Research Article



Do Law and Regulations of Unregistered Drug Enough? : Pharmacists' Perspective

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ABSTRACT

The unregistered drugs are the phenomena that are growing tremendously in Malaysia and also in other developing countries. Law and regulations are one of the solutions to manage this problem. The objective of this study is to explore pharmacist's views on the law and regulations towards unregistered drugs. The semi-structured interview guided was developed and distributed to experienced pharmacists of the area of Klang Valley. These pharmacists or respondents are working in various fields (hospital, enforcement, and community). A total of 16 pharmacists were interviewed. Two categorical themes were identified; factors of the main issues of the law and regulations and solution to emphasize the use of current laws and regulations. This study concluded the main issues of the law and regulation were ineffective and lack of efficiency in implementation stage, and the public and retailers do not fully aware or bother on the existence of the law. The law and regulations can be used effectively to manage unregistered drugs if the best practices such as intelligent decision making and proactive thinking applied amongst the public, authorities and health care professional. Moreover, the law and regulations can be work efficiently if the combination of implement, monitor and verify have been practice together to strengthen the regulatory framework.

Keywords: unregistered drugs, law and regulations, pharmacist, perspectives

INTRODUCTION

he definition of the law and regulation is; a principle, rule, or law designed to control the countries. In Malaysia, there is already law and regulation that is implemented to manage unregistered drugs. The law and regulations are from the book of 'Malaysian Laws on Poisons and Sale of Drugs' 2013. The books' include four act. The acts are, Poison Act 1952 (PA), Sale of Drug Act 1952 (SODA), Registration of Pharmacist Act 1951 (ROPA) and Medicines (Advertisement and Sale) Act 1956 (MASA). All of the definition, requirements and rules that need to be obey by the manufacturer and retailers can be finding in the act and pharmacists are compulsory to use this as references.

Worldwide have some issues towards the definition of unregistered drugs because there is no standard on specific and legal definition of this matter because different definition among countries. In 2011, the World Health Organizations (WHO) and multilateral body defined a new name of counterfeit drugs as substandard, spurious, falsely-labelled, falsified and counterfeit (SSFFC) medicines. The above term proposed by WHO is a bit controversial because the term is not stated the specific and legally term such as counterfeit drugs and substandard drugs¹⁻³.

In Malaysia, term of unregistered drug is used to define this problem. Definition of **"Product"** is; A *drug* in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a *medicinal purpose*; or A *drug* to be used as an ingredient of a preparation for a *medicinal purpose*^{4,5}. Although in Control of Drugs and Cosmetics Regulations 1984 (CDCR) prefer to use registered products, thus in this study term of registered drugs is used. The term of registered drug it seems to look more specific to indicate the medicinal purpose and can reduce the possibilities for the public to misinterpret with the common products such as handbags, gadgets and etc.

Counterfeit drugs are the worldwide issues, regardless develops or developing countries. According to Enforcement Pharmacy annual report in the year 2012, the number of the raid shows an increasing trend since 2010 until 2012 and possibly to increase year by year⁶. The Department of Enforcement staffs' perceptions, the increasing trend of the statistic, reflecting on the effectiveness of the pharmacists from Department of Enforcement in seizing unregistered drugs in the market⁷. The UK, the USA or other developed countries believed the increasing trend of counterfeit drugs means the indication on the possible risk to consumers in consuming the products^{3.8}.

Moreover, the increasing trend on statistic of unregistered drugs in Malaysia will also give a bad image to Malaysia. The existence and increasing trend of unregistered drugs will give a negative impact on pharmaceutical companies and pharmaceutical investors from other countries in conducting their business in Malaysia^{9,10}.



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This phenomenon is a bad news that has alarmed the pharmacy-bounded authority to handle this issue seriously.

The phenomenon of the abundance of unregistered drugs in Malaysian market showed on the needs this issue to be explored through the qualitative method by including professionals (pharmacist) as the respondents.

Moreover, there are limited studies that use the qualitative method to explore the cause of the existence of unregistered drugs in Malaysia market particularly amongst health care professionals, thus it has made this method suitable to answer the problem statement. This study is done specifically to explore pharmacist perception on the law and regulations towards unregistered drugs based on their profession and experience.

The issues are still occurred because many retailers and drug manufacturers keep selling and the public continuously purchased these unregistered drugs.

Their bad attitude, finally have contributed to increasing the drugs seized every year. The central question to this issue that needs to be answered; do current law and regulations are effective to manage unregistered drugs in Malaysia?

Thus, the aim of this study is to evaluate the view from the pharmacists specifically towards these matters.

MATERIALS AND METHODS

The respondents were interviewed using semi-structured interview guided questionnaire.

A semi-structured interview guided was developed using previous literature and designed accordingly to answer the research questions and were validated by an expert in a qualitative study (Table 1). The questions have bilingual languages; English and Malay languages.

The first author, the researcher did all the interviews. The researcher has abundance experience in the field of pharmacy and had experience in clinical pharmacy, therapeutic drug monitoring, and enforcement. These experiences may help the researcher to conduct the interviews and achieves the research objectives. The role as the researcher in this study was to identify and interpret the data that extracted from respondents. Consequently, the researcher is expected to identify any biases or limitation that developed throughout this study.

Table 1: Semi-structured interview guided

Interview questions		Areas addressed by primary question	
1)	What do you think of the current law and regulations towards unregistered drugs?	Perception of the current law and regulations towards unregistered drugs	
2)	What is your suggestion to improve the current law and regulations?	Views in improvement current law and regulations	

Table 2: Demographic characteristics of participants

Working Area	Age Range (Years)	Education	Sex
5 (EP)	27-40	Local University	Female (n=4) Male (n=1)
3 (CPH)	28-30	Local University	Female (n=2) Male (n=1)
4 (DIH)	29-33	Local University(n=3) Oversea University (n=1)	Female (n=3) Male (n=2)
4 (CP)	27-31	Local University (n=1) Oversea University (n=3)	Female (n=1) Male (n=2)

Table 3: Categorization and themes in the data for the current law and regulations

Factors of the lack of laws and regulations	Solution to emphasize for the use of current laws and regulations
Implementation	Law amendment
Lack of awareness	Education and promotion
Manufacturer attitude	Improvement
Lack of man power	Investigate manufacturer
Corruption	Public and media role
	Create drug police



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Respondents and setting

Health care professionals, who are experts in pharmacy, are selected to acquire their perception and opinion in giving a better solution for managing unregistered drugs. Three fields of pharmacists were chosen because different working fields have different perceptions and experience of pharmacists with unregistered drugs. The pharmacists involved must have working experience of 5 years and above in their respective fields.

The three selected working fields are enforcement, hospital and community. As enforcement pharmacists, one of their duties is to manage unregistered drugs in the market. They have much experience in handling unregistered drugs and knowledgeable in managing these drugs. Pharmacists who are working in hospitals were divided, into two groups; Drug Information Centre (DIC) and Ward Pharmacy. DIC is the unit that handles any inquiries about pharmaceutical products from various callers such as the public, retailers, manufacturers and healthcare professionals. While, pharmacists that are working in the wards are closer to the patients. Their duties are to communicate with patients in identifying medications, supplements, or traditional medicines that they are taking and when get counseling from pharmacists. Finally, community pharmacists are the persons who own pharmacies and have direct contact with the public that purchase their pharmaceutical products in their pharmacy stores.

The inclusion criteria, only focus on the pharmacists working in hospitals or enforcement or community based in Klang Valley area, who understand both Malay and English languages and have working experience five years and more in their field. Working experience is very important because, in Malaysia, pharmacists are divided into three categories, which are Provisionally Registered Pharmacist (PRP), Registered Pharmacist (RP) and Fully Registered Pharmacist (FRP). Different categories have different number of years in working experience; PRP (less than one year), RP (1-3 years) and FRP (3 years and above). Five years of working experience were selected in this study because usually after five years, these pharmacists have more experience, independent and knowledgeable. Therefore, pharmacists with 5-year working experience are appropriate and eligible more than enough for pharmacists to give their perceptions in this scope of the study.

The exclusion criteria were included those who were blind, had cognitive impairment, did not sign consent letters and did not agree the conversation to be audiotaped. The consent letter and the agreement to record pharmacists' voice are crucial because the conversation needs to be recorded for this study. After the selected pharmacists accepted the conditions, the pharmacists were approached using email and were contacted individually. Permission was granted from the directors of the research departments to conduct this research. All the respondents signed the consent letters after the purpose of the study was clearly explained to them, as well as being informed about the official permission from the relevant authority. This study proceeds, upon ethics approval by the University Technology MARA Committee on Ethics in Research Development.

RESULTS

The data obtained from interviewing experienced pharmacists on their opinions were gathered. All respondents have agreed to provide information as long as they remained anonymous and been interviewed individually. In Malaysia, it is the common norm for a person to be comfortable in expressing their opinion and suggestions if they are anonymous and not interviewed in the crowd or group discussion. Therefore, the researcher has conducted the interview discreetly in a form of leisure meeting and the interviewed was the face to face and one to one interviewed.

The final sample comprised of 16 pharmacists from different fields. The pharmacists' ages ranged from 27 to 40 years. Ten were women, and six were men (Table 2). All pharmacists involved were graduated from either in local (n=12) and overseas universities (n=4). Majority respondents were from Enforcement Pharmacist (EP) followed by Drug Info Hospital (DIH), Community Pharmacist (CP), and Clinical Pharmacist Hospital (CPH).

The law and regulations of unregistered drugs in Malaysia

The main themes identified for the perception of the current law and regulations towards unregistered drugs and views in improvement current law and regulations are categorized into two categorizations (Table 3).

Most of the pharmacists believe that inefficiency of laws and regulations on this issue stems from the shortage of law implementation itself. Also, they believed that the laws governing this issue need amendments.

Factors of the inefficiency of laws and regulations

Implementation

The majority of the pharmacists believed that the current laws and regulations can well manage unregistered drugs, but the implementation must be done effectively. Many of them also believed that enforcement has done inspections and raids to manage unregistered drugs in the market, yet is still unsuccessful in finding the cause of the problem.

"Right now we have the law, but less implementation. I think there is a kind of law, action, and the implement existing, but the problem still proliferate like mushrooms. Today, we are taking the unregistered drugs but then, tomorrow there still exist". (7DIH)

Lack of awareness

The pharmacist believed the awareness among public citizens; retailers and manufacturers were important to



ensure that they know the penalties if they sell or manufacture unregistered drugs.

"From a legal point I feel there is no problem. I just think in terms of enforcement activities such as awareness. For where there is demand, there is a sale. If people are aware, and there is no demand, I think it would be easier controlled". (5EP)

Many pharmacists believe that response such as complaint from the public would help enforcement to eliminate this problem. Therefore, awareness and education amongst the public is very important because both give the synergistic effect in helping the enforcement unit in managing this problem. If the public is aware and recognizes unregistered drugs, it would help influence them to complaint to enforcement for further action.

"Now there is a law, but the authorities to take action to the companies still require a response from the public to make reports." (6CPH)

Manufacturer attitude

Many of the pharmacists believed the awareness among public citizens is also the main factor to solve this problem. There is still demand for the products from consumers; if manufacturers will not stop providing unregistered products. Unfortunately, many manufacturers and retailers only consider profit maximization compared to the safety of the products^{11,12}.

"The law is existing, but the law is sometimes not giving the impression of fear or guilt to the retailers and manufacturer. So perhaps, one of which we can be more of a dissemination of the information to the public, in terms of the offense and the bad side effect of the products."(3EP)

Lack of man power

The pharmacists also believed that the difficulties in managing unregistered drugs are due to the abundance of unregistered drugs in the market. Lack of man power is why enforcement pharmacy still faces problems in handling this issue efficiently.

"There is nothing wrong with the law from Malaysia. Enforcement is also available. But perhaps that is too many products on the market, probably the enforcement officer could not cope all and there is difficult to cover everything". (12CPH)

Corruption

Some of the pharmacists believed that corruption and smuggle are one of the techniques to bring the unregistered drugs into Malaysia. Smuggling will happen if there is corruption involved amongst the officer in the entry points^{13,14}.

"The current law does force us not to allow the sale of unregistered medicines, but, for some reason, the problem is still there in our market. There may be issues of smuggling, or ineffective enforcement, or possible corruption. There is possible the leaking somewhere in our management system, the lack of awareness among the smugglers, retailers and patient also one of the issues that need the improvement". (14CP)

Solution to emphasize the use of current laws and regulations

The data shows that implementation of the law and regulation have to be emphasized and the strictly imposed. It can make the wrongdoers feel scared to commit any offenses. The amendments to the current law are also crucial because the current law needs upgrades for synchronization with the current world of technology's challenges¹⁵.

Law amendment

The majority of pharmacists believe that current advertisement law is not well-implemented because there is still abundance of unregistered drugs' advertisements found online or via mass media. They suggested amendments to the current law to let all advertisements published through any mediums such as mass media, online, etc. are screened first before distributed to the public.

"Probably, that control must be held at mass media. The censorship in the media is the compulsory before it was issued. Rather than after the ad was released. The law against companies producing commercials must amend, for example, the magazine. The close control of the mass media that there must be". (8DIH)

Education and promotion

Some of the pharmacists believed that the authorities need to educate the public about unregistered drugs and to encourage them to report and to be responsible if they see any unregistered drugs in the market.

"For the authorities they need to be closer to the general public. They need to encourage them to report any unregistered drugs in the market". (6CPH)

"The enforcement officer takes action in raiding and the enforcement department can educate teachers. Do a lot of workshop in public healthcare service to make awareness amongst healthcare providers and also the public. And since our young generation is growing and become a consumer, maybe we can educate them since the school". (13CPH)

Improvement

The pharmacist believed that most of the actual fines that stated in law and regulations are always open to appeal; hence the wrongdoers pay only half of the amount after successful appeals. Most of the pharmacist believed that if the fines are not open for appeals, a reduction in some cases of unregistered drugs in the market can see as the actual fine imposed is guite high.



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"After we have made a raid, we need to catch them. After that, make sure, they been fined with the actual fine that already stated in the law and regulations without appeal". (15DIH)

Investigate manufacturer

Pharmacists viewed that the main problem lay with the manufacturing companies. Strict company registration rules need to be developed to ensure the facilities follow the requirements. The aim and plan of manufacturing companies have to be clear, and the products that they plan to manufacture must also state upfront.

"I think the company needs to mention what kind of company they would do. For the first, they must make registration of the company. So, we need to know what they are doing; we have to see their manufacturing, office, and SOP. We must not make easy the rules to build the company meaning that we need to strengthen the requirements". (7DIH)

Mass media role

The pharmacist believes that there is a lack of information on products that raided in electronic media. In most raid cases, the manufacturing company and its products are not exposed to social media and mass media.

"Produce the real raid, no need to censor the products and name of the company if published in the newspapers." (15DIH)

Create drug police

Some of the pharmacists believe that lack of manpower is one of the factors that contribute to the increase in trends of unregistered drugs in the market. Then, the suggestion is to develop a police workforce for medicines that will collaborate with the enforcement pharmacy unit to regularly monitor the presence of unregistered drugs in the market. If any cases reported needs pharmacists' involvement, pharmacists would then be involved in the raid.

"The established of the drug police specifically to monitor unregistered drugs." (16CP)

DISCUSSION

By exploring pharmacist's perception towards law and regulation of unregistered drugs, we identified various factors that may affect current law and regulations. In Malaysia, there is already a law that is implemented to manage unregistered drugs. Based on the interview findings, the main issues that made the law and regulation ineffective is because of the lack of efficiency during the implementation stage and the law is not fully observed by the public.

The theme from the interview suggests that the current management of unregistered drugs is more challenging due to the lack of implementation. All law decreed in most countries are supposed to work in curbing illegal activities, but even the best plan would fail if the implementation is ineffective^{3,18}. The pharmacists also believed that even though they are aware that enforcement officer did raid and inspection, the situation of the unregistered drugs is still recurrent. Thus, these issues reflected negatively towards the authority unit's image^{5,14}. The ineffective practice such as late to reply, or only action towards complaint regarding unregistered drugs from the public made the enforcement team far behind the manufacturer of the unregistered drugs to stop them. Traditional medicine is regulated under various laws and regulations, including the Control of Drug and Cosmetic Regulations 1984, Poison Act 1952, Sale of Drug Act 1952, Advertisement and Sale Act 1956 and Protection of Wild Life Act 1972. But it is questionable if these are fully enforced, or if they are actually enforceable at all. Take the example of the traditional ointment known as minyak angin. It is almost unimaginable that all the available minyak angin in the market are registered with the authorities and undergo tests as rigorous as conventional medicines, or that all minyak angin bottles will clearly list their active ingredients. Thus, no one can be totally certain if an ointment cures or causes certain conditions.

Based on data, most of the unregistered drugs are sold by general retailers. Even though consumers can report the manufacturers; a fine can be easily deflected by the wrongdoer using an appeal to court. When the wrongdoers are allowed to appeal from the court by only paying a small amount of the fine, they become braver to repeat the offenses since the implementation is not strict. Therefore, a good planning and framework of activity should be improved by the particular governing institutions¹⁴. Finally, the findings also suggested that to start a strict execution of the law, the institutions required efficient staff and manpower to achieve the aim of the implementation. The lack of manpower made the authorities difficult to manage unregistered drugs effectively. Therefore to improve current management of unregistered drugs, the need for involvement every organization is one of the solutions to solve the manpower problem¹⁶.

The pharmacists need to educate and give awareness to the public and also to the general retailers about this issue. Some information that needs highlighted is the bad impact of consuming unregistered drugs and the law and regulations.

Moreover, the findings shown, there is a minority of pharmacist do not know about current law and regulations even though experience more than five years in their field. These indicate that the important of continuous pharmacist education in refresh their knowledge regarding unregistered drugs and law and regulations.

Health care providers especially pharmacists need to aware and well educated of the meanings and understanding of the current law and regulations. It is



important for the future for the pharmacists to educate and give the correct information to the public.

The pharmacist believed the current law and regulations need the amends because the law is outdated. For example, the MASA 1956 function to control and manage the advertisements only had been revised on 1983¹⁹. The current situation that involved technology and social media made the advertisement difficult to be control and needed improvement and amended¹⁷. Reviews from the literature on law and regulation towards unregistered drugs had discovered there is a template for strengthening the national laws known as "Model Law on Medicine Crime" produced by Amir Attaran, Canada. The legal provisions of the Model Law divided into nine thematic. One that need to highlight and can be implemented in Malaysia law and regulations is the provisions to give a financial reward to whistleblowers who report drugs crime. Only a few countries reward whistle-blowers, the tactic can be very effective because the public will become more alert to report and cooperate with authorities.

The key to improving current law and regulations is a strict implementation, especially towards wrongdoer. At the same time, the law need to be review frequently (every five years) because the technology is very fast growing, and the law and regulations need to be parallel with them. The law and regulations can be used effectively to manage unregistered drugs if the best practices such as the intelligent decision making and proactive thinking applied amongst the public, authorities and health care professional^{20,21}.

Strengths and Limitations

The first qualitative research to explore in depth Malaysia pharmacists' perceptions and views on law and regulations of registered drugs. Our method and study design enabled us to access our respondents' views during the interviews, thereby enhancing the quality of the data. We also selected different field of pharmacists to get the various information from a different view of pharmacists. The findings also can provide information to the authorities as a reference to improve current law and regulations. The limitation of the study is we only focus the area of Klang Valley area and generalize the population as a representative for the entire pharmacists in Malaysia. A further limitation arises from the absence of qualitative work involving pharmacist from other minority ethnic groups such as Borneo area. The suggestions for the future study to involve small sample from the Borneo region as a representative and the findings be used for comparative purposes.

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Conflict of Interest: None.

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