%) of the noncompliance with this provision was attributed to general practitioners not recording the full address of the patients on the prescription book as required under this provision.

Labelling of dispensed medicine

Regulation 12 of the Poisons Regulations of 1952 governs the labelling of dispensed medicine. This area is of great interest, as multiple studies in the Malaysian setting have assessed the compliance of community pharmacists and general practitioners with this provision. Previous studies on this matter had shown that the compliance of community pharmacists and general practitioners was poor. [5,9,10].

Conclusions

The compliance rate of community pharmacists and general practitioners has improved throughout the years. The highest noncompliance rate was in the recording provisions on the supply of medicine. Warning letters had been the most effective enforcement actions.

Limitations

The findings are not generalizable to the Malaysian population as they only involved community pharmacists and general practitioners in the state of Sarawak.

Recommendations

Future study should involve the community pharmacists and general practitioners in the whole country of Malaysia, so that the findings can be generalizable to the population. Further exploration on the reason behind the practitioners struggle to comply with the recording provisions is warranted as it has been shown by this study that the recording provision had the highest number of noncompliance committed.

Acknowledgments

The authors would like to express their gratitude to the Director General of Health, Malaysia, for his approval to publish this article. The authors would also like to thank the Director of Sarawak State Health Department and the Deputy Director of Pharmaceutical Services Division for their unconditional support and approvals for data collection. Finally, credits to all colleagues in Sarawak Pharmacy Enforcement Branch who have devoted their efforts unreservedly in the data collection process to make this study possible.

Ethics Approval and Consent to Participate

The study was approved by Malaysia Research Ethics Committee with the approval number: NMRR-21-1159-60164 (IIR); KKM/NIHSEC/P21-1319(6)

Consent for Publication

The study has been approved for publication by the Director General of Health, Malaysia.

Availability of Data and Materials

The data sets used and/or analysed during the current study are available from the corresponding author on request.

Competing Interests

The authors declare no competing interests.

Funding

Departmental Operating Fund and no other funding sources.

Authors' Contribution

Conceptualisation: Luqman Nulhakim bin Said, Cannilia Kerine, Ebson Ngumbang, Wan Aziyani Yazmin binti Wan Yeit

Project Administration: Benodict Apok anak Talin

Methodology: Luqman Nulhakim bin Said, Loo Shing Chyi

Data Curation: Cannilia Kerine, Ebson Ngumbang, Lily Siao, Lu Sing Ling, Wan Aziyani Yazmin binti Wan yeit, Tan Sin Min

Investigation: Cannilia Kerine, Ebson Ngumbang, Lily Siao, Lu Sing Ling, Wan Aziyani Yazmin binti Wan Yeit, Tan Sin Min

Formal Analysis: Luqman Nulhakim bin Said, Loo Shing Chyi

Visualisation: Luqman Nulhakim bin Said

Writing – Original Draft: Luqman Nulhakim bin Said

Writing – Review & Editing: Loo Shing Chyi

Supervision: Benodict Apok anak Talin

Validation: Benodict Apok anak Talin

References

1. Board E. Rational use of medicines: progress in implementing the WHO medicines strategy. Ital J Public Health. 2006;3(1):1–7.
2. Division PS. Malaysian National Bibliography. Vol. 20. 2017. 271pp p.
3. Laws of Malaysia. Malaysian Laws on Poisons and Sales of Drugs. 2021.
4. Farmasi BP. Program Perkhidmatan Farmasi (Internet). 2021 (cited 2021 May 30). Available from: https://www.pharmacy.gov.my/v2/ms/entri/bahagian-penguatkuasaan-farmasi.html
5. Ting CY, Loo SC, Ting H, Ang WC, Jabar AHAA. Compliance of Community Pharmacists and Private General Medical Practitioners With Malaysian Laws on Poisons and Sale of Drugs. Ther Innov Regul Sci. 2017;51(4):439–45.
6. L. Naing, T. Winn BNR. Practical Issues in Calculating the Sample Size for Prevalence Studies. Arch Orofac Sci 2006. 2006;1(1):9–14.
7. Alrasheedy AA, Alsalloum MA, Almuqbil FA, Almuzaini MA, Aba Alkhayl BS, Albishri AS, et al. The impact of law enforcement on dispensing antibiotics without prescription: a multi-methods study from Saudi Arabia. Expert Rev Anti Infect Ther (Internet). 2020;18(1):87–97. Available from: https:// doi. org/ 10.1080/14787210.2020.1705156
8. Hattingh HL, Varsani J, Kachouei LA, Parsons R. Evaluation of pseudoephedrine pharmacy sales before and after mandatory recording requirements in Western Australia: A case study. Subst Abus Treat Prev Policy (Internet). 2016;11(1):1–9. Available from: http://dx.doi.org/10.1186/s13011-016-0075-0
9. Neoh C, Hassali M, Shafie A, Awaisu A, Tambyappa J. Compliance Towards Dispensed Medication Labelling Standards: A Cross-Sectional Study in the State of Penang, Malaysia. Curr Drug Saf. 2009;4(3):199–203.
10. Loo SC, Said LN, Nakaswaram L, Hui Lee Y, Ming Yii E, Anak Talin BA. Compliance of Private Primary Health Care Facilities Towards Requirements of Labelling of Dispensed Medicine in Sarawak. Curr Drug Saf. 2022;17(3):176–82.