

The Development of the Problem Solving Framework in Managing Unregistered Drugs: Pharmacists Perspectives

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Abstract

Background: Unregistered drug is one of the main important issues in Malaysia and is being taken very vigorously by the Malaysian Ministry of Health (MOH). However, the performance of the Pharmacy Enforcement Division amazingly increased but the problem still remains. **Objective:** The objective is to develop the problem solving framework by exploring the pharmacist perceptive on unregistered drugs. **Methods:** This study took place in pharmacist practice (hospital, community pharmacy and enforcement pharmacy unit) in Klang Valley. Sixteen pharmacists participated. The data were analysed using constant comparison method. **Results:** During the interview, many themes had emerged and some issues have been considered and some themes are either acceptable or unacceptable to be implemented in the framework. The findings are then categorized into three categorical themes: Current situation, contributing factors of unregistered drugs and solution. The findings had emerged two different pathways which are the themes that increased unregistered drugs and the themes that decreased unregistered drugs. Those themes are the perceptions from the pharmacist as respondents towards the unregistered drugs problem in Malaysia. Majority of them believed if there is the problem it must have the solution. **Conclusion:** As a conclusion, this study is to develop solutions and strategies in managing unregistered drugs in Malaysia by exploring practitioner (pharmacist) who practically with this issues and have experienced with consumers. The development of a problem-solving framework is useful and beneficial for future studies and the framework acts as a professional audit for comparison with the current situation and practice.

Key word: Unregistered drugs, Problem-solving framework, Pharmacist, Perspectives, Malaysia.

INTRODUCTION

Counterfeit drugs are the common worldwide issues that public and authorities need to know or concern about. The reason behind is, public is the end user of the products and authorities is the person that responsible to manage this problem. The authorities are refers to health authorities, police, customs, the judiciary, manufacturers, wholesalers, retailers and health professionals. Moreover, this issue is important to care of because this problem is not only caused human impact but also economy impact.^[1,2] Some of the cases of consuming counterfeit drugs can also cause death and moreover, millions of dollars are been stolen by counterfeiters by selling counterfeit drugs.



The counterfeit drugs marketed in many countries worrying all sectors in the worldwide. Therefore, the investigation about the root origin of the counterfeit drugs was done by the United Nations Office on Drugs and Crime (UNODC), July 2010, reported that the increase flow of counterfeit drugs to Asia contributed to the world statistic of counterfeit drugs.^[3] China and India is the countries that produce many of the counterfeit drugs and then distribute them to the other countries and also to the Asian countries.^[4] There are many factors contribute to the China and India to become the leading in the production and manufactured of the counterfeit drugs. One of the factors, Ullekh, 2013, stated that there are thousands of manufacturer which is small companies and it is difficult to be access by the authorities. Then, both of the countries don't have a proper enforcement to do the surveillance and the penalties to the counterfeit drugs producer.^[5] Therefore, easy for China and India to do the manufacture and export to the other countries.

Asia countries have 6 regions; Eastern Asia, Southern Asia, Central Asia, South East Asia, Western Asia, Russia (Asia). Counterfeit drugs are everywhere in every regions. Every country in the regions had different problems and management of unregistered drugs. Meanwhile, they have similarity of the problems. Most of the problems are lack of regulations and regulator, lack of government efforts, lack budget and leak boarders.^[6] Therefore, because of the contributing factors, these contributed to the increasing of the counterfeit drugs in Asian regions. As a conclusion, counterfeit drug is not a minor problem but it is the worldwide problem that needs special attention not only from the authorities but also from the public because it's involved everyone. Asia is the origin of this problem, so the Asian legacy such as Malaysia needs to give an extra attention to investigate the root cause of the problems.

The phenomenon of the abundance of unregistered drugs in Malaysian market can be explored through qualitative method by including professionals (pharmacist) as the participants. In addition, the limited studies that use the qualitative method to explore the root cause of existence of unregistered drugs in Malaysian market have made this method suitable to answer the problem statement.

Following the problem identification, this study intends to address the following research questions:

What contributing factors influenced the existence of unregistered drugs in the Malaysia market?

a. What is the perception of pharmacists towards the existence of unregistered drugs in the Malaysia market?

- b. What is the current management of unregistered drugs in managing unregistered drugs in Malaysia?
- c. How do current management of unregistered drugs in managing unregistered drugs in Malaysia?
- d. Why current management of unregistered drugs still lacking in managing unregistered drugs in Malaysia?

METHOD

This study was conducted in Klang valley in October 2014 till Jun 2015. It was included the interviewed, observation and analysed (Figure 1). The interviewed using a semi-structured interview guide. Moreover, the interviewed were transcript verbatim. All the respondents were pharmacists in different fields (hospital, community pharmacy and enforcement pharmacy unit).

The choice of this kind of selected because different pharmacists would have different experienced in handling the unregistered drugs. All the respondents were contacted on an individual basis using emailed or phone call in explaining purpose of the study to them, as well as being informed about the official permission from the relevant health authority. Then, the respondents must also agree that the interviewed must be audiotaped and finally sign the consent letter. The interviews took an average of 20 minutes. Analysis followed the principle of the constant comparative method. Data analysis occurred concurrently with data collection so that the authors could generate an emerging understanding about research questions, which in turn informed both the sampling and the questions being asked. The study approved by department of pharmacy practice, Faculty of Pharmacy, Universiti Teknologi MARA, Kuala Lumpur, Malaysia.

RESULTS

The final sample comprised of 16 pharmacists from different fields. The pharmacists' ages ranged from 27 to 40 years. All of the pharmacists are from the Klang Valley area and had experience for more than 5 years in their respective fields.

Every question in the interview was transcribed and the questions are divided into subtopics. The subtopics cover the pharmacists' understanding of unregistered drugs' terms and the current situation in Malaysia, their experiences with unregistered drugs, the bad impact of unregistered drugs, law and regulations, advertisements and internet influences, socio-demographic effects, people's influence, education influenced, and awareness influenced

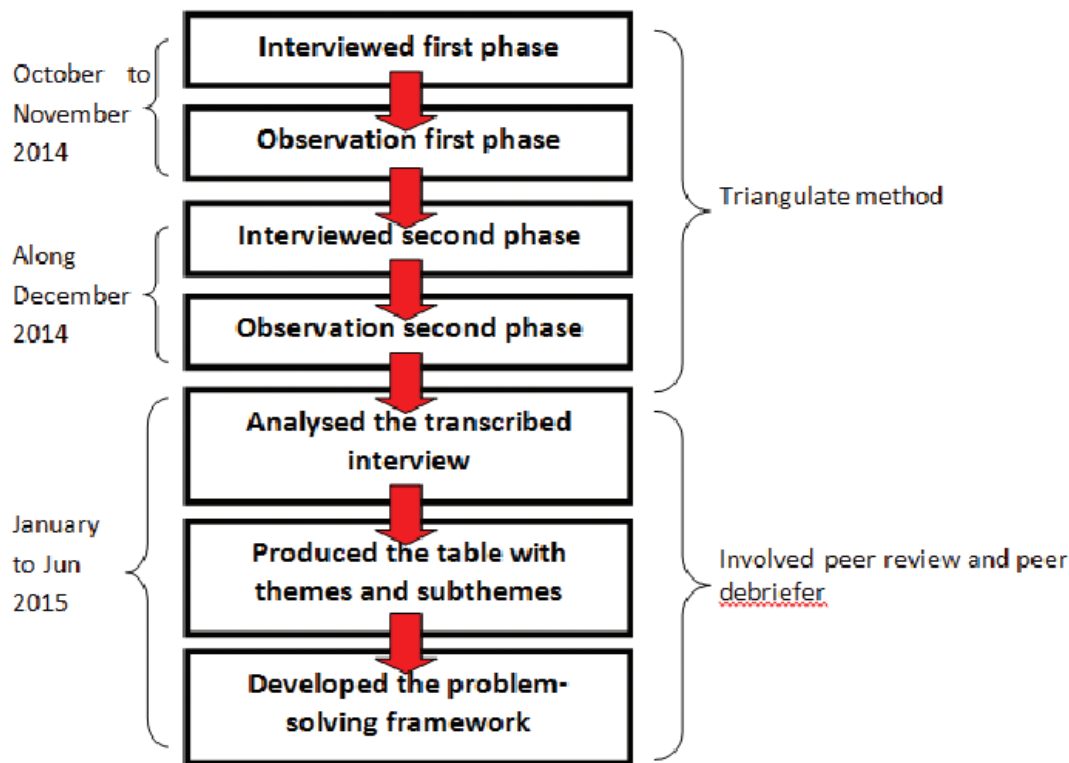


Figure 1: The study design in developed the problem-solving framework.

Our findings showed that pharmacists' perception towards unregistered drugs could be understood through 25 themes as presented in Table 1.

Every theme also has sub themes to define the themes. From the themes, the themes were rearranged to be implemented into the framework. The findings are then categorized into three categorical themes: Current situation, contributing factors of unregistered drugs and solution. The findings had emerged two different pathways which are the themes that increased unregistered drugs and the themes that decreased unregistered drugs (Figure 2). The pathways were emerged starting from the themes abundance. Majority of the pharmacists (n: 14) mentioned that there is still abundance of unregistered drugs in Malaysia market.

Current situation

The current situation is the categorical themes that emerged two themes which are bad impact and abundance. Majority of the pharmacists believed that the abundance of unregistered drugs might possible increase the risk of bad impact to the consumer if they consumed the products.

There is still not having exact statistic of the existence of unregistered drugs in Malaysia. Majority of the pharmacists believed that the unregistered drugs also can be finding anywhere such as, 'Jamu' shop, night market, street market, exclusive shops and internet.

"A lot of unregistered drugs in Malaysia and we don't know how many percentage out there" (13CPH)

"Sales are widespread all over everywhere" (7DIP)

Most of pharmacists believed that unregistered drugs can cause damage to the body such as, complication, adverse drug reaction, long term complication, allergy and toxicity. There is because the unregistered drugs contain adulterated ingredients. Furthermore, they also believed that all of the unregistered drugs have unknown safety, no security assurance, no clinical trial, unknown status of ingredients, unknown quality and unknown mechanism of action.

Contributing factors of unregistered drugs

This categorical theme is related with the abundance. All of these themes are possible to contribute to increase the unregistered drugs in the market. The themes are divided

Table 1: Themes and sub-themes in the data

Theme	Sub-theme
Health literacy	confirmation, consider, advance, exposure, assessment, investigate, uncertain, comprehend
Bad impact	Complication, adverse drug reaction, long term complication, allergy, toxicity, adulterated ingredients, unknown safety, no security assurance, no clinical trial, unknown status of ingredients, unknown quality, unknown mechanism of action
Characteristic of consumers	INCOME (poor) cheap (AGE (younger) more explore (elderly) more concern (LEVEL EDUCATION (low) (GENDER (female) beauty and slim (male) sex enhancement, incomprehensible, self-awareness, self-medication
Consumer utility	fast effect, cheap, trusted manufacturer, fast, desperate, easy, trusted advertisement, privacy, others alternatives, benefit, trusted practitioner
Good business strategic plan	false claimed, testimony, interesting advertisement, multiple medium for promotion, technology, online business
Lack awareness and knowledge	PUBLIC, RETAILERS, MANUFACTURER, HEALTH CARE PROFESSIONAL AND SMUGGLER: Registration identification, registration checking, safety, effectiveness, advertisement, law and regulations, complication, side effects
Consumers' demanding	healthy, traditional, Indonesia products, slimming and beauty, trend online shopping
Abundance	ANYWHERE: 'Jamu' shop, night market, street market, exclusive shops, internet
Promotion and advertised	law and regulations, advertised social media, advertised media, national level, updated information, impactful information, campaign, continuous advertised, community pharmacy, strategic area, printed on the products
Effective services	drug info centre, module learning, compulsory learning, fostering community, pharmacists' role, public's role, media involvement, create drug police
Implementation	AUTHORITIES: improvement, close monitoring, strict management, strict punishment
Equitable access to information	target population, everyone, every location
Word of mouth	share, advice, suggest, encourage
Competency	effective, cured
Government's role	enforcement effort
Authorities' obstacle	corruption, lack man power, accessibility, immigrant influenced
Law amendment	increase fine, old regulation, advertisement law
Persistent	vast budget, frequently, school campaign, daily basis
Retailers & manufacturers' attitude	brave, stubborn, profit
Trusted and respecting person	family, parents, friends
Collaboration	mass media, pharmacy community, NGOs
Consumers' belief	cultural influenced, safe, effective, famous, false assumption
Social influenced	friends, family
Seek for professional advice	PUBLIC AND RETAILERS: confirmation, report, opinion
Investigate manufactured	strict registration company

into three sub group of peoples who related with the themes; manufacturers and retailers, authority and consumer.

Majority of the pharmacists believed that the good business strategic plan is the main key for the manufacturer and retailers to get the profit from their products. Most of the pharmacists believed the strategies might influence the consumers to purchase their products because most of the unregistered drugs advertisement is interesting. Moreover, most of the advertisement is using false claimed and false testimony in promoting their products.

“The promises listed on the label, for example can shape up in 7 days, or can be added stamina and can whiten the face in 4 hours. Words like that can be fooled and makes people want to buy and try these products.” (2EP)

The pharmacists believed that the retailers and manufacturers' attitude have a major influenced in contributing the unregistered drugs in the market. The pharmacists also believed that majority of the retailers and manufacturers are brave to sell the unregistered drugs because they only care of the profit without concern of risk to the consumer.

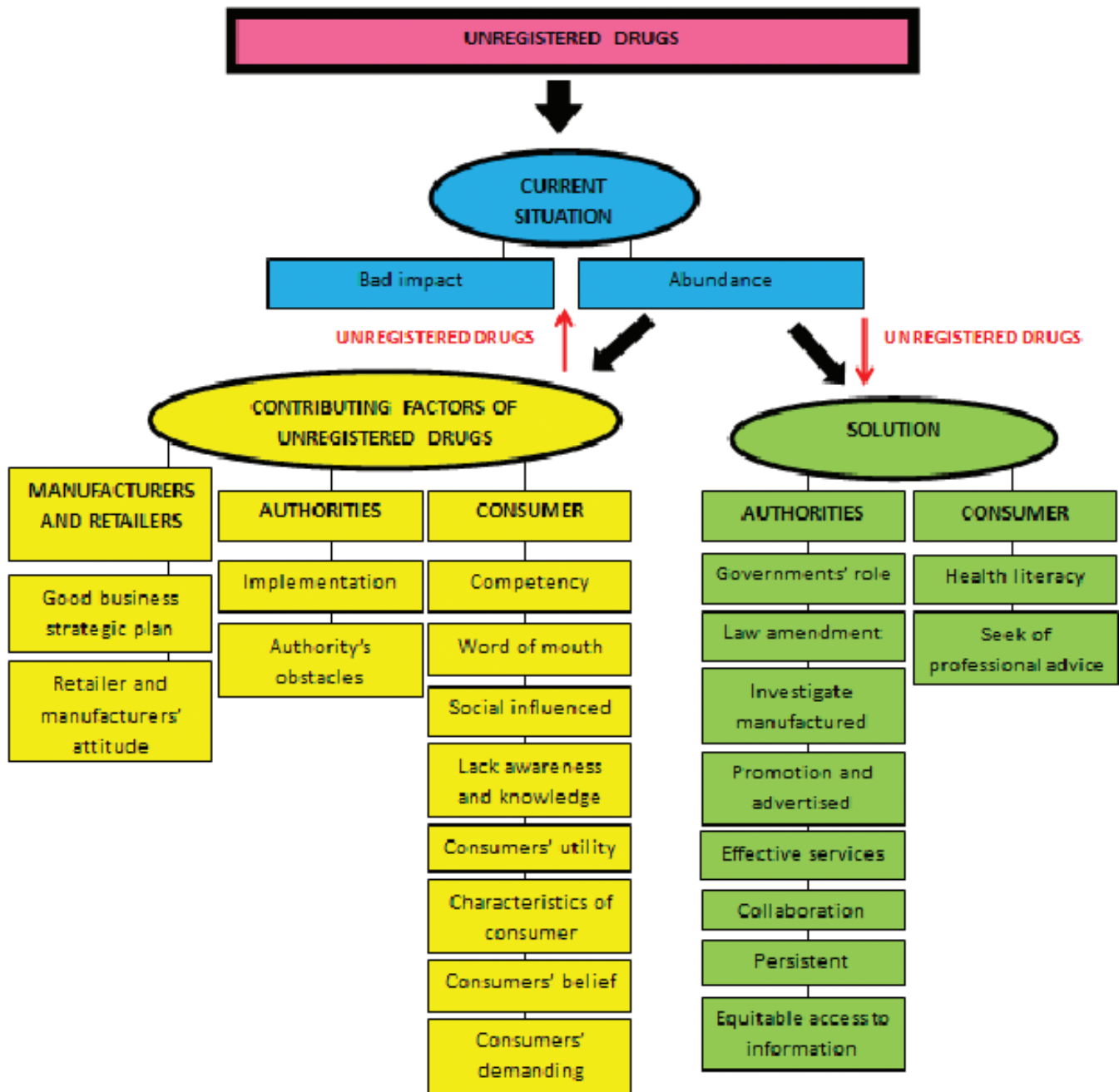


Figure 2: The problem-solving framework in managing unregistered drugs.

"I just wonder why they are so brave manufacture unregistered products to the public without think the risk at the public but only think of the profit alone." (6CPH)

Pharmacists believed there are some of the obstacles that the authorities need to concern at such as the issues of immigrants. Moreover, most of the pharmacists believed that there are many aspects need to investigate and it needs enough staff to cover all the aspects.

"There are still many immigrants comes such as Indonesian people. Many unregistered drugs from their country were brought in by them to be selling in the area where they live and their population. There are also sources of online sales, remedies from oversea, or who come from oversea." (5EP)

Majority of the pharmacists believed that have several of consumers have utility means that the consumers believed the satisfaction is beyond their judgement and understanding. There was a statement from 13CPH.

"I am myself buying unregistered drugs. Habab.. I was desperate and I trust the practitioner when they prescribe the unregistered products." (13CPH)

Solution

This categorical theme is also related with the abundance. All of these themes are possible to contribute to reduce the unregistered drugs in the market. The themes are divided into two sub groups of people; authority and consumer. The pharmacists believed that promotion and advertised about the information of registered drugs is one of the main solution to let every consumers get the same information and made use of it. They also believed that with the effective services the consumers can call the information centre if they need any confirmation, report or opinions about their health or products that they consumed or purchased.

"To enhance this awareness program, we need a campaign; we also already have a phone line running to receive calls 24 hours. For the ads on TV, we need provide quality and impactful advertisements such as Petronas ad as it is distressingly give impact to the audience. If we, as pharmacists can produce the advertisement, it can help raise the awareness. Advertising on TV, as well as YouTube or health oriented government websites can be linked." (9DIP)

Most of the pharmacists also believed the efficiency of the enforcement effort in managing unregistered drugs is very important. They also believed with the collaboration with other agency and sector might help to reduce the enforcement pharmacy division burden of responsible in managing unregistered drugs alone.

"Hmmm ..This difficult. I think, we have to get nearer to the public. How much the ad cost awareness that we have to spend to keep on doing it for the public awareness campaign? It has to be on -going, consistent and in the way its practical example in a daily basis. At any of the sales of medicines, community pharmacy, everyone will go buy just go to the drug community pharmacy to buy medicine and Panadol. So, has the intervention nearby; You are buying something here, this is the leaflet for you to read we start from the base. We will cost thousands of ringgit just for one day campaign and tomorrow who come forgot already. It is the waste." (7DIP)

DISCUSSION AND CONCLUSION

There are several of the themes emerged from the interviewed. Majority of pharmacists believed if there is the problem it must have the solution. One of the issues is about the immigrant. Immigrant is the nation problem and it is beyond the enforcement pharmacists' job scope.

Furthermore, the issues of smuggling and corruption are difficult to handle because this need cooperation with the immigration unit who responsible to manage and control the borders.^[7] Currently, there is a national collaboration with the Ministry of Domestic Trade and Consumer Affairs, Customs Department, Police, Pharmaceutical Industry, Consumer Association and Health Professional Group.^[8] This collaboration is helping enforcement pharmacists in managing the unregistered drugs problem.

As a conclusion, this study is used the concept of action research meaning it is to develop solutions and strategies in managing unregistered drugs in Malaysia by exploring practitioner (pharmacist) who practically with this issues and have experienced with consumers. The development of a problem-solving framework is useful and beneficial for future studies and the framework acts as a professional audit for comparison with the current situation and practice. The further action plan and strategies can be summarized as further sub heading.

Strategies and Action Plan

- Reviewed the law and regulations to increase the penalties or amend are appropriate.
- Provide a user friendly awareness website that specifically about unregistered drugs that can be access and understand by consumers with different social demographic characteristics.
- A strong commitment, shared responsibility and coordination from different organizations. To discuss any problem related with unregistered drugs and come out with a better solution.
- Improve international collaboration, together to help in combating these issues.
- Increase the technology improvement in the detection of unregistered drugs. For example, kits to detect food or drink of health products that contaminate with poison example, Viagra, Sibutramine and Steroid.
- Districts, Municipal and City Council need to have a rules/agreement to be sign by general retailers that want to sell any health products or OTC drugs; to ensure they aware or understand what registered drugs is.
- MOH under Enforcement Division need to consider increasing pharmacist, public and general retailers' awareness and knowledge in this field by making the current awareness programmed more advertising throughout Malaysia.
- The Enforcement Pharmacy Division must be proactive, means their evaluation and judgment must be beyond the counterfeiter's strategies.

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CONFLICT OF INTEREST

No conflict of interest

ABBREVIATION USED

MOH:Malaysian Ministry of Health; **EP:** Enforcement pharmacist; **CPH:** Clinical pharmacist hospital; **DIP:** Drug info pharmacist.

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