

Awareness of Custom Officers on Counterfeit Pharmaceutical Products And The Roles Of Pharmacy Enforcement Officers

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ABSTRACT

Background: Counterfeit pharmaceutical products (CPP) is a lucrative business for illegal operators who constantly try to smuggle their products into Malaysia. Full understanding of the roles and duties of pharmacy enforcement division as well as CPP by Royal Malaysian Custom (RMC) officers are pre-emptive to optimize the operation against drug smuggling.

Objective: This study is aimed to examine the awareness of RMC officers on CPP and the roles of Pharmacy Enforcement Division (PED) officers at custom ports. **Methods:** A self-administered structured questionnaire was developed based on the review of relevant Acts and Guidelines. The questionnaire was reviewed by 4 key officers and pre-tested. Stratified purposeful sampling was adopted to recruit RMC officers who worked at 16 custom ports in Sarawak where PED officers were stationed. Ethics approval and permission to collect data were obtained prior to data collection. **Results:** A total of 110 RMC respondents (48.9% response rate) were sampled. As a whole, the mean scores of awareness level towards CPP and the roles of PED officers are satisfactory at 4.12 (\pm SD 0.967) and 4.21 (\pm SD 0.785) respectively. RMC officers who have worked for more than 10 years are significantly having greater awareness towards

CPP as compared to those who have worked for 10 years or less. **Conclusion:** This study reveals that the awareness of RMC officers towards CPP and the roles of PED officers are sufficient to curb the entering of CPP through the collaboration of PED officers. However, the awareness program for the RMC officers who have less experience is necessary to reinforce their understanding of CPP.

Key words: Awareness, Counterfeit Pharmaceutical Products, Pharmacy Enforcement Division, Royal Malaysian Custom Officer.

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INTRODUCTION

Counterfeiting is a thriving industry and is considered as one of the most profitable occupations in the world.¹ Consequently, the types of products being counterfeited have expanded from luxurious goods to inevitably health related products, especially pharmaceutical products.² Unlike other tangible goods, the spread and use of counterfeit pharmaceutical products (CPP) have not only violated the intellectual property rights of the proprietary drug company,³ but have also had negative impact on public health. The World Health Organization (WHO) describes CPP as a silent epidemic which can cause drug resistance and death.⁴ WHO further states that the projected rate of counterfeit medicines among the global medicines trade is as high as 10%.⁵ In fact, the problem is expected to be much more severe than what is reported if not due to difficulties in detecting the illegal trades.⁶ Hence, some nations had imposed a compulsory pharmaceutical product's security features as a measure to detect counterfeiting despite additional cost incurred to pharmaceutical companies.⁷ Although pharmaceutical counterfeiting is a perennial conundrum worldwide, Asia is reported to be the top region most frequently linked to pharmaceutical crime activities.⁸ The rampancy of pharmaceutical counterfeiting is not only due to failures to enforce the laws effectively but also the exploitation of deficiency in border control.⁸ Hence, the smuggling and illegal importation of CPP remain rife in many countries in Asia.

In Malaysia, the baseline on the prevalence of CPP was reported to be approximately 6% in 1997 and there was a slight decrement to 5% in 2005.⁹ According to the report of World Health Professions Alliance, the value of CPP confiscated was about MYR 18.4 million in 2006.⁸ In the following year, the value of seizures was recorded higher as much as MYR 35.8 million. Malaysia reported its biggest seizure in year 2010 when the custom officers seized a container from Singapore loaded with 142 boxes of CPP.¹⁰ In addition to the aforementioned, a surprising confiscation by the Ministry of Health at Port Klang in 2009 revealed a million pills of counterfeit Viagra alongside with millions of pseudoephedrine, the latter of which was the precursor to the manufacturing of hard drug Methamphetamine.⁹ These seizures have no doubt implicated the massive scale of pharmaceutical syndicates that have been undermining the existing public health system. In responding to the issues on hand, the Minister of Health urged for stricter checks on medicine imports with more rigid collaboration with the Royal Malaysian Customs (RMC) Department.¹¹ Such collaboration was strongly encouraged by WHO. Nevertheless, the awareness of relevant authorities in combating the importation and trading of CPP through education was highlighted as one of the key objectives in the Declaration of Rome.⁵

The RMC Officers are appointed under Section 4 of Customs Act 1967 (Laws of Malaysia, Act 235). Under Section 112 to Section 114 of the

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Act, the RMC Officers are given power to screen on the importation of goods and possessions of the persons who enter the country. "Customs" is known as a tax-gathering arm of government and is responsible for screening possessions of those who enter the country or bring goods in.¹² As such, Customs has significant roles in health-related function, and that includes halting illicit drugs and hazardous products together with the public health authorities.¹² On the same note, under the Custom Act 1967 (Act 235, Law of Malaysia), the RMC officers are given authority to open packages and examine goods as well as seizing them at custom ports if there is "reasonable cause to suspect that there has been committed any offence against this Act or any regulation made thereunder, or any breach of any of the provisions of this Act or of any regulation made thereunder or of any restriction or condition subject to or upon which any license or permit has been granted". At the same time, the Regulation 7(1) Control of Drugs and Cosmetics Regulations 1984 stipulate that the importations of pharmaceutical products are prohibited except under an import license or permit from relevant authorities, such as Pharmacy Enforcement Division (PED) under Ministry of Health Malaysia. Under the umbrella of PED, each state has its own Pharmacy Enforcement Branch to provide services within the region. At custom port, PED officers act as technical advisors to the RMC officers regarding the screening of commodities classified under the tariff code which are controlled by PED.¹³ Subsequently, PED officers may provide suggestion to the RMC officers to seize and forfeit consignment that contravenes the Laws and Regulations enforced by PED.

By knowing the roles of both RMC and PED at the custom ports in preventing the entry of CPP, the collaboration between both sides are highly dependent on their awareness towards the roles of one another.¹³ The positive correlation between awareness and adoption of service is well supported by extant literatures.^{14,15} However, given the fact that information pertaining to CPP is contained in the Drug Registration Guidance Document under Ministry of Health Malaysia, the RMC officers might not be fully aware or have vivid understanding about the implication of such policy towards them in combating the entering of CPP. Hence, without substantial awareness towards such policy, the RMC officers might fail to work collaboratively with PED in addressing CPP. It can be concluded that the effectiveness of detecting and seizing the CPP is hinged upon high awareness of custom officers towards the CPP and the roles of PED.

Confining to Sarawak, a state of Malaysia and an emerging market in Asia, it has the largest territory and also the most custom ports compared to other states.¹⁶ According to the report of PED, there are nine borders between Sarawak and Kalimantan, Indonesia which do not have PED officers due to lack of manpower and logistic problem.¹⁶ This puts the state at higher risk of becoming points of CPP importation. The other states also report similar problems, where the incumbent PED officers are unable to cope with the demand at custom ports. This inevitably provides the smugglers opportunity to exploit the shortcomings by bringing in CPP without being detected by law enforcers. This is reflected from the number and value of seizures of CPP in the Malaysian market as mentioned earlier.

To date, there is very minimal information pertaining to the level of awareness of RMC officers towards CPP since little is studied and documented in academic literature and RMC official website.¹⁷ However, such information is critically important and would serve as a baseline study in planning the awareness-rising strategy to ensure the roles of RMC officers in combating CPP are upheld and reinforced. Hence, the present study is a step towards the right direction by examining the awareness level of RMC officers towards CPP and the roles of PED officers in Sarawak and Asiatic region.

MATERIALS AND METHODS

The study used both qualitative and quantitative approaches in a sequential manner, with the focus on the latter approach. The relevant Acts and Guidelines were firstly reviewed and content-analysed so as to generate items pertaining to the awareness towards CPP and the roles of PED. These items were then incorporated into a self-administered and structured questionnaire. By combining both approaches, it is believed that the study would yield findings which are more insightful and relevant to the phenomenon under investigation.¹⁸

The target population of this study was the RMC officers at custom ports in Sarawak where PED officers were also stationed. Those RMC officers operating at custom ports without PED officers were thus excluded because they had limited exposure to PED officers and thus their awareness towards the roles of PED officers would be biased. As such, stratified purposeful sampling was deemed most appropriate to sample the respondents.¹⁹

Official consent by Director of Sarawak RMC Department was obtained to conduct the research and collect data from the RMC officers prior to the study to ensure ethical issues were not compromised. Subsequently, paper questionnaire was distributed to all RMC officers at custom ports who fulfilled the criterion in order to get desirable sample size and facilitate analysis with adequate statistical power.²⁰

Every respondent was given an informed-consent document before attempting the questions to show that they were fully aware of and understood the purpose of the study, and that they were willing to participate in the survey voluntarily. Once the questionnaire was completed, the officers returned the questionnaires by putting them into a black box prepared by the researchers. The period of data collection was from 24th June 2016 until 10th July 2016.

The relevant Acts and Guidelines were firstly reviewed by the researchers using content analysis.^{16,24} The coded data were then constructed as statements and listed in separate columns, one for the awareness towards CPP and another for the awareness towards the roles of PED. Four key informants from PED and Sarawak RMC department were invited to examine the statements to further ascertain their relevance, thus enhancing the validity of the content. Together with the researchers, discussions and revisions on wordings were done based on joint knowledge and experiences to omit ambiguous, irrelevant and redundant items.^{21,22} Besides, five RMC officers were selected as pre-test sample. They were asked to explain to the researchers their understanding of every statement to ensure there was no discrepancy between the intended meaning and the interpreted meaning of the statements.

Once it was all done, the self-administered and structured questionnaire was designed. It consisted of three sections, namely demographic characteristics (Part A), the awareness towards CPP (Part B) and the awareness towards the roles of PED officer (Part C). Categorical scale was used in Part A whereas five-point Likert scale anchoring two ends of agreeability was utilized in Parts B & C. The informed consent was enclosed as the first page of the questionnaire and it contained the description of the purpose of the study as well as assuring the confidentiality and anonymity of the respondents. The statements were written in Bahasa Melayu (Malaysian official language) by using collaborative translation to ensure that the respondents understood the words, statements and instructions, filled up the questionnaire at their comfort, and most importantly gave valid responses.

A total of 225 copies of questionnaire were distributed to all target officers in 16 RMC institutes throughout Sarawak. A total of 122 copies were subsequently collected, which yielded a response rate of 54.2%. However, 12 copies were found to have straight-lining responses and missing values, thus they were removed from the observation. A total of

110 usable copies were retained with an effective response rate of 48.9% for data entry and analysis. Statistical Package for Social Science (SPSS) version 21.0 was used whereby Frequency and Descriptive analyses were performed to describe the awareness towards CPP and the roles of PED officers, as well as independent t-test and ANOVA to test the difference of awareness by demographic characteristics.

RESULTS

Table 1 shows the demographic profile of the 110 RMC officers sampled at custom ports throughout Sarawak. It is evident that most of the respondents are assistant officers and majority of them have no more than 10 years' length of service. Understandably, most of them are sampled at Kuching division as it is the capital city of Sarawak. It is worth noting that most officers have their highest education at secondary school level. To interpret the level of awareness towards CPP and the roles of PED, it is useful to define it based on the mean scores with practical meaningfulness. Using the two anchors of agreeability, the mean score of 2.50 or less is defined as "very little awareness". Despite being above midpoint, the mean scores from 2.51 to 3.50 and from 3.51 to 4.00 are defined as "little awareness", and "moderate awareness" respectively as RMC officers are expected to be well aware of CPP and the roles of PED to fulfil their obligation to curb the importation of CPP effectively. Hence, a mean score of 4.01 or above is regarded as "high awareness", and only such level of awareness is deemed satisfactory. Results are illustrated in Table 2.

Generally, the awareness level towards CPP (mean=4.04) and the roles of PED officers (mean=4.16) are high, with the mean scores of 4 and above. However, it is necessary to point out that the RMC officers only have moderate awareness about CPP without the registration number on the product label (mean=3.97). This could denote a potential loophole in the effort to curb the entry of CPP.

Comparisons of major variables with demographic characteristics are carried out. Table 3 shows that no significant difference is found between groups based on position, and division of duty with regard to the awareness towards CPP and the roles of PED officers, except for length of service. Post Hoc Bonferroni Test reveals that the RMC officers who have worked more than 10 years are significantly different from those who have worked less. It is no surprise that the former have greater awareness towards CPP than the latter. Nevertheless, what is striking is the fact that the RMC officers with 10 years or less experience are not well aware of CPP as one would hope for (mean = 3.76 and 3.83).

DISCUSSION

In general, the awareness of RMC officers towards CPP is high. However, their awareness on the features of CPP specifically is comparatively lower, which is rated as 79.4% (mean=3.97) and 81% (mean=4.1). Such awareness is deemed to be crucial for the RMC officers to detect CPP at custom ports. The mechanism of identifying CPP in Malaysia has been convenient to authorities and general public since policy makers have enacted a compulsory registration process for all pharmaceutical products by Drug Control Authority under the umbrella of Ministry of Health Malaysia.²³ Nonetheless, such enactment is a substantial move to safeguard the quality, safety and effectiveness of all pharmaceutical products in the country.²³ With such enactment, two features to differentiate a registered pharmaceutical product from an unregistered pharmaceutical product or CPP are compulsorily imprinted on the outer packaging of every pharmaceutical product, namely registration number and Meditag™ Hologram.²³ Similar measure to prevent the counterfeiting of medicine is taken by U.S. through the introduction of drug pedigree.²⁴ The ability to identify the features of registered pharmaceutical products has basically enabled the general public and relevant authorities to iden-

tify CPP. According to National Survey on the Use of Medicine in year 2012, the level of awareness on the pharmaceutical product registration among general public was found to be 85.9%.²⁵ The lower level of awareness among the RMC officers compared to general public has urged the PED to provide an immediate and comprehensive exposure to the RMC officers on the mechanism of identifying CPP. On the other hand, the awareness level of RMC officers towards the roles of PED is found high (mean > 4.0). Such awareness level shows the RMC officers are more likely to recognize the importance of their roles and accept services provided by PED.^{14,15}

Awareness level of RMC officers on the roles of PED officers (mean=4.16), implies the mutual understanding between both departments. Scholars have suggested that such mutual understanding is crucial in enhancing the collaboration of both parties with minimal conflicts.¹³ As mentioned earlier, information pertaining to CPP and the roles of PED is contained in the policies under Ministry of Health, thus such high level of awareness is strongly related to the long working relationship between two departments and also dialogue organized between two departments biannually. Besides, talks and exhibition related to CPP and the roles of PED have also been given by PED through invitation from RMC. The results supported the importance of close working relationship and further underscores a long-term collaboration between both departments in combating the entering of CPP into Sarawak through continuous awareness raising campaign among RMC officers.

In addition, the position of RMC officers does not have significant association with the awareness level towards CPP and the roles of PED officers. This finding is contrary to the finding of Mancinelli and Kafai, which claimed that the position in an organization hierarchy is a factor affecting the awareness towards organization policies.²⁶ Apart from that, no significant difference is found between groups based on division of duty with regard to the awareness towards CPP and the roles of PED officers.

The length of services, however, is found to be a factor that significantly affects the awareness of RMC officers towards CPP. Specifically, RMC officers who have worked for more than 10 years have significantly greater awareness on CPP than those who have worked for 10 years or less. Hence, the awareness program for the RMC officers who have less experience (length of service not more than 10 years) should be prioritized. Given the fact that they make up more than half of the studied population (56.1%), such program is of utmost importance to the new and less experienced officers. Through more focused awareness rising strategies, the collaboration between the RMC and PED personnel would be intensified in combating the importation and trading of CPP. As a result, the smuggling, illegal importation and supply of CPP into market will be reduced, which would in turn safeguard the wellbeing of the people.

Although the present study cannot correlate less awareness towards CPP to the importation of these products in Sarawak, the RMC officers at custom ports are expected to be well aware of CPP. It is thus essential to look into the matter and take remedial actions with urgency so as to reassess the severity of the importation and trading.

Limitations of the Study and Suggestion for Future Research

Notwithstanding the importance and implications of the study, there are a few limitations which are worth noting for consideration and future investigation. Firstly, only the RMC officers working at custom ports where the PED officers were on duty were sampled. This might limit the actual assessment of the awareness level of all RMC officers, especially those without the assistance of PED officers, because the RMC officers sampled in this study might have gained knowledge from the PED officers on duty. Secondly, despite being acceptable in survey research, the

Table 1: Demographic Profile of Respondents

Demographics	Categories (n = 110)	Frequency (n)	Percentage (%)
Position	Officers	20	18.2
	Officer Assistants	90	81.8
Length of services	0 - 5 years	32	29.1
	6 - 10 years	30	27.3
	11 - 15 years	8	7.3
	16 - 20 years	11	10.0
	21 - 25 years	3	2.7
	26 - 30 years	7	6.4
	31 - 35 years	13	11.8
Academic Qualification	36 - 40 years	6	5.5
	Primary School	2	1.8
	Secondary School	72	65.5
	Diploma	17	15.5
	Degree	18	16.4
Division of Duty	Master	1	0.9
	PhD	0	0.0
	Kuching	61	55.5
	Sibu	24	21.8
Division of Duty	Sarikei	4	3.6
	Bintulu	10	9.1
	Limbang	11	10.0

Table 3: Comparison of Major Variables with Demographic Characteristics

Demographics	Awareness towards CPP		t / F (p value)	Awareness towards Roles of PED		t / F (p value)
	Mean	SD		Mean	SD	
Position						
Officers (n = 20)	4.21	0.721	0.806 (0.422)	4.43	0.678	1.429 (0.156)
Assistant Officers (n = 90)	4.04	0.853		4.16	0.813	
Length of Service						
0 - 5 years (n = 32)	3.76	0.734	9.497 (0.001)	4.07	0.631	3.055 (0.051)
6 - 10 years (n = 30)	3.83	0.944		4.03	0.984	
>10 years (n = 48)*	4.44	0.671		4.41	0.701	
Division of Duty						
Kuching (n = 61)	4.02	0.846	0.747 (0.562)	4.05	0.874	1.825 (0.130)
Sibu (n = 24)	4.12	0.871		4.31	0.675	
Sarikei (n = 4)	4.00	0.490		4.79	0.210	
Bintulu (n = 10)	4.48	0.612		4.50	0.539	
Limbang (n = 11)	3.95	0.921		4.39	0.611	

* Post Hoc Bonferroni Test shows that the RMC officers who have worked more than 10 years are significantly different from those who have worked less (p < 0.01).

Table 2: Awareness of RMC Officers towards CPP and Roles of PED officer

Code	Awareness towards CPP (n = 110)	Mean	SD	Alpha
B1	If there is no Meditag™ Hologram on the label/outer packaging of a pharmaceutical product, then it is a counterfeit pharmaceutical product.	4.05	0.937	0.894
B2	If there is no registration number which starts with "MAL" printed on the label of a pharmaceutical product, then it is a counterfeit pharmaceutical product.	3.97	1.000	
B3	A counterfeit pharmaceutical product is not guaranteed with quality.	4.11	1.008	
B4	A counterfeit pharmaceutical product is not guaranteed with efficacy.	4.06	1.007	
B5	A counterfeit pharmaceutical product is not guaranteed with safety.	4.17	0.994	
	Mean (B1-B5)	4.04	0.850	-
Code	Awareness towards Roles of PED officer (n = 110)	Mean	SD	Alpha
C1	PED officers may detain/seize any imported poison unless importer possesses license issued under Section 26 Poisons Act 1952.	4.19	0.829	0.966
C2	PED officer may at any place demand and select and take or obtain samples of the said drug for the purpose of analysis.	4.21	0.889	
C3	PED officer may require such person to produce for his inspection any books or documents dealing with reception, possession, purchase, sale or delivery of any such drug or other substance.	4.16	0.841	
C4	PED officer acts as a technical advisor of RMC Department regarding the screening of imported commodities classified under the tariff code which are controlled by PED.	4.25	0.840	
C5	RMC should refer the consignment to PED officers whenever the commodities imported are classified under the tariff code enforced by PED.	4.21	0.847	
C6	PED officers may give suggestion to RMC officers to seize and forfeit consignment that contravenes the Laws and Regulations enforced by PED.	4.22	0.850	
	Mean (C1-C6)	4.16	0.810	-

non-response rate of the study could indicate the unwillingness of the RMC officers to expose their awareness level, given the fact that the study is approved by the director from the RMC department; hence creating statistical biases.²⁷ However, scholars have argued that such high non-response rate may not necessarily induce statistical bias as the cut-off point for high or low non-response rate remains un-concluded.^{28,29} Lastly, this study does not further examine the relationship between awareness and the practice of RMC officers on CPP. It is thus imperative to connect the cognitive aspect to the behavioural responses so as to assess its causality and determine how awareness would impact the actual practice to curb the importation and trading of CPP for the betterment of the community in Sarawak and Malaysia.

CONCLUSION

This study reveals that the awareness of RMC officers towards CPP and the roles of PED officers are sufficient to curb the entering of CPP through the collaboration of PED officers. However, the awareness program for the RMC officers who have less experience is necessary to reinforce their understanding of CPP. The findings of this study have provided essential insights to policy makers and officers of both RMC and PED departments in formulating strategies and solutions to increase the awareness of RMC officers towards CPP and the roles of PED.

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CONFLICT OF INTEREST

The authors declare having no conflict of interest.

ABBREVIATIONS

CPP: Counterfeit Pharmaceutical Products; **DRGD:** Drug Registration Guidance Documents; **GISCP:** Guideline of Importation Screening at Custom Ports; **PED:** Pharmacy Enforcement Division; **PA'52:** Poisons Act 1952; **RMC:** Royal Malaysian Custom; **SODA'52:** Sales of Drugs Act 1952; **SD:** Standard Deviation; **WHO:** World Health Organization.

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