

The Number of Pharmacy Enforcement Inspections Conducted on Premises without Pharmacists that Sell Over-The-Counter Medicines and Cosmetics (PWPOTC) in Labuan

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Abstract

Introduction: The pharmacy enforcement officers under the Ministry of Health Malaysia routinely inspect the premises without pharmacists that sell over-the-counter medicines and cosmetics (PWPOTC) to ensure the quality, efficacy and safety of the products in the market.

Objective: This study analysed the number and characteristics of PWPOTC inspected for the first time by the Labuan Pharmacy Enforcement Branch from January 2016 to December 2018, within the Federal Territory of Labuan, Malaysia.

Methods: This was a retrospective study that analysed secondary data gathered from the inspection reports of PWPOTC from 2016 to 2018. The list of 435 PWPOTC licensed in 2017 was obtained from the local authority. The PWPOTC were categorised into 24 areas based on their locations in Labuan.

Result: Overall, 300 and 135 PWPOTC were located in the town and outskirts areas, respectively. Of these, 249 (57.2%) of the PWPOTC were inspected, with most (n=181, 72.7%) located in the town areas. Most of the areas with less than half of the PWPOTC being inspected were from the outskirts (8 out of 13 areas), compared to town areas (5 out of 11 areas). Notably, three areas that had none of the PWPOTC being inspected were all from the outskirts. The most common category of PWPOTC being inspected were grocery shops, medicine shops and supermarkets.

Conclusion: The findings reflect the unequal proportion of PWPOTC being inspected in different areas in Labuan. A strategic plan for exhaustive coverage of inspections towards PWPOTC by the authority is urged. Similar studies may also be useful for other pharmacy enforcement branches in Malaysia.

Keywords: inspection, over-the-counter medicines and cosmetics, Pharmacy Enforcement, unregistered

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Introduction

The pharmacy enforcement officers under the Ministry of Health Malaysia (MOH) routinely inspect licensed premises that sell or manage medicines such as pharmacies and clinics. Inspections can also be carried out on premises without pharmacists that sell over-the-counter medicines and cosmetics (PWPOTC). Inspection is the act of examining or looking closely at all drugs attributes and the condition of all facilities that deal with drugs (1). In Malaysia, pharmacy enforcement officers have jurisdictions under the Sale of Drugs Act (SODA) 1952 to inspect all premises that sell drugs, cosmetics and over-the-counter medicines (OTC) (2). This includes PWPOTC such as traditional medicine shops, grocery stores, mini markets, supermarkets, hair salons, beauty salons, direct sales businesses and cosmetic shops.

Inspection activities are part of the MOH's efforts to ensure that all drugs and cosmetics on the market comply with the standard of quality, efficacy, and safety set by the authority. The aim of inspection is to ensure the health and safety of the public and to see if there are any breaches to the guidelines and legislation enforced by the pharmacy enforcement services under MOH (3). Unregistered medicines are often associated with tens of thousands of deaths, mainly in young children in poor countries. Poor-quality

drugs cause economic losses of up to US\$200 billion annually and contribute to the increasing of antimicrobial resistance (4).

Unregistered medicines and unnotified cosmetics can still be found in the Federal Territory of Labuan after decades of implementation of SODA 1952. Every year, raids were carried out on PWPOTC in Labuan. There were 17 raids on PWPOTC with confiscation of unregistered medicines and unnotified cosmetics worth RM23,178 in 2016, 16 raids with confiscation value of RM23,866 in 2017 and 15 raids with confiscation value of RM21,589 in 2018 (5). This observation is a concern to the Labuan Pharmacy Enforcement Branch as unregistered medicines are a real threat to public health. Therefore, there is a need for the pharmacy enforcement officers to carry out routine inspection on all PWPOTC. This could help to reduce premises that sell unregistered medicines and cosmetics, so that enforcement officers can then concentrate to take action on illegal online sales of medicines.

Activities carried out by pharmacy enforcement officers during PWPOTC inspection include checking the security label and registration number on medicines' outer packaging to ensure that the products are registered with MOH (6). The status of notified cosmetics and registered medicines are verified through the QUEST3+ database in the National Pharmaceutical Regulatory Agency (NPRA) website. The pharmacy enforcement officers will seize any illegal products such as unregistered medicines and unnotified cosmetics if found. Education will also be given to the owners and staffs of PWPOTC using leaflets and pamphlets during inspections (3).

In view of the importance of inspection activities, the Labuan Pharmacy Enforcement Branch aimed to inspect all the PWPOTC in Labuan within five years period, from 2016 to 2020. Hence, the objective of this study was to analyse the proportion and characteristics of first-time inspection among PWPOTC in Labuan from 2016 to 2018. By knowing the progress of inspection, the Pharmacy Enforcement Branch can plan and strategise their manpower for the remaining years (i.e. 2019 and 2020) to ensure that all PWPOTC in Labuan were inspected.

Methods

This was a retrospective study that analysed the secondary data gathered from routine inspection reports of PWPOTC, from 2016 to 2018. This study included PWPOTC licensed by the local authority (Labuan Corporation) in year 2017. Any new PWPOTC licensed after year 2017 and PWPOTC that were inspected before year 2016 are excluded in this study.

The list of PWPOTC licensed in year 2017 was obtained from Labuan Corporation as a baseline to know the number of PWPOTC existed in Labuan at the mid-term of this study. The locations of the premises were also provided by Labuan Corporation. PWPOTC included in this study were categorised into five groups. Group 1 consisted of medicine shops, grocery shops, mini markets and supermarkets, group 2 consisted of hair salons, beauty salons, spa and aromatherapy, group 3 consisted of kiosks, group 4 consisted of direct sales premises, and group 5 consisted of traditional and complementary medicine (TCM) practitioners. The PWPOTC were further categorised into 24 areas based on their geographical locations in Labuan.

A Microsoft Excel workbook was created to record all the PWPOTC information obtained from Labuan Corporation. The inspected premises were analysed according to the year and location of premises. The percentage of PWPOTC that were inspected for the first time during 2016-2018 were calculated. The findings were presented using descriptive statistics which was frequency (n) and percentage (%). Microsoft Excel was used to collect information, analyse data and generate descriptive results. This study was registered with the National Medical Research Register (NMRR) and exemption for ethics approval was granted by the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia.

Results

In total, 435 PWPOTC were included in this study. Three hundred premises were located in the town area and 135 premises were in the outskirts area (Table 1). Most of the owners of the business were Malay (54.7%, n=238) and Chinese (25.5%, n=111).

Of the included premises, 249 (57.2%) of PWPOTC were inspected for the first time during 2016-2018, with most of them (n=181, 72.7%) located in the town areas (Table 2 and Table 3). Most of the areas with less than half of the PWPOTC being inspected were from the outskirts areas (8 out of 13 areas), compared to town areas (5 out of 11 areas). Notably, three areas that had none of the PWPOTC being inspected were all from the outskirts. The number of inspections done in 2016 was 114, 2017 was 103 and

2018 was 128. Out of all these 345 premises inspected, only 249 were first-time inspections. Others were repeated inspections of the same premises or inspection on premises that were not in the list of local authority. This study also found that 18 PWPOTC at the outskirts areas were not in operation in 2018.

The most common group of PWPOTC being inspected was group 1 premises (grocery shops / medicine shops / mini market / supermarket) (70.3%, n=175), followed by the group 2 premises (beauty salon / spa / aromatherapy / hair salon) (16.1%, n=40). Among the first-time inspected PWPOTC, all direct sales premises (n=5) and TCM practitioners (n=2) were inspected.

Table 1: Characteristics of PWPOTC included in this study (n=435)

Race of owner	Location		Total, n (%)	
	Town area, n (%)	Outskirt area, n (%)		
Malay	145 (60.9%)	93 (39.1%)	238	(54.7%)
Chinese	77 (69.4%)	34 (30.6%)	111	(25.5%)
Indian	6 (100%)	0	6	(1.4%)
Others	37 (82.2%)	8 (17.8%)	45	(10.3%)
Company	35 (100%)	0	35	(8.0%)
	300 (69.0%)	135 (31.0%)	435	(100%)

Table 2: First-time inspected PWPOTC in Labuan town area in 2016-2018 (n=300)

Town Area	Total premises	Inspected, n (%)
1. Town area (Financial Park)	90	65 (72.2%)
2. Town area (Others)	50	34 (63%)
3. Market Central	25	20 (80%)
4. Patau-Patau	32	12 (37.5%)
5. Town area (Jalan Kemajuan)	23	10 (43.5%)
6. Lazenda (Town area)	22	10 (45.5%)
7. Ranca-ranca	12	8 (66.7%)
8. Town area (Jati)	17	7 (41.2%)
9. Town area (Jalan Merdeka)	7	6 (85.7%)
10. Times Square	8	5 (62.5%)
11. Town area (Jalan OKK Awang Besar)	10	4 (40%)
Total Premises	300	181 (60.3%)

Table 3: First-time Inspected PWPOTC in Labuan outskirt area in 2016-2018 (n=135)

Outskirt Area	Total premises	Inspected, n (%)
1. Tanjung Kubong/Lubok Temiang/Tanjung Aru	17	13 (76.5%)
2. Bebuloh/Sg. Lada/Buton	19	13 (68.4%)
3. Pohon Batu/Batu Manikar	12	11 (91.7%)
4. Ganggarak/Merinding/Lajau	8	8 (100%)
5. Sungai Keling	12	7 (58.3%)
6. Gersik/Batu Arang/Kerupang	16	6 (37.5%)
7. Sg Bedaun/Sg Labu/ Bukit Kallam	16	4 (25%)
8. Sg Bangat	7	3 (42.9%)
9. Kilan/ Bukit Kuda/Layang-layangan	8	2 (25%)
10. Sungai Miri	5	1 (20%)
11. Durian Tunjong/Kg Pantai	6	0 (0%)
12. Belukut	3	0 (0%)
13. Taman Mutiara	6	0 (0%)
Total Premises	135	68 (50.4%)

Table 4: Categories of first-time inspected PWPOTC in 2016-2018 (n=435)

Category	Total premises, n (%)	Inspected premises, n (%)	Percentage (n=249)
1. Grocery shops / medicine shops / mini market / supermarket	321 (73.8%)	175 (54.5%)	70.3%
2. Beauty salon / spa / aromatherapy / hair salon	47 (10.8%)	40 (85.1%)	16.1%
3. Kiosk	60 (13.8%)	27 (45.0%)	10.8%
4. Direct sales premise	5 (1.1%)	5 (100%)	2.0%
5. TCM practitioner	2 (0.5%)	2 (100%)	0.8%
Total	435	249 (57.2%)	100%

Abbreviation: TCM – traditional and complementary medicines

Discussion

This study analysed the proportion and characteristics of first-time inspection among PWPOTC in Labuan from 2016 to 2018. Similar activities of inspection of drug store were carried out by the inspectors in Tanzania, which includes looking for prohibited products, checking of drug expiry dates and storage of the products (7). According to a study in Tanzania, most shops which sell unregistered medicines or noncompliance to the law are likely due to lack of inspections, poor knowledge of regulations, a failure of authority to charge and silent consent of enforcement officers (7). Therefore, inspection is one of the way to increase compliance rate.

Overall, the owners of the PWPOTC in Labuan were similar to the percentage of races of the population in Labuan where Malays are the majority race in Labuan and then followed by Chinese (8). Only slightly more than half (57.2%) of the PWPOTC in Labuan were inspected for the first time during the three-year period, from 2016 until 2018. Since we have identified the 186 premises that have not been inspected yet with their location, we will ensure that all these premises will be inspected within the next two years by closely monitoring the inspection progress. We hope to first reduce the sale of unregistered medicine and unnotified cosmetics in the physical market so that we can then have more time to target the illegal sale of unregistered medicines and unnotified cosmetics online.

Majority of the PWPOTC were in the town areas. This observation was expected because town areas can attract crowds easier as a lot of shops were at town areas. This study found that inspections from 2016 to 2018 were mainly concentrated in town areas. Hence, in order to achieve 100% of PWPOTC inspection by year 2020, future inspections should focus more on the uninspected premises which are located further from the town or the pharmacy enforcement office. Priority to uninspected premises must also be given by the pharmacy enforcement officers.

The common contributing factors of difficulty implementation of inspections are due to insufficient resources. The availability of transport was reported as one of the limiting factors in a study in Tanzania (7). In terms of manpower, at least two enforcement officers are required to conduct an inspection on one premise. Referring to the MOH Inspection Guideline, at least two pharmacy enforcement officers are needed during an inspection as enforcement officers will inspect status of registration of medicines and cosmetics, advertisement and educate the public using leaflets. The presence of two officers will reduce the chance of bribery or improve the safety if the premise owner become abusive (3).

Although public campaigns such as “Know Your Medicines” had been carried out widely to raise consumers’ awareness to safe and effective use of medicines, pharmacy enforcement officers also play an educational role during inspection. Improving consumer awareness are part of the objectives of inspection activities. It is necessary to educate the public on the importance to consume genuine and registered medicines. The awareness activities were also aimed to business owners as poor knowledge of regulations was identified as potential causes for infringements of pharmaceutical regulations(9).

This study found that 18 PWPOTC at the outskirts areas were not in operation in the year 2018. This was based on no notice at the door of the closed premises, and there was no sign that the premises were still in operation. It is advisable that enforcement officers contact the owners first before they inspect premises at outskirts areas, or an updated list needs to be requested from the local authority yearly. Strengthening and co-ordination of information between stakeholders would ensure that premise inspection can be conducted smoothly in the future.

After identifying the PWPOTC and their location which have not been inspected within 2016-2018 from this study, the percentage of first-time inspected PWPOTC has successfully increased from 57.2% to 80% in 2019 and 100% in 2020. We hope to use this technique of more effective monitoring of inspected premises with Microsoft Excel inspection workbook and avoid repeated inspection of the same premises unless necessary, to ensure that all PWPOTC can be inspected within the next three years instead of five years for the new cycle (year 2021-2023).

Conclusion

The findings reflected the unequal proportion of PWPOTC being inspected in different areas in Labuan. The findings also provided insights to the Labuan Pharmacy Enforcement Branch to improve the coverage of inspections in the future. A similar study could also be useful for other pharmacy enforcement branches in Malaysia.

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Conflict of Interest statement

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