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REVIEW ARTICLE

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Are We on the Right Track?: Overview of Unregistered Drugs in Malaysia

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Abstract

Background: The Ministry of Health (MOH) under their sub-division, the Pharmacy Enforcement Division (PED) has a crucial role in managing unregistered drugs in Malaysia market. The unregistered drug is like a silence killer in the pharmaceutical industry. It does damage not only the pharmaceutical economy but also the consumers' health. PED aims are to ensure that every pharmaceutical, traditional and cosmetic are quality, safe and efficient to be used meaning they need to be registered and notify. However, the problem of unregistered drugs still remains and this needs to be worried. **Objective:** This paper aims to get the overview of the seriousness of this issue, the current management and the impact on the consumers and nation. **Conclusion:** Therefore, with the cumulative evidence from this paper can provide the vision or suggestions what is the need to be done in combating unregistered drugs for the future in Malaysia.

Key words: Unregistered drugs, Pharmacy Enforcement Division, Ministry of Health, Malaysia, Counterfeit drugs.

INTRODUCTION

World Health Organization (WHO) provided 60 countries to give feedback regarding their use of the term "counterfeit drugs" and equivalent in national legislation[1] to the evaluation of responses to Circular Letter C.L. 25.2009; majority of countries use "counterfeit" (34) in their national legislation and others used, "falsified" (5), "illicit", "illegal", "unregistered", "unauthorized", "adulterated".[1] Malaysia is the one of the countries that involved with this terminology survey. Overall from the study, the evaluation finds that there are various definitions from the countries that involved but the majority of the countries using counterfeit drugs. In Malaysia, there is no precise definition of counterfeit drugs in Malaysian Law, but in The Sale of Drug Act (SODA) 1952 there are specific provision under regulation 7(1) (a), 7(1A) (a-g) Control of Drugs and Cosmetics Regulations (CDCR) 1984 which requires all medicinal products to be registered with National Pharmaceutical Control Bureau (NPCB) of the MOH before entering the market and follow a process which requires stringent evaluation and final approval by the Drug Control Authorities (DCA). After the medicinal products going through all the requirements it known as registered drugs or registered products.

The terms that used in this paper is the counterfeit drug if correctly explaining or citing literature from other countries than Malaysia. Moreover, the terms of unregistered drugs were used if citing the Malaysian literature and if explaining the situation in Malaysia.

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In the authors' perspective, she wants to maintain the definition of the terms that be used in the research because she believed the terms itself has defined the situation that happens in those countries.

Overview of counterfeit drugs issues in worldwide

Counterfeit drugs are the standard global problems that public and authorities need to know or concern. In the United States, the exact number of counterfeit drugs is unknown, but the existence is increasing in trend.[3] In the United States of America, a report from Centre for Medicine, since 2005, sales of counterfeit drugs is increase 92%, which is US$ 75 billion in 2010.[4] The counterfeit drugs are the profitable industries. It summarized (Fig. 1.1) to show the situation of the counterfeit drugs in this world. [5] According to the figure, concluded that the counterfeiters or the producer are making profitable, public or consumer had been cheated and risk to harm, and towards the end the legal manufacturer would lose their profit.

Also, Pharmaceutical Security Institute (PSI) had a report in 2008 showed over 100 countries reported incidents of counterfeit drugs. The report is increasing throughout the year, and some of the private sectors claimed that the incidence of counterfeit drugs on the market increased approximately 25% each year over the past years back.[6] The increasing of the reports, cases and incidents in the market is a bad sign to the public. They may consume the health products that adulterated with poison or unsafely or unclean products because all of the counterfeit drugs do not comply with the GMP requirements. It is impossible to gather and develop the data of counterfeit drugs throughout this world because it is everywhere. Meanwhile, there is the report of counterfeit drugs by therapeutic class received by WHO, 1999-2002 (Figure 1.2). Based on the figure, there are various therapeutic areas counterfeited because the highest percentages are others with the 14 therapeutic classes and followed by antibiotic. Any medication counterfeited, and it depends on the demands from the public for the specific therapeutic area. At the same time, it also depends on the area of the countries. In developed countries, increase counterfeited of lifestyles drugs such as sex enhancement, slimming and hormones whereas in developing or underdeveloped countries, increased production of life-saving drugs such as antibiotic, painkillers.

The prevention or the management of the counterfeit drugs is different from the country and there have different boards or agency that plays a role in preventing the counterfeit drugs from widespread. Since 1988, WHO started to detect the fake drugs problems and identified the increasing of the cases. Then, the WHO established International Medical Products Anti-Counterfeiting Taskforce (IMPACT) in February 2006.[7] IMPACT involved various sector such as pharmaceutical manufacturers, Non-Government Organizations (NGOs), regulatory and enforcement agencies. The aim of IMPACT is to have the improvement in the relationship with the other countries and finally the production and the mechanism of counterfeit drugs' business will shut down. So, to accomplish this aim, IMPACT has five keys that need to fulfill. The keys are legislative and regulatory infrastructure, regulatory implementation, enforcement, technology and communication. IMPACT also has proven effective in promoting awareness of the public health dangers of counterfeit drugs and in forging international consensus on global strategies and solutions.[8]

Overview of counterfeit drugs issues in Asia

There is low prevalence of counterfeit drugs in the Japan and South Korea because their countries have organised and well management of nations. But it still exists means, most of the counterfeit drugs found on the black market and difficult to find them in the legal premises like pharmacies and hospitals. Different with India and China, there is high prevalence of fake drugs in these countries. Most of the reports claimed that India is the main leader in manufacturing and producing counterfeit drugs. About 35% India contributed to the worldwide counterfeit drugs sales followed by Nigeria, 23.1% and Pakistan, 13.3%.[8] Moreover, Pharmaceutical Security Institute (PSI) documented that China exports their counterfeit drugs and diverse them around the world. In addition, the United Nations Office on Drugs and Crime (UNODC) reports approximately two billion counterfeit drugs worth $8.2 billion are produced annually in China.[9]

The counterfeiting industry is synonym with the Chinese, meaning anything counterfeited in the China. There is no specific research to describe this situation but it may possible because of their economics or their cultural.[10] Felix *et. al.*, 2014, stated that there are many products can be counterfeited such as computer software, bags/handbags, clothing/shoes, watches, cosmetics, eyewear, medicine and many more. Most of the products would not cause harm if the public purchased them except for the medicines. According to Felix *et. al.*, 2014, the majority of the consumer know the risk if they consumed the counterfeit drugs compare to others products because they believed that anything that not original if enter their body might cause possible harm to them. The problem arose when the consumer claimed it 's hard to identify the authentic and the counterfeit drugs in the markets. This problem occurs and needs particular attention from authorities to figure

out the solution and the practical ways to let public identify themselves the counterfeit drugs. Fortunately, countries like Malaysia are beginning to concern in combating the problem of counterfeit drugs. Our countries have the managing and authorities that specifically handle this situation.

The Scale of the Problem

Approximately 5% of the medicines in Malaysia are counterfeit drugs stated in the report by the Emerging Markets network (EMHN) in February 2013 and the value is increasing in trend and persists. Moreover, the growth of traditional products described by the agenda WHO Western Pacific meeting report published in 2001 estimated that the Malaysian traditional medicine market achieved RM2 billion. The increasing of the traditional and herbal products development and production give the platform for the unregistered drugs industry to adulterate those products with poison to increase the effectiveness.

In fact, Harris, Mydin, Stevens, & Morris (2011) stated in their report that the usage of traditional medicinal products or known as 'ubat kampung' that claimed safe or sufficient to cure or treat variety of diseases by their proprietors cannot be alone to guarantee the effectiveness, safety and quality of the products because those products also need to comply with pharmaceutical testing and evaluation. The report from WHO Global Survey 2005 said that the traditional products market since 1999 achieved RM4.55 billion estimated four times larger than the value of drugs used in government hospitals and clinics and the market growing annually at the rate of 8 to 15 percent. The traditional medicinal, pharmaceutical industry developed tremendously and there is a high possibility some of the products does not follow the Good Manufacturing Practices (GMP) rules or the registration procedure.

The popular counterfeited drugs are sex drugs. The customs in Malaysia experienced the largest drug seized in March of 2007 when it seized 142 boxes (1.4 million pills), worth USD 4 million, of fake Viagra. Furthermore, there are also the traditional medicinal products have been adulterated with the other substances such as Sibutramine, Sildenafil and Glibenclamide. There is the example of several traditional products contaminated with the poisons to enhance the action of the drugs (Figure 2.1). According to the figure, the packaging looks authentic and seems to look like registered drugs. Also, some of the packagings also contain fake hologram and MAL number. Consumers' who is lacking awareness and knowledge influenced towards registered drugs to purchase without the doubt. The possibilities of the public to experience side effects and multiple health complications without doctor monitoring is high. Moreover, the products cannot confirm the quality, safety and efficacy of the products because those products do not register with the DCA. One of the obstacles that authorities need to come out with the solution to manage this issues because the existence of these products not only give bad impact to the health but also to the nation.

Officially, Malaysia introduced Meditag programme in 2005, which required all products registered with the Malaysian DCA to bear a holographic security device, allowing pharmacists and consumers to check the authenticity of a drug's assigned Meditag using decoder units available at pharmacies. There is also the proactive approach taken by the industries to changing the new packaging to combat counterfeit. One of the tips to identify the counterfeit drugs is by examination of counterfeit drugs using organoleptic test (Figure 2.2). According to the figure, as a public or consumers, there is a bit difficult for them to remember and identify by themselves the characteristics of the differences on the packaging unless this test used for the authorities or manufacturer to identify the counterfeit drugs, then it might benefit. For consumers, the relevant information that they need to understand is the criteria of the registered drugs which need the hologram label and the MAL number. Then, the consumers also need to use the Meditag decoder if to ensure the hologram sticker is authentic. Therefore, the sufficient awareness and educational programme need to spread this information throughout the nation to everyone in this country.

There is some example of conventional drugs been counterfeited such as Viagra, Cialis, Norvasc, Panadol, Eye Mo, 'Minyak Cap Kapak' and 'Ubat Batuk Cap Ibu & Anak'. Also, the common adulterants are the steroid, drugs for erectile dysfunction, antihistamine, NSAID's and slimming agents (Figure 2.3). Tragically, public might assume that products that they bought are safe consumed because the majority of the adulterated products are food and drink based. Therefore, it needs a close monitoring and consistent market surveillance amongst the drink and food products in the market.

The business of unregistered drugs is profitable. According to the statistic of the amount of seizures from 2008-2012, there are increasing in trend (Figure 2.3). The value is double for only four years. As a conclusion, this visualised that pharmaceutical industry growing together with the unregistered drugs. The concrete reason behind this phenomenon is still not clearly stated. Various factors that contribute to this issues and this need further investigation to know the cause of the problem. There are very limited

researches to investigate further in unregistered drugs in Malaysia. But, there is still have references that used as the reference for this paper. There is the report entitled "Keeping it Real Combating Fake Drugs in Malaysia" by the Institute for Democracy and Economic Affairs (IDEAS) in 2011, that can be used to get an overview or story about this phenomena.

The IDEAS is the non-profit organizations that play their roles such as to improve the level of understanding and acceptance of public policies based on the principles of rule of law, limited government, free markets and free individuals. The IDEAS had reviewed the situation of unregistered drugs in Malaysia with the worldwide situation and made the comparisons amongst them and finally come out with the action proposal. The findings in the report are from the IDEAS perspectives and the actions that need to be improving or upgrade are:

- Public awareness
- Legislation and enforcement
- Technology
- Open market

The main action proposed by IDEAS can be used as benchmark to improve current management of policies in managing unregistered drugs.

The Current Management of Unregistered Drugs in Malaysia

National Pharmaceutical Control Bureau (NPCB): NPCB is the unit that responsible for implementing the drug registration or cosmetic notification scheme, the regulatory scheme on the quality of pharmaceutical products, the product recall scheme and the licencing scheme for pharmaceutical manufacturers, importers and wholesalers including a licencing scheme for the clinical trial. Also, NPCB also encourages the local pharmaceutical producer to use the GMP for upgrading their products equivalent to the requirements from the WHO. Moreover, NPCB also responsible for managing adverse drug reaction program, disseminates information and policies or news, carry out research and give training for the pharmaceutical officers through local training or international training. The roles and function of NPCB need to achieve because NPCB aims are to determine all pharmaceutical, traditional and cosmetics are quality, safety and efficacy (Figure 2.5).

The quality products are the products that have GMP certification and pass product testing such as product specification, heavy metals and microbial limit test. The manufacturer gets the GMP certificate, after passing the inspection of the premise, standard operating procedures (SOP), the manufacturing records and recall system. Safety products are the products that pass the heavy metals test in traditional products and have the toxicology studies or animal studies. The products also need to mention in the product information any warning labels, precaution, drug interaction and adverse effects if have any. Both of these criteria are compulsory for both cosmetic and traditional medications.

Finally, the efficacy is for pharmaceuticals products such as new chemical entity, biological products and generics products. The efficiency needs to pass clinical efficacy data which are the clinical trial, phase 2 and phase 3. All of these criteria are important to ensure consumer and patients get benefit from the product but not to get harm if used or consumed the products.

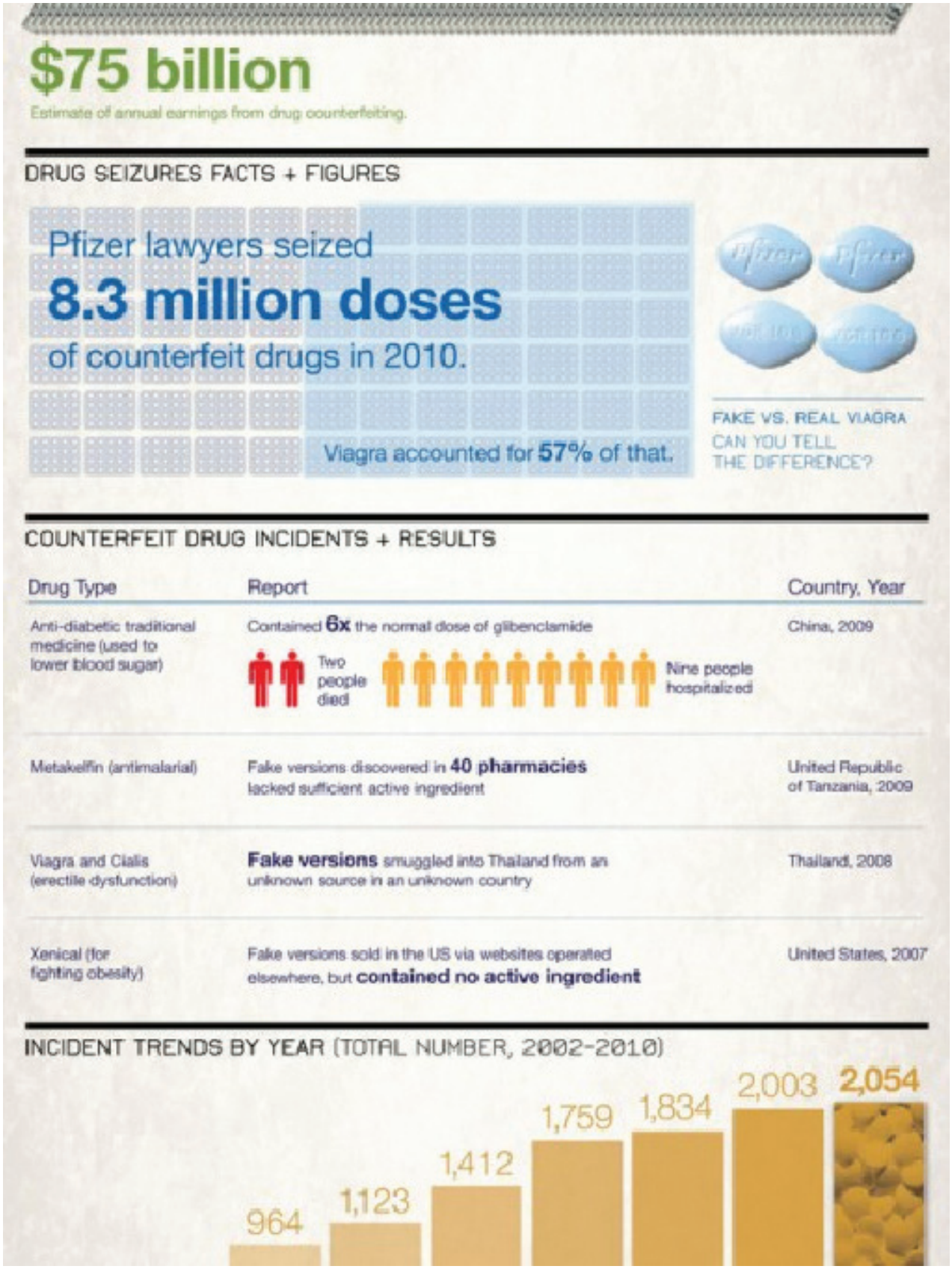
The Drug Control Authority (DCA) acts as the licencing authority (Regulation 3, CDCR 1984). The NPCB functions as the secretariat of the DCA. After the NPCB evaluate the products, the DCA have to make the decision whether the products is approved or rejected to be registered. If the product is rejected, the applicant can appeal to Minister of Health for review of DCA's decision.

Pharmacy Enforcement Division (PED):

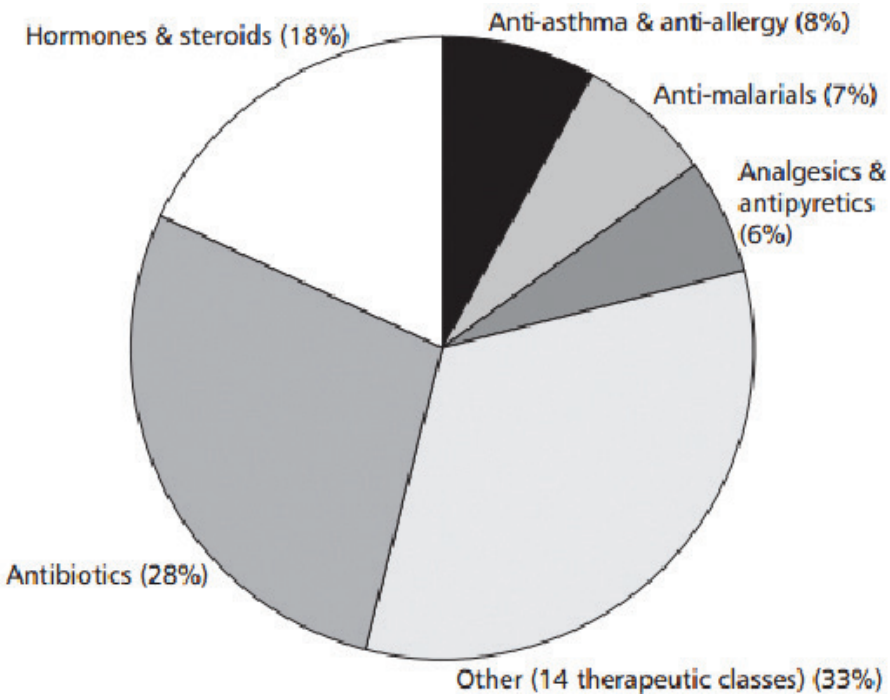
The PED was formed on 1st January 1976 under the Pharmacy Service Division to carry out the enforcement of legislations about pharmacy and the pharmaceutical trade in the country in a more efficient approach. PED objectives are to ensure all pharmaceutical and health products in the market are of quality, safe, efficacious and medicinal products and medical services advertisements comply with the rules and legislations enforced and also increase the consumers' awareness on the usage of the registered products. The PED structures are divided into branches such as;

- Intelligence and Operation
- Licencing and Control at Entry Point
- Legislation
- Advertisement and Innovation
- Protection and Consumer Awareness

All of the branches have different aims in managing unregistered drugs. There is various effort of enforcement in handling unregistered drugs. The increasing trend of



Source: WHO 2014
Figure 1.1 The summarization situation of the counterfeit drugs.



Source: WHO Impact Report, updated May, 2008
Figure 1.2 Reports of counterfeiting drugs by therapeutic class received by WHO, 1999-2002.

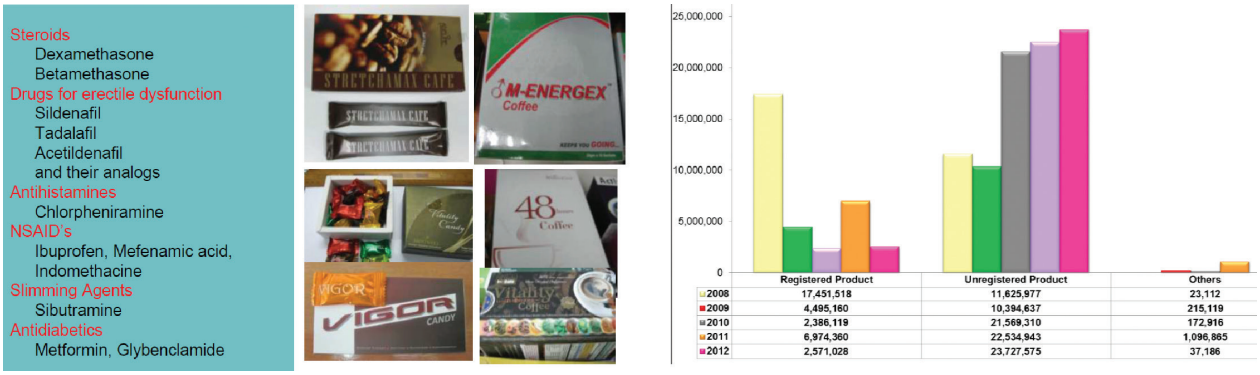
Figure 2.1 Example of illegal sexual enhancement drugs (2008-2009).

seizing statistic is also one of the evidence of the efficiency PED to combat unregistered drugs. Around Jun 2015, the cooperation of PED with the Operation PANGEA VIII 2015 for seven days is worth it because during the operation, 45,317 parcels and 130 premises were inspected, with a total seizure worth RM 830,663. Among the most common products seized were sex stimulants, slimming products, adulterated cosmetics and traditional products which were not registered with the Ministry of Health. This operation aims are the illegal online medicine trade, electronic payment systems and delivery services. From the operation, a finding is to design awareness and educational program on danger and risk of purchasing medicine through the internet.

Conclusion

Are we on the right track? This question is a big question mark that we need to answer. We are refer to consumers,

Figure 2.2 Examination of counterfeit drugs using organoleptic test



Source: Mazlan, 2013[2]
Figure 2.3 The common adulterants and the Amount of seizures 2008-2012 (MYR).

PED, others authorities, pharmaceutical company and also the health care provider. The overview in this paper can be visualizes that Malaysia have a stringent registration process and well managed enforcement department in managing the unregistered drugs. The collaboration with the international agency is one of the platforms to improve and decide what the next step is needed to strengthen and emphasize. Moreover, the combating the unregistered drug is not the easy task because the effort need to be the consistent, persistent and ongoing process. As long as the implementation, the right strategies and the enormous momentum from the authorities are same or more than the counterfeiters, the future with zero unregistered drugs might possible to be achieved. Future study is critical to focus more on finding what is the lacking in the current system and the root cause of this problem.

To ensure all of the people in this world on the right track in term of knowledge of counterfeit medicines; people itself might need to have initiatives to develop their knowledge and to have the desire to learn and think before they buy any health products, cosmetics, and medications.

To achieve the target or aim, all of the organizations

Figure 2.5 Criteria of registered products.

throughout the world need to tackle theirs population to let all of theirs people get equality of information towards registered drugs or counterfeit medicines. As we know; No Customers, No Profit, with this quote, with the power of knowledge, we can collapse the existing of counterfeit drugs worldwide.

Are we on the right track? Everyone can answer yes if we know the danger of the counterfeit and unregistered drugs to us. Below is the poetry about counterfeit drugs entitle 'Save You Life- Counterfeit Drugs Can Kill'.

In the technology growth, we get cheat easy,

Easy for manufacturer, easy for consumer,

People become obsess, and using technology,

To make money, or to make order using IT.

Please don't blame IT 100%,

We must know how to deal with THEM,

We are HUMAN, we have Brain to THINK,

Think before buy, or order using IT.

People must know where to refer with,

We have FDA, WHO, VIPPS, etc….

They are your teacher, learn with them,

Dig the knowledge with them, before decide to buy.

Sibutramine, Viagra are people choice worldwide,

Different type of dosage forms can be find using IT,

Easy get influenced if desire more than brain,

Heart damage, cardiovascular problems exist without fear.

THINK before everything become too late,

Think your FAMILY, think your own LIFE,

Develop the awareness & knowledge,

Of course using IT, but in different way.

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CONFLICT OF INTEREST

No conflict of interest

ABBREVIATION USED

PED: Pharmacy Enforcement Division; **MOH:** Malaysian Ministry of Health; **WHO:** World Health Organization; **SODA:** The Sale of Drug Act; **CDCR:** Control of Drugs and Cosmetics Regulations; **NPCB:** National Pharmaceutical Control Bureau; **DCA:** Drug Control Authorities; **PSI:** Pharmaceutical Security Institute; **IMPACT:** International Medical Products Anti-Counterfeiting Taskforce; **NGOs:** Non-Government Organizations; **UNODC:** United Nations Office on Drugs and Crime; **EMHN:** Emerging Markets network; **GMP:** Good Manufacturing Practices; **IDEAS:** Institute for Democracy and Economic Affairs.

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