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THE CONTROL OF COUNTERFEIT MEDICINE IN MALAYSIA BY PHARMACEUTICAL ENFORCEMENT DIVISION

NORAIMI BINTI NGARIP

A ACADEMIC PROJECT SUBMITTED IN PARTIAL FULFILLMENT FOR THE DEGREE OF MASTER OF CRIMINAL JUSTICE

FACULTY OF LAW

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In the name of Allah, The Most Merciful and The Most Compassionate.

Praise be to Allah. Blessing and peace be upon Prophet, Muhammad (pbuh) his family and companions. First and foremost, I would like to express my gratitude to Allah for His consent, I can complete this research project. Without the guidance of the Creator, it would be impossible for me to reach this far.

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ABSTRACT

This research provided an overview of the control of counterfeit medicine in Malaysia. Counterfeit medicine is a major concern due to its impact on the public health, healthcare system, economics and the country at large. This study outlined and described existing methods to curb counterfeit medicine in Malaysia as employed by the Pharmaceutical Enforcement Division, Ministry of Health, with an evaluation of current responses towards counterfeit medicine and suggestions of suitable improvements in the methods of preventing availability of counterfeit medicines. Library-based research and semi-structured interviews were conducted to collect all relevant information during the research. This study revealed a lack of definition and specific provision on counterfeit medicine in existing legislations. The current laws may be able to control the counterfeit medicine to some extent but are not sufficiently comprehensive due to some weaknesses which need to be remedied. The weaknesses of the laws should be reviewed and resolved by the government. This study further recommended the steps that the authority and policy makers should look into to tackle the counterfeit medicine problems. Recommendations from this research might not be final, but it can be useful in assisting the policy makers to implement laws, policies and standards on the issues.

ABSTRAK

Kajian ini meninjau kawalan ke atas ubat-ubat palsu di Malaysia. Ubat-ubat palsu mendapat perhatian khusus kerana kesannya terhadap kesihatan awam, sistem penjagaan kesihatan, ekonomi dan negara. Kajian ini menyenaraikan dan menerangkan kaedah kawalan terhadap ubat-ubat palsu yang sedia ada di Malaysia yang dijalankan oleh Bahagian Penguatkusa Farmasi, Kementerian Kesihatan Malaysia. Dengan menilai reaksi semasa terhadap ubat-ubat palsu, kaedah penambahbaikan yang sesuai dikemukakan untuk menghalang wujudnya ubat-ubat palsu. Kajian perpustaakn dan temuramah dijalankan untuk mendapatkan maklumat-maklumat yang relevant. Kajian mendapati terdapatnya kelemahan dari segi tiadanya definisi dan provisi khusus dalam undang-undang yang ada. Walaupun perudangan sedia ada dapat mengawal ubat-ubat palsu tetapi ia tidak menyeluruh kerana wujudnya kekangan-kekangan yang perlu diperbaiki. Kelemahan undang-undang perlu disemak dan dieprtimbangkan oleh pihak Kerajaan. Kajian ini juga mencadangkan langkah-langkah yang perlu diambil perhatian oleh pihak berkuasa dan penggubal dasar dalam usaha mengawal ubat-ubat palsu. Cadangan yang dikemukakan bukanlah sesuatu yang muktamad tetapi ia dapat membantu pihak berkuasa dalam menggubal akta, dasar polisi dan piawai bagi membendung masalah ubat-ubat palsu.

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LIST OF ABBREVIATIONS

CDCR	*Control of Drugs and Cosmetics Regulation 1984*
PED	Pharmacueutical Enforcement Division
SODA	*Sale of Drug Act 1952*
MOH	Ministry of Health
GMP	Good Manufacturing Practices

CHAPTER 1

INTRODUCTION TO THE RESEARCH

1.0 INTRODUCTION

This chapter consists of the research background, problem statement, objectives of the research, research methodology, scope and limitations of the research and significance of the research. All components of the research will be detailed here.

1.1 RESEARCH BACKGROUND

Drugs or medicines play an important role in improving human health and promoting well-being. In order to produce the desired effect, medicines must be safe, effective and of acceptable quality. The use of ineffective or poor quality drugs will endanger the health or life causing unnecessary morbidity and mortality, as well as eroding public confidence in medicines and health structures.[1] Therefore, it is important for

[1] Cockburn,R., Newton,P.N, Agyargo,E.K, Akunyili, D., White, N.J. (2005). "The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers." *Plos Medicine*, Vol.2, no.4, pp. 0302-0308.

government of each country to regulate the production, storage, distribution and use of drugs.[2]

The pharmaceutical products are not exempted from the practice of counterfeiting. Counterfeiting will harm consumers by putting their health and safety at high risk when they purchased poor quality products.[3] Counterfeit means things made or done so that it is similar to another thing, in order to deceive. It is also interpreted as fake.[4] Counterfeiting is one of the fastest growing economic crimes of modern times which devalued corporate reputations, hinders investments, funds terrorism, and costs hundreds of thousands of people's livelihoods every year.[5] Counterfeiting of commercial products has long existed in the market. However, counterfeit drugs are a new phenomenon where the problem of counterfeit medicine was first highlighted at the international level in 1985 at the Conference of Experts on the Rational Use of Drugs in Nairobi.[6]

In Malaysia, drugs or medicines are controlled by the Pharmaceutical Enforcement Division (PED). Specific acts and regulations were enacted to ensure the safety, quality and efficacy of the products in the market and to control importation, manufacture, sale, supply and administration of all drugs or medicines. Indirectly, Pharmaceutical Enforcement Division also controlled counterfeit medicines.

Ineffective drug regulation and enforcement could facilitate the counterfeiting of pharmaceutical products. Legal systems which are not equipped to deal with the serious

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[2] Wondemagegnehu, E. (1999). "Counterfeit and Substandard Drugs in Myanmar and Viet Nam, Reports of a Study Carried Out in Coorperation with the Governments of Myanmar and Viet Nam." World Health Organization. Geneva.

[3] Union des Fabricants, "Counterfeiting & Organised Crime". Retrieved 12 June 2010 p4 from http://www.gacg.org/Content/Upload/Documents/rapport_uk.pdf,

[4] Hornby, A.S. (2007), *Oxford Compact Learner's English-Malay Dictionary*. Kuala Lumpur: Oxford Fajar Sdn Bhd, p.314.

[5] "Counterfeiting Intelligence Bureau". Retrieved 12 June 2010 from http://www.icc-ccs.org/index.php?option=com_content&view=article&id=29&Itemid=39

[6] World Health Organization, "Counterfeit Medicines". Retrieved 12 June 2010 from http://www.who.int/medicines/services/counterfeit/en/

consequences of counterfeit medicines, and the penalties imposed which are too light as deterrence will also contribute to this problem.[7]

Punishment is always seen as an effective crime control mechanism. People will be deterred to commit crime if harsh punishment is imposed by the criminal justice system as punishment is always involved in the idea of retribution.[8] Absence of deterrence legislation in many countries is one of the factors that encourage counterfeiters, where they can continue their activities without fear of being apprehended and prosecuted.[9] The disregard of public safety shown by the counterfeiters should be taken into account when considering the solution of this serious problem. A tough measure should be devised to ensure that they will be deterred from committing the offence for easy profits.

Apart from punishment; legislation, enforcement, and preventive steps are also important in a crime prevention action. Thus, this research aims, among others, to evaluate the steps taken by Pharmaceutical Enforcement Division in monitoring and preventing counterfeit medicine in Malaysia. It is possible to suggest that weaknesses in the enforcement powers of Pharmaceutical Enforcement Division might hinder its ability to meet the standards of surveillance on counterfeit medicine by the World Health Organization (WHO). Hence, it is necessary to study the current legal and enforcement powers of Pharmaceutical Enforcement Division in order to evaluate its capability to deal with the problem of counterfeit medicine.

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[7] World Health Organization, "Counterfeit Medicines". Retrieved 12 June 2010 from http://www.who.int/medicines/services/counterfeit/en/

[8] Mays,J.B. (1975). *Crime and Its Treatment*. United Kingdom: Longman Group Limited, Second Edition page 90.

[9] World Health Organization, "Factors Encouraging Counterfeiting of Drugs". Retrieved on 12 June 2010 from, http://www.who.int

1.2 PROBLEM STATEMENT

Current legal powers and enforcement methods of the Pharmaceutical Enforcement Division is not adequate to tackle the problem of counterfeit medicine in Malaysia.

1.3 RESEARCH OBJECTIVES

There are three objectives in this study:

i. To outline and describe existing methods curbing counterfeit medicine in Malaysia as employed by the Pharmaceutical Enforcement Division, Ministry of Health

ii. To evaluate current response towards counterfeit medicine in Malaysia

iii. To suggest suitable methods of improvements in the preventing counterfeit medicines in Malaysia

1.4 RESEARCH METHODOLOGY

The research is based on the following method:

i. Library-based research was conducted to collect all relevant information relating to the aspect of various laws regarding the counterfeit medicines. The references,

which include statutes, textbooks, articles, journals, and research papers, were analyzed for broader views.

ii. Internet-sourced materials were also collected by using online databases, such as Lexis Nexis, the Current Law Journal (CLJ) database, and the Lawnet database; other websites; and Google and other search engines. The information obtained through online databases and internet searches includes online newspapers, articles, statutes, journals and annual reports.

iii. Apart from that, interviews were conducted with officers from the Pharmaceutical Enforcement Division, Ministry of Health. Selections of these officers were based on the officer's exclusive knowledge due to position and experiences. The purpose of these interviews is to gain direct information from the officers about the actual problems in dealing with counterfeit medicine available in the market. The information from these interviews is used in various areas of discussion in this dissertation. The interviewees are as below:

Interviewee 1: Senior Principle Assistant Director, Consumer Protection Unit, Pharmaceutical Services Division, Ministry of Health Malaysia.

Interviewee 2: Deputy Director, Operation & Investigation Unit, Pharmaceutical Services Division, Ministry of Health Malaysia.

Interviewee 3: Senior Principle Assistant Director, Prosecution Unit, Pharmaceutical Services Division, Ministry of Health Malaysia.

1.5 SCOPE AND RESEARCH LIMITATIONS

There are some limitations the researcher had to face during this study. The small number of research in Malaysia, particularly in the research-related topic, makes it difficult to gather more information and renders it impossible to do comparison. The researcher also found difficulty in collecting data and statistics on counterfeit medicine as they were not properly documented. This study focuses provision in Sale of Drug Act 1952, Poison Act 1952 and Control of Drugs and Cosmetics Regulation 1984. Advertisement offences under the Medicines (Advertisement and Sale) Act 1956 and Regulations are excluded.

1.6 SIGNIFICANCE OF THE RESEARCH

The findings of this research may contribute towards a more effective control of counterfeit medicine by PED hence, the Ministry of Health. It is also hoped that the findings of this research would also contribute to a better understanding of the nature of the counterfeit medicine crime and the ways to tackle it. Furthermore, the research may be useful in assisting policy makers in implementing and improving the relevant laws and regulations. Better enforcement will also ensure compliance with the international standards for better public protection.

1.7 CHAPTER OUTLINE

This dissertation is divided into five chapters. The first chapter is an introduction of the study in whole. It describes the research background, problem statement, research objectives, research methodology, research limitations, and the research significance. Chapter two looks into the nature of counterfeit medicine globally and also the situation in Malaysia. The second part of this chapter will look into the contributory factors as well as describing the counterfeiters.

Chapter three reviews the counterfeit medicine control framework in Malaysia. Relevant laws and regulations as well as the approaches taken to control this crime by Pharmaceutical Enforcement Division will be analysed. The weaknesses of the regulations and preventive actions in controlling counterfeit medicine will also be identified.

Chapter four will analyses the problems in controlling counterfeit medicine and make recommendations to tackle them. The last chapter provide the conclusion of the research.

1.8 CONCLUSION

Based on discussion above, it is important to control counterfeit medicines due to the undesired effects arising from poor quality, safety and efficacy. Counterfeit medicine is a serious threat to public healthcare systems and, specifically, the community. A greater attention should be paid to the control of counterfeit medicine because it involves

invaluable human lives. Therefore laws and regulations on counterfeit medicines need to be strengthened to curb the illegal activities. Identification of the causes of counterfeit medicines present in the market is important in order to implement suitable approaches to curb the problem. Consequently in the following chapter, the nature, description, impact and contributing factors of the counterfeit medicine crime will be discussed.

CHAPTER 2

AN OVERVIEW OF COUNTERFEIT MEDICINE

2.0 INTRODUCTION

This chapter will discuss the nature of counterfeit medicine and its impact on to public health, healthcare systems, country and economic. This chapter further described the extent of the problem globally and in the Malaysian context. Factors that contributed to the production and sale of counterfeit medicine were also included in this discussion. To ensure the enforcement control of the counterfeit medicine is effective, the factors above must be taken into consideration in order to tackle the problem at all angles. Priority must be given to enforcement duty can also considered due to the seriousness of the problem with regards to the impacts of the counterfeit medicine.

2.1 WHAT IS COUNTERFEIT MEDICINE?

The word counterfeit medicine is very ambiguous in the medical terminology. There is no specific definition on counterfeit medicine in medical dictionary. [10] The word drug and medicine are often used interchangeably. "Medicines" means any drug or remedy.[11] "Drug" means substance used as or in a medicine.[12]

The legal definitions of counterfeit medicine vary from country to country and there is no universal definition of counterfeit drugs.[13] Although in actual fact there is no uniform definition of counterfeiting available,[14] the definition by the World Health Organization (WHO) can be used as basis. The first international meeting of counterfeit drugs was held from 1 to 3 April 1992 in Geneva. A joint workshop organised by WHO and the International Federation of Pharmaceutical Manufacturers Association reached a consensus on the definition of counterfeit medicines which was defined as "one which is deliberately and fraudulently mislabelled with respect to its identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging."[15]

According to World Health Organization, counterfeit medicine is defined as:

> "A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply both branded and generic products and counterfeit products may

[10] Dzulkiply, N.D. (2007). Counterfeit Medicines in Malaysia: Problems and Solutions, Unpublished bachelor's thesis, Universiti Sains Islam Malaysia, Negeri Sembilan.
[11] Shoin, I. (1995). *Dorland's Illustrated Medical Dictionary*, 26th ed., W.B. Saunders Company, p.785.
[12] Hornby, A.S. above n 4 , pg 2.
[13] Wondemagegnehu, E. above n 2, pg1.
[14] Ibid.
[15] Department of Essential Drugs and Other Medicines. (1999). "Counterfeit Drugs, Guidelines for the Development of Measures to Combat Counterfeit Drugs". Geneva: World Health Organization, pg 8.

include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging.[16] "

From this definition, we can say that any medical product with fake packaging containing correct quantity of correct ingredient, with wrong ingredient, no active ingredient or incorrect quantity of correct ingredient can be considered as counterfeit medicine. Medicines with genuine packaging but deliberately contain either wrong ingredient, no ingredient or incorrect quantity of ingredient are also considered as counterfeit medicine. In cases where medicine with genuine packaging not deliberately contains incorrect quantity of ingredient it is considered as substandard medicine.[17] Any kind of adulterated medicine can also be classified as counterfeit medicines.[18]

2.2 THE PROBLEM OF COUNTERFEIT MEDICINE

Counterfeit medicines problem is alarming globally. They can result in treatment failure or even death.[19] Counterfeit medicine can range from medicines for the treatment of life-threatening conditions to inexpensive generic versions of painkillers and antihistamines.[20] All kinds of medicines have been counterfeited including both branded and generic versions.[21]

[16] Department of Essential Drugs and Other Medicines. (1999). "Counterfeit Drugs, Guidelines for the Development of Measures to Combat Counterfeit Drugs". Geneva: World Health Organization, pg 8.
[17] Department of Essential Drugs and Other Medicines, above n 15, pg 9.
[18] Ibid.
[19] World Health Organization. Medicines: Counterfeit Medicines. Retrieved on 18 May 2010 from http://www.who.int/mediacentre/factsheets/fs275/en/
[20] Ibid.
[21] Ibid.

Counterfeit medicines are dangerous because their unknown content and quality.[22] Counterfeit products post serious threats to the community and the counterfeiting of medicines cannot be viewed as the same light as counterfeiting of other goods which often have no effect on public health and human life.[23]

Early incidents of counterfeit medicine primarily targeted life-style drugs then expanded to over-the-counter (OTC) pain medications, antibiotics, insulin, cholesterol drugs, hormone replacement therapy, flu medications, anti-arthritis drugs, cardiac drugs, anti-parasitic drugs, antihistamines and many more.[24] More and more medicines were counterfeited as the phenomenon developed to include anticancer drugs and antivirals particularly for HIV/AIDS treatment.[25] The counterfeit medicine market has burgeoned and matured spanning the spectrum from lifestyle drugs to lifesaving drugs. It is likely that all citizens are potentially affected.[26]

People can be killed or become very sick due to the toxicity of counterfeit substances. For example, cough mixture diluted with poisonous solvent ethylene glycol an ingredient in antifreeze instead of glycerin, has led to the deaths of more than 500 patients in Argentina, Bangladesh, India, Nigeria and Haiti.[27] Similarly include a lack of active ingredient in anti-malarials and anti-cancer medicines has resulted in persistence of the disease[28] and acceleration of disease in prostate cancer case.[29] Other examples

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[22] Clive, B. (2006). "Counterfeits: Reducing the Growing Threat". *Pharmaceutical Technology Europe*, Peer Reviewed, p.36.
[23] Datuk Seri Chua Soi Lek. (2006). "Speech of Seminar on *Counterfeit Pharmaceuticals: A Global Perspective*".Minister of Health Malaysia. Bandar Sunway, Selangor.
[24] Cockburn, R., Newton, P.N., Kyerematen Agyargo, E., Akunyili, D.& White, N.J., above n 1, pg 1
[25] World Health Organisation Drug Information. (2006). "Counterfeit Medicine". Vol 20, Issue 1, p.3.
[26] Rozendaal, J. (2001). "Fake Antimalaria Drugs in Cambodia". *The Lancet*, Vol 367, p.890.
[27] Reidenberg, M. & Conner, B.(2001). "Counterfeit and substandard drugs". *Clinical Pharmacology & Therapeutics*. Vol. 69, no. 4, pg189-193.
[28] Ibid.
[29] Csillag, C.(1998). "Sao Paulo: Epidemic of counterfeit drugs causes concern in Brazil". *The Lancet*. Vol. 352, no.28, p.553.

included fake inhalers manufactured for paediatric cystic fibrosis and parental cancer drugs simply contain tap water.[30]

2.2.1 The Impact of Counterfeit Medicine

The nature and extent of counterfeiting vary from country to country so the facilitating factors are different. Therefore, there is no single or simple way to eliminate the problem. By taking all the factors into account, each country should develop a strategy adapted to its specific situations and the magnitude of the problem.[31]

There is a view that counterfeiting is a crime with no real victims. People have always desired well-known brands but with lower cost. However, the impact of counterfeit medicine cannot be taken lightly because it involves the lives of the consumers which are priceless. Counterfeit medicine causes considerable impact on public health, healthcare system, economics and country at large.

2.2.1.1 Public Health

Counterfeit medicines have risks, which are judged on the known toxicity and side-effects of the drug, the possibility that unforeseen adverse reactions may occur and abused by patients may occur.[32] There have been reports of counterfeit and substandard drugs contributing to increased mortality.[33]

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[30] Bryan, A.L. (2006). " Fade to Black: Importation and Counterfeits Drugs". *American Journal Law & Medical*.Forthcoming, p32.
[31] Department of Essential Drugs and Other Medicines, above n 15, pg 9
[32] Alagaratnam, R. & Gwee, C.E.M. (1977). "Safety, Efficacy & Quality of Medicine". Univeristy of Singapore: Department of Pharmacy and Pharmacology. pg66.
[33] Rozendaal, J., above n 26, pg12.

U.S Food and Drug Administration (FDA) had proposed a ban on over-the-counter sales of cosmetics product containing hydroquinone, a skin bleaching (lightening) ingredient. Evidence showed that hydroquinone is a carcinogenic chemical and can cause ochronosis of which the skin becomes dark and thick. Hydroquinone had been banned in Japan, Australia and the European Union for these reasons.[34] Photoaging is most effectively treated by tretinoin but it has teratogenicity effect. Although topical application is proved not to increased the risk of spontaneous malformation in fetus, defering tretinoin therapy for patients who are trying to conceive actively is the best prevention to avoid wrongful blame for congenital defects that may occur by chance.[35] This is a very serious side effect of tretinoin that may occur in the victims using cosmetics containing hydroquinone and tretinoin unknowingly.

Analgesics can cause severe consequences to people having gastric problems. Consuming analgesics with an empty stomach may cause serious ulcerogenic effect since it has the same mechanism of action as the peptic acid production in stomach.[36] People may not be aware of the precaution because they are taking medicine without knowing the existence of analgesic inside the preparation. Anti-histamine on the other hands can cause hypersensitivity to those who cannot tolerate it. As it can cause drowsiness, improper warning or taking herbal medicine without knowing it contains antihistamine is dangerous when driving or handling a machine.[37] Consumers may not realize they are taking those controlled medicine after they had been diagnosed with the illness or were traumatized in accidents.

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[34] Stoppler, M.C. FDA Proposes Hydroquinone Ban, MedicineNet.com. Retrieved on 13 June from http://www.medicinenet.com/script/main/art.asp?articlekey=64167.

[35] Kang, S, Fisher, G.J. & Voorhees, J.J. (1998). " Photoaging Therapy With Topical Tretinoin: An Evidence-Based Analysis". *Journal of American Academy of Dermatology*. Vol. 39, No.2, Part 3, pg 59.

[36] Engelhardt, G., Homma, D., Schlegel, K, Utzmann, R. & Schnitzler, C. (1995). "Anti-inflammatory, analgesic, antipyretic and related properties of meloxicam, a newer non-steroidal anti-inflammatory agent with favourable gastrointestinal tolerance". *Infammation Research*. Birkhauser Verlag, Basel, Volume 44, No. 10, 423-433.

[37] Gengo, F.M. & Manning, C. (1990). "A review of effects of antihistamines on mental processes related to automobile driving". *Journal of Allergy and Clinical Immunology*. Vol 86, Issue 6, Part 2, pg 1034-1039.

With its norepinephrine and serotonin reuptake activity, Sibutramine was approved for weight management in patients who are unable to lose weight by means of diet and exercise alone.[38] In general, sibutramine is well-tolerated. The most common side effects include abdominal pain, acne, rash, chest pain, anxiety, joint pain, back pain, excitation, depression, sweating, dizziness, drowsiness, changes in taste, irregular or painful menstrual periods, flu-like syndrome, increased cough, muscle pain, nausea, vomiting, neck pain, nervousness, and palpitations, tingling of the extremities, sore throat and sinus congestion.[39]

Sibutramine should be excluded from use for patients with preexisting cardiovascular disease because of the increased risk of non fatal myocardial infarction and non fatal stroke.[40] This is very dangerous as consumers are prone to think what they consume is purely natural ingredients, and thus assumed to be harmless. Ranges of mild to life-threatening adverse effects have been associated with weight-loss products containing various illicit agents such as sibutramine.[41]

2.2.1.2 Healthcare System

A serious if not fatal consequence is the erosion of confidence in health-care systems.[42] The public or patients will lose confidence in the health-care system if they perceived that the drug quality is poor. Apart from public or patient, the health care providers or practitioners will also lose confidence in the genuine medications that they rely upon.

[38] James, W.P.T., Carterson,I.D., Countinho, W., Finer, N., Gaal, F.V., Maggioni, A.P. & et al.(2010) "Effect of Sibutramine on Cardiovascular Outcomes in Overweight and Obese Subjects". *The New England Journal of Medicine*. Massachusetts Medical Society, Vol 363, No.10, pg 905.

[39] James, W.P.T, Astrup, A., Finer, N.,Hilstled, J, Kopelman, P., Rossnar & et.al. (2000). "Effect of Sibutramine on Weight Maintenance After Weight Loss: A Randomised Trial" *The Lancet*, Vol 356, 23/30, pg 2123.

[40] James, W.P.T., Carterson,I.D., Countinho, W., Finer, N., Gaal, F.V., Maggioni, A.P. & et al. above n 41, pg14.

[41] Tang, M.H.Y., Chen, S.P.L., Ng, S.W., Chan, A.Y.W., Mak, T.W.L. "Case Series on a Diversity of Illicit Weight-reducing Agents : From The Well Known To The Unexpected". *British Journal of Clinical Pharmacology*. Retrieved on 2 August 2010 from http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2125.2010.03822.x/pdf

[42] Reggi,V.(2007). "Counterfeit Medicines: An Intent to Deceive". *International Journal of Risk & Safety in Medicine*. IOS Press,19, pg105-108.

The consequent failure of the treatment may result in frustration of the health care providers.[43]

Use of counterfeit medicines may result in treatment failure as consequent to lack of effect, which in turn could result in worsening of disease condition, deformity and death. Counterfeit medicines could introduce new adverse drug reactions (ADRs), dangerous interactions or intensify already known ones.[44] One of the most worrying implications of global bloom in counterfeit medicines is the acceleration of new, drug resistant strains of viruses, parasites and bacteria, and also heavy metal, mercury and arsenic.

Antimalarials rank among the therapeutic groups that have developed resistance in very quick succession. From quinine, chloroquine, sulphadoxine-pyrimethamine, primaquine, mefloquin to halofantrine strains of the plasmodium parasite resistant to these agents have been reported, resulting in continuous change of antimalaria policy, treatment guidelines, ways to tackle new side effects, adverse reactions and of course lots of other changes for the industry as well. Malaria causes the death of over two million people per annum, mostly in the endemic regions of Southeast Asia and tropical Africa. The wide and intense counterfeiting of antimalarials might have contributed considerably to the resistance to antimalarial medicines and subsequent treatment failures. Often, these antimalarials are not analyzed to ascertain their quality prior to use. Therefore, it is difficult to ascertain if perceived resistance is due to the organism or to substandard products such as counterfeits.[45]

[43] Reidenberg, M. & Conner, B., above n 27, pg12.
[44] Akunyili, D.N., Nnani, I.P.C., Risk of Medicines: Counterfeit drugs, *International Journal of Risk & Safety in Medicine*, (2004), Vol. 16, p.187.
[45] Reidenberg, M. & Conner, B., above n 27, pg12.

2.2.1.3 Economics

Counterfeiting is not a non-victim crime and is not a pure economic crime.[46] The first victims of counterfeiting are businesses or the companies producing the genuine product. Not only they lose sale revenue, market share and investments but also suffer from the devaluation of their brand image and investments in research and development.[47]

In 2003, the United Kingdom-based anti-counterfeiting group estimated that 5.8% of the pharmaceutical company annual revenue is lost due to counterfeiting,[48] and recent estimate ranges even higher.[49] It has been estimated that the fake medicines market is worth US$35-44 billion per year and money is lost because the patients and their families must bear with increased costs of suffering and sometimes death.[50]

Counterfeiting certainly damages the legitimacy of commerce. It undermines the margins of the drug companies, not only reducing profits but also reducing the capital for reinvestment for new drugs research, and also reduces the tax revenues of the country.[51]

[46] United Nation Interregional Crime and Justice Research Institute. "Counterfeiting". Retrieved on 12 June 2010 from http://www.unicri.it/risks.php
[47] Union des Fabricants, above n 3, pg 2.
[48] The Anti-Counterfeiting Group.(2003). "Why You Should Care About Counterfeiting". Retrieved on 12 June 2010 from http://www.a-cg.com/guest_frames.html
[49] Bryan, A.Liang, above n 30, pg13.
[50] Newton, P.N, Green, M.D., Fernandez, F.M., Day, N.P.J. & White, N.J. (2006). "Counterfeit Anti-Infective Drugs". *The Lancet Infectious Diseases*. Elsevier Ltd, Vol 6, Issue 9, pg 602-613.
[51] Swaminath, G. (2008). "Faking It- The Menace of Counterfeit Drugs". *Indian Journal of Psychiatry*. Medknow Publications.

2.2.1.4 Country

A lack of willingness to recognize the existence or the seriousness of the problem may cause a country being labelled as the producer of counterfeit medicines. Although Malaysia was not yet labelled as a producer, statistics shows that a large proportion of counterfeit medicine originates in Asia.[52] In 2001, China was already reported to have 500 illegal medicines factory. It was also reported in the same year that 1,300 factories were closed while 480,000 cases of counterfeit drugs worth $57 million were under investigations.[53] Apart from China, the other countries that always contributed to the counterfeit medicines producer statistics were India, Nigeria and Cambodia.[54]

The impact of being labelled as producer by the world may negatively affects the country's reputation and indirectly hinders country development.

2.3 THE EXTENT OF THE PROBLEM OF COUNTERFEIT MEDICINE IN MALAYSIA

In Malaysia, counterfeit medicine was detected by the Pharmaceutical Enforcement Division as early as 1980's.[55] This may be due to the alerts highlighted by WHO at international level in 1985. Counterfeit medicine was first found to be distributed to the medicine shops by the counterfeiters. In early 1990's, PED found that adulterated herbal medicine contains steroid, analgesics, or antihistamine. These were considered as counterfeits product as the active ingredients were not the same as labelled. Steroid,

[52]Morris, J. & Stevens, P.(2006). "Counterfeit Medicines in Less Develop Countries". *International Policy Network*. International Policy Press, pg 3.
[53] Ibid.
[54] Ibid.
[55] Ibid.

analgesics and antihistamines have an anti-inflammatory effects that makes herbal remedies' claims to be true.[56] The most popular type of counterfeit medicine during that time was "ubat papan"[57] which claimed to be herbal medicine but contained steroid.[58]

Some of the products seized and analysed by PED as adulterated with steroids were 357 Nasal Spray, Makjun Taufiq Dua Istimewa, Majun Dua Istimewa, Ginseng Jin Fui Wan, Maajun Tenaga Herba-Ubi Jaga, Jamu Tradisional Jaya Asli (Anti Asam Urat), Red Brand Ginseng Plus Zheng Fei Capsules, Air Ikan Haruan, Pil Resdong, Penawar Sendi Tulang and others.[59] As discuss in the previous chapter, according to World Health Organization definition, any medicine with either fake or genuine packaging contain wrong ingredient is considered as counterfeit medicine.

In late 1996, the era of cosmetics adulterated with hydroquinone and tretinoin had come into market. Here again cosmetics adulterated with hydroquinone and tretinoin can be considered as counterfeit product because it contained the wrong ingredient. Most of the cosmetics came from the Philippines. The market then were flooded with cosmetics containing hydroquinone and tretinoin to attract consumers who want a smooth and clear skin[60] as hydroquinone is an antipigmentation agent[61] and tertinoin is used to improve photoaged skin.[62] Hydroquinone[63] and tertinoin[64] are listed under the First Schedule Poison Act 1952 which require prescription from medical practitioner and are

[56] Anti–inflammatory agents. Retrieved on 15 September 2010 from http://www.Britannica.com/EBchecked/topic/171942/drug
[57] See appendix 1.
[58] Interviewee 2, Deputy Director, Pharmaceutical Enforcement Division, Ministry of Health. Condcuted on 15 October 2010.
[59] Enforcement News. Retrieved on 1 October 2010 from http://www.pharmacy.gov.my/index.cfm?menuid=152&parentid=14
[60] Interviewee 2, above n 58.
[61] Nordlund, J.J., Grimes, P.E. & Ortonne, J.P. (2006). "The Safety of Hydroquinone". *Journal of The European Academy of Dermatology and Venerology*. Vol. 20, Issue 7, pg781-781.
[62] Cuce, L.C., Bertino, M.C.M., Scattone, L. & Birkenhauer, M.C. (2001). "Tretinoin Peeling". *Dermatologic Surgery*, Vol 27, Issue 1, pg12-14.
[63] First Schedule, *Poison Act 1952*, pg 61.
[64] Ibid at pg 102.

prohibited in cosmetics preparation.[65] Beauty creams and soaps, such as Eriesya Spa Beauty Cream, Atika Beauty Renewal Cream, Temulawak Whitening Pearl Cream Papaya, Ratna Sari Whitening Night Cream, Tia Amelia Krim Jeragat, Chantique Whitening Night Cream, Rzac White Pearl Cream, Nuris Day & Night Cream, Elite Rias Er Cream, R&Z Whitening Cream, Natasya Cream Herba Gold, Natasya Krim Herba and many more, were among those analysed as containing either hydroquinone or tretinoin or both.[66]

The Ministry of Health, Malaysia (MOH) carried out two studies in 1997 and 1998 to gauge the magnitude of counterfeit medicine in the local pharmaceutical market. The study involved western pharmaceuticals in 1997 and traditional medicines in 1998.[67] For western pharmaceuticals, 5.3% (64 out of 1212 samples) were found to be counterfeited and 0.35% (2 out of 570 samples) of the traditional medicines was also found counterfeited.[68] Recent data was not available because there is no other study done regarding this matter.

This phenomenon continued until late 2002 when the enforcement bodies aggressively raided these herbal medicines and cosmetics. Counterfeiters had to change their modus operandi after their businesses were detected by the authority.[69] Recently, their ranges of products were changed to slimming products. Slimming tea, slimming pills containing sibutramine had been detected in the market.[70] Sibutramine is a controlled medicine listed under the First Schedule of Poison Act 1952 that requires a prescription

[65] Guideline for Control of Cosmetic Products in Malaysia. Retrieved on 1 October 2010 from http://portal.bpfk.gov.my/index.cfm?menuid=63&parentid=34
[66] Enforcement News, above n 59, pg19.
[67] Ministry of Health Malaysia. (1998). Annual Report, p.219.
[68] Ibid.
[69] Interviewee 2, above n 58, p.19.
[70] Ibid.

and monitoring from medical practitioner.[71] Several products in the market found to contain sibutramine were Kintop, Amberine, Pyhtoshape, Body Beaus, BIM-9 Xylimming Capsule, Senna Plus Capsule, Lami, Obexlim, Body Lift Biodex, Slimax Coffee, Beaute Fit Bondy Contour, Body Trimz, etc.[72] We can see in Malaysia, most of the counterfeit medicine seized contain the wrong ingredient.

Apart from cosmetics and slimming products for women, the current trend of counterfeit medicines are sex stimulant products for men. Viagra was first brought in to Malaysia by Pfizer Sdn Bhd and registered with the National Pharmaceutical Control Bureau (NPCB) in 1998. It was seen as a lifestyle drug rather than serious medical therapy for those who suffer erectile dysfunction.[73] Counterfeit Viagra ranges from original appearance of blue diamond shape of Viagra pills to the products adulterated with the active ingredients. Products included traditional medicine, over the counter medicine, herbal drink, herbal food, candy, coffee and the latest fruit juice.

A wide range of products were found to be adulterated with sildenafil and its analogues. These included traditional medicine(Pronoton, Venergy Capsules, Cosa Grande Platinum and etc); candy (Candigold, Candy 193, Vitality Candy, Red Energizer Candy for Men, Vigor Candy and etc); pre-mix coffee and tea (Café Abang Yes Spartan, King Cappucino, Knight Coffee, Kolekcafe Power Plus, Kopi Anggok, Kopi Asmara, Kopi Bagus AAA, Kopi Campuran Kedai Kopi Ali Bagus, Kopi Pahlawan HBW Ice Lemon Tea and etc); energy drink (Extend Up Energy Drink, Extremen, Goji Guarana, Goji Guarana Extra, Goji More, Goji Yumberry and etc); fruit juice (XKL Skyfruit Juice Premix). All these detected to contain sildenafil which is the active ingredient of Viagra

[71] First Schedule, *Poison Act 1952.*
[72] Enforcement News, above n 59, p19.
[73] Keth, A. (2000). "The Economics of Viagra, A New Blockbuster Drug Raises Important Questions About What is Viewed As "Medical Necessity" by Insurers". *Viagra Economics*. Project HOPE, Vol. 19, No. 2, pg 147.

or thiosildenafil or thiodimethylsildenafil, hydroxythiohomolsildenafil or acetildenafil or homosildenafil or aminotadalafil, or tadalafil[74] which is the active ingredient of Cialis.[75] Different analogues were found and special attention should be given because some of these analogues were not scientifically approved for safety and had adverse effects. Such analogues are difficult to detect by ordinary laboratory methods, and might be used in an attempt to evade regulatory inspection. Without stringent drug testing procedures, the adverse effects of these chemicals remain largely unknown and unpredictable.[76]

From our data, registered medicine found adulterated with controlled medicine included Pronoton, Venergy Capsule, Spartan, Jinglida, Tomabest, VNG400, VEGROW, Goji Plus Capsule, Promax Capsule, Kintop, Amberine, Phytoshape, Body Beaus, BMI-9 Xlimming Cpsules, Senna Plus Capsule and 357 Nasal Spray. These showed legitimate manufactures were involved in the crime of counterfeiting medicine.

In addition to the adulterated products mentioned above, Panadol,[77] Eye Mo, Ubat Batuk Cap Ibu dan Anak, Minyak Mestika, Tunjuk Langit Capsule, Sensoil, Minyak Angin Cap Kapak and Gold Sheep Placenta Plus were amongst the counterfeit medicines seized by PED.[78] Detection of these products followed complaints from the product registration holder as they were the only persons who can detect the physical differences.

[74] Enforcement News, above n 59, pg 19.
[75] Ibid
[76] Poon, W.T., Lam Y.H., Lai, C.K., Chan, A.Y.W & Mak,T.W.L. (2007). "Analogues of Erectile Dysfunction Drugs: An Under – recognized Threat". *Hong Kong Medical Journal*, Vol.13, No.5, pg 359.
[77] Appendix 2.
[78] Ismail, M. (2009). "Presentation: Prevalance of Counterfeit Medicine s In Malaysia, Pharmacy Enforcement Perspective" Petaling Jaya, Selangor.

The value of seized counterfeit medicine in the Malaysian market amounted to RM 35.8 million in 2007 compared to RM 25.9 million in 2004.[79] Counterfeit medicines also accounted for about 5.28 per cent of over-the-counter self-medication products in Malaysia.[80]

2.4 CONTRIBUTING FACTORS TO COUNTERFEIT MEDICINE

Factors facilitating the occurrence of counterfeit medicine vary for each country. However, the most common factors are considered to be lack of legislation prohibiting counterfeiting drugs, weak penal sanctions, weak or absence of national drug regulatory authorities, weak enforcement of drug laws, shortage or erratic supply of drug, lack of control of drug to export, trade involving several intermediaries and free trade zone; corruption and conflict of interest. It is important to identify the contributory factors in order to implement the most suitable approach to overcome the problem.[81]

2.4.1 Weakness in Legislation and Enforcement

According to World Health Organization (WHO), legal systems which are not equipped to deal with the serious consequences of counterfeit medicine in most countries significantly contribute to the counterfeit medicine. The absence of deterrent legislation in many countries is one of the key factors that encourage counterfeiters since there is no fear of being apprehended and prosecuted.[82]

[79] Editorial. (22 September 2008). "New Bill to help curb Counterfeit Medicines". *New Straits Times*, p.17.
[80] Ismail, M., above n 78, pg22.
[81] Department of Essential Drugs and Other Medicines, above n 15, pg 10.
[82] World Health Organization. Above n 9, pg 3

Counterfeiting is greatest in regions where regulatory and enforcement systems for medicine are weakest. In the most industrialized countries with effective regulatory systems and market control, for example Australia, Canada, Japan, New Zealand, most of European Union and United States of America, the incidence of counterfeit medicines is extremely low. According to the estimation of the countries concerned, the incidence is less than 1% of market value. Many African countries, and in parts of Asia, Latin America, and countries in transition, reported that a higher percentage of the medicines on sale may be counterfeit.[83]

Counterfeiting is an easy business because it is relatively easy to hide and smuggle medicines. Counterfeiters are also difficult to detect with a small consignment which may have a high market value.[84] There are very few countries which have customs control that is specialized in detecting counterfeit medicines. This business also does not require huge investment and the equipment is easy to move from one site to another. Money is the primary reason for the explosion of the counterfeit market. Counterfeiting is cheap, financially lucrative and has low risk[85] compared with making illicit drugs such as heroin and cocaine which is difficult, expensive and highly risky activity[86] to the counterfeiters. Penalties for counterfeit drugs are weak in most of the countries. An unintended consequence of creating inappropriate penalty of making illegal drugs has shifted the clandestine productions to counterfeiting legal drugs.

[83] World Health Organization. Above n 9, pg 3
[84] Reidenberg, M. & Conner, B., above n 27, pg12.
[85] Capell, K., Timmon, S., Wheatly, J. & Dawley, H. "What's in That Pill?". *Business Week*. Retrieved on 23 July 2010 from www.businessweek.com/magazine/content/01_25/b3737153.htm
[86] Reidenberg, M. & Conner, B., above n 27, pg12.

2.4.2 Difficult to Detect

The identical appearance of the actual medicine and fake medicine complicates the detection of problem in counterfeit medicine. A counterfeit medicine packaging and shape often appear identical to the genuine item that no one, not even the best specialist can tell the genuine packaging from its fake. And no one, not even the best specialist can tell the genuine medicine from its counterfeit unless the product is subjected to chemical analysis. As a result every consumer is at risk from counterfeit medicines.[87]

Furthermore, difficulty in detection extends to the problem where physicians and nurses who have lower index of suspicion that a fake drug may be the cause of therapeutic failure.[88] They generally attribute poor clinical outcomes to human variation. Similarly, patients, their physicians, and their families may not know that they have been harmed by a fake drug, akin to patients dying without knowing they had a treatable illness. Patients may also be too frail, elderly, and/or very ill and this further limits their suspicion. Providers rarely ask where the drugs were purchased, and even in the unlikely event that they do, patients may reluctant to disclose that the medicines were bought over internet or from a foreign country.[89] Furthermore, the medication packaging is often thrown away. The medicinal material is metabolized by the body once taken and only few lab tests are normally available to detect the thousands of drugs that patients could be taking. Hence drug levels are not easily obtained.[90] Consequently, no one suspects, no one tells, and any evidence available is discarded or digested.[91] This situation makes it tremendously difficult to investigate forensically where, how and

[87] Bryan, A.L., above n 30, pg12.
[88] Radio Free Asia. (29 June 2005). "Father Was Told Dying Daughter Was Fine After Illegal Vaccination". Retrieved on 23 July 2010 from http://www.fra.org/english/news/social/2005/06/29/china_vaccinations
[89] Bryan, A.L., above n 30, pg12.
[90] Reidenberg, M. & Conner, B., above n 27, pg12.
[91] Sun Star. (21 August 2005). "Philippines: Doctors Involved in Spreading of Fake Drugs". Retrieved on 23 July 2010 from http://www.sunstar.com.ph/static/pan/2005/08/21/news/12.doctors.involved.in.spreading.of.fake.drug.health.office.html

what occurred in a circumstance that may implicate fake medicines. Such frustrations are stymieing investigations into recent counterfeit drug deaths.

The counterfeiters' activities are also difficult to detect as false address and information were provided on the packaging. Furthermore, payment transaction is always via cash, losing the link to trace the origin of the counterfeiters.[92]

2.4.3 Consumer Demand

High cost in medicines may also be a significant factor that drives individuals with low family income to seek for a cheaper substitute as counterfeit medicine is always cheaper than the genuine product. They have no choice and yet believe that the counterfeit could give same effect as the genuine medicine. With the existing demand in the market, it is tough to stop the circulation of counterfeits. Counterfeit medicines are also easily available in rural areas of developing countries. People in the rural areas do not always have access to other healthcare sources. They are those who are frequently victimized.[93]

Counterfeit is also defined as deceptive counterfeit and non-deceptive counterfeit by some literature. Deceptive counterfeit is when the consumer is not aware that the goods or item that they bought is not genuine, while non-deceptive counterfeit is when the purpose of the counterfeits is not to defraud but to satisfy unmet needs.[94] Consumer demands can be seen as a root problem and the ultimate destination of counterfeit products.[95] They may assume that taking herbal medicine is safe and effective without

[92] Interviewee 2, above n 58, pg19.
[93] World Health Organization, Medicines. Above n 19, pg10.
[94] Wong, N.(2004). "Counterfeit Medicine: Is It Curing China?". *Asian-Pac Law. & Policy Journal.* No.5,155, p.171.
[95] Yoo, B., & Lee, S.H.(2004). "The Buyers of Counterfeit Products in South Korea". *Journal of International Businesses.* Vol 3, pg 95-97.

realizing that traditional medicine is adulterated with controlled poison which could give the undesired outcomes.

2.5 The Counterfeiters

Detecting the counterfeiters will help in curbing the counterfeit problems. With identification of the sources, the problem of counterfeit medicine will be totally eradicated. Here, the two main culprits will be discuss as they are the most important persons to start the existence and distribution of counterfeit medicine to the end consumers in the medicines supply chain.

2.5.1 Manufacturer

Counterfeiting medicines has attracted organized crime, but it also requires the cooperation of people with some expertise in pharmaceutical manufacturing and distribution. In the entire supply chain, manufactures and distributors are considered as the major criminals of counterfeiting activity. China is found to be the global centre for distributing counterfeit drugs. In China, counterfeit factories and warehouses are often owned by local military and political grandees.[96] The People Liberation Army also participates where trucks with military license plates were seen to transport goods in and out of the pharmaceutical market.[97]

[96] Bate, R. & Porter, K.(2009). "The Problems and Potential of China's Pharmaceutical Industry, American Enterprise Institute for Public Policy Research". *Health Policies Outlook*, Vol 3, pg 3.
[97] Goodman,P.S. (2002). "China's Killer Headache: Fake Pharmaceuticals". *Washington Post.*

India is also noted to become a major producer of the world's counterfeit drugs.[98] Thirty generic drugs blacklisted by the Food & Drugs Administration (FDA) were manufactured by a company which failed to adhere to current Good Manufacturing Practices (GMP) requirements in India.

From these reports we can see that they are legal manufacturers which have licence with the state authority and yet are producing counterfeit medicine. Similarly legal licensed manufacturers were in Malaysia found to produce adulterated medicine that was also considered as counterfeit medicine.

Drug companies or manufactures may have kept information about counterfeit products which they have detected. They are feared if the secret becomes known people will stop buying their products and instead purchase a competitor's product even after the counterfeit has been destroyed.[99] Hence, indirectly they are protecting the criminals.

2.5.2 Organized Crime

Counterfeit drugs or medicine are commonly made and distributed by criminal gangs, who are attracted by the high profit margin of the trade.[100] These gangs also peddled other illicit items, such as narcotics, arms and fake jewelleries. Many counterfeiters use fake address in Western countries to impress the patients and doctors from less developed countries.[101]

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[98] Jain, S.K. (2006). "The Spurious Drug Menace and Remedy". *Health Administrator.* Vol 19, pg29–40.
[99] Ibid.
[100] McGivering, J. (2007). "Chinese Gangs 'Behind Fake Drugs". *BBC News.*
[101] Atemnkeng,M.A., Cock, K.D., & Jacqueline P.V.(2007). "Quality Control of Active Ingredients in Artemisinin-Derivative Antimalarials within Kenya and DR Congo". *Journal of Tropical Medicine & International Health.* Vol 12, no. 1, pg68-74.

Counterfeiting pharmaceuticals usually carries far lower penalties than producing and selling narcotics and becoming just as lucrative and is therefore a booming business. The extent of this problem is shocking when counterfeit drugs manufactured by South Americans narcotics gangs or unregistered chemical workers in China have infiltrated legitimate supply chains and ended up in pharmacies, clinics, and hospitals all over the world.[102]

The production of counterfeit medicine often occurs through a "multi-national chain of production and sale" that originates in countries which either do not recognize or loosely enforce patent laws. Drugs can be synthesized or their component parts bought. A copy manufacturer from one country could purchase the raw ingredients from another country and then start to press the tablets or make the pills and print counterfeit labels.

Organized crime has a strong presence in China, producing fake medicines that fall below the radar of law enforcement officials who are more interested in halting the trafficking of illegal drugs.[103] Corruption in military and police personnel further facilitate the counterfeit trade. These resulted in China becoming a veritable breeding ground for the distribution of fake pharmaceuticals worldwide.[104]

[102]Saul, S. (2005). "FDA Hoping for Indictment over Fake Pills". *New York Times*; and Hansen, C. (2006). "Inside the World of Counterfeit Drugs". Dateline, NBC. Retieved on 6 June 2010 from http://www.msnbc.msn.com/id/13137839

[103] Wong, N., above n 94, "[The counterfeit pharmaceutical distributor] will make a substantial profit based upon his non-existent research and development, lack of advertising costs, and dependence upon the public's trust of the name brand's product reputation, which he is taking advantage of with counterfeit goods."). *See also* Saywell & McManus, *supra* note 8, at 37 ("Counterfeiters can make fakes for 80% less than what it costs legitimate manufacturers.").

[104] Ibid.

2.6 Conclusion

Based on the discussion above, there is no definition of counterfeit medicine in laws currently enforced by PED; hence, limiting the action which can be taken against the counterfeiters. Apart from that, identification of the weakness of legislation and the counterfeiters involved can help in developing appropriate measures and strategies to combat the problems. Evaluation of laws enforced by PED will be detailed in following chapter.

CHAPTER 3

THE COUNTERFEIT MEDICINE CONTROL FRAMEWORK IN MALAYSIA

3.0 INTRODUCTION

This chapter briefly discusses on the counterfeit control framework provided by the law for the Pharmaceutical Enforcement Division in Malaysia. The legal framework provided by the Sale of Drug Act 1952,[105] Control of Drugs and Cosmetics Regulation 1984[106] and Poison Act 1952[107] will be examined. Directives of counterfeit medicine control by the Pharmaceutical Enforcement Division will be identified. The aims are to analyse the weaknesses in the framework and whether any improvement could be done to further strengthen the framework. A strong legal framework is important because a weakness in legislation and enforcement will contribute to counterfeit medicine. Although there is no specific definition of counterfeit medicine as mentioned earlier, PED control counterfeit medicine in different terms. Although there is no specific law regarding the control of counterfeit medicine, the current approach taken by the PED is by using the provisions related to the adulterated products, unregistered products and possession of poison for sale.

[105] *Sale of Drug Act (Act 368).*
[106] *Control of Drugs and Cosmetics Regulations 1984.*
[107] *Poison Act (Act 366).*

3.2 COUNTERFEIT UNDER PENAL CODE

In Malaysia, the definition of counterfeit is available under the Penal Code but 'counterfeiting' refers to the counterfeiting of documents, currency notes and bank notes as stipulated under Chapter XVIII of the Penal Code. There is no explanation about counterfeiting of medicine under the Penal Code and furthermore, Penal Code is under the jurisdiction of Royal Malaysian Police Force, not Pharmaceutical Enforcement Division (PED). Likewise, there is also no specific interpretation of counterfeit medicine under the laws currently enforced by the PED.[108]

Counterfeit is defined as crime in the criminal law due to the serious forms of violence and dishonesty. The degree of harm proscribed under the criminal law is greater than in civil law. This shows that counterfeiting is not a matter of dishonesty but it is more serious than a private matter as the prevention and prosecution has public interest.[109]

Section 28 of the Penal Code stated:[110]

> A person is said to "counterfeit", who causes one thing to resemble another thing, intending by means of that resemblance to practices deception, or knowing it to be likely that deception will thereby practiced.
>
> Explanation 1 – It is not essential to counterfeiting that the imitation should be extract.
>
> Explanation 2 – where a person causes one thing to resemble another thing and the resemblance is such that a person might deceived thereby it shall be presumed until the contrary is proved that the person is causing the one thing to resemble the other thing intended by means of that resemblance to practice

[108] Interviewee 3, Senior Principle Assistant Director, Prosecution Unit, Pharmaceutical Services Division, Ministry of Health conducted on 27 October 2010.
[109] Simester, A.P. & Sullivan, G.R. (2000). Criminal Law: Definition and Application, *Criminal Law Theory and Doctorine*, Hart Publishing Ltd, pg3.
[110] *Section 28 of Penal Code.*

deception or knew it to be likely that deception would thereby be practiced.

For the purpose of this study, adulterated medicine and unregistered medicine are considered as counterfeit medicine which will be further detailed in the next chapter.

3.2 PHARMACEUTICAL ENFORCEMENT DIVISION

Pharmaceutical Enforcement Division is a law enforcement unit under the Pharmaceutical Service Programme which is a department under the Ministry of Health. PED plays an important role in protecting the consumers from hazardous medicines, misleading medicine advertisements, and unscrupulous practice through the related pharmacy legislation.[111] Providing the best pharmacy service for the health and well being of the nation as a vision and to lead a dynamic pharmacy service emphasizing on the highest level of integrity, professionalism and excellence that meet the aspirations and challenges of the nation as a mission place a very huge burden on PED to achieve its objectives.[112]

Intelligence gathering, operation, investigation, prosecution and law drafting are the main part of enforcement activity.[113] Apart from controlling the medicine or registered products in the market under the Poison Act 1952, Sale of Drug Act 1952(SODA 1952) and Control of Drug and Cosmetic Regulation 1984 (CDCR 1984), PED also controls the advertisement of the registered products under the Medicines (Advertisement and Sale) Act 1956. PED branches are located in each state in Malaysia. Licensing, Legislation, Investigation, Prosecution, Consumer Protection, Diversion Control,

[111] Laporan Tahunan 2007, Bahagian Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia, pg 4.
[112] Pharmaceutical Services Division, Ministry of Health. Retrieved on 10 September 2010 from http://www.pharmacy.gov.my
[113] Ibid.

Precursor, Advertisement, Quality, Surveillance and Operation are the eleven units that made up the organisation. Each activity is carried out by the Drug Enforcement Officer appointed.

As law enforcement, the collective term for professionals who are dedicated to upholding and enforcing the laws and statutes currently enforced in given jurisdiction,[114] PED is responsible for the control of counterfeit medicine in the market. They are appointed as analysts, officers and inspectors under section 3 of the Sale of Drugs Act 1952. Two main goals that law enforcement seeks to achieve are to prevent the occurrence of a crime that is in some way will harm the human being or the society as a whole, and to ensure that suspected criminals are tried in a manner that is in compliance with local laws.[115]

The Pharmaceutical Enforcement Division is the responsible authority for the control of counterfeit medicine. It must be emphasized that there is a lack of definition of counterfeit medicine in the laws currently enforced. According to interviewee 1 and 3:

> "..we do not have specific definition or specific law for counterfeit medicine. Current powers of PED to deal with aspects of counterfeit medicine are vested in the Sale of Drug Act, the Control of Drug and Cosmetic Regulation and also the Poison Act...."[116]

Nevertheless, powers governed to PED by the Sale of Drug Act 1952 to control the adulterated medicines may also be used to control counterfeit medicine[117] where adulterated medicine is also considered as counterfeit medicines as mentioned in the

[114] Tatum, M., "What is Law Enforcement". Retrived on 1 October 2010 from http://www.wisegeek.com, accessed on 1 October 2010, p.1.
[115] Ibid.
[116] Interviewee 3, above n 108, pg 31.
[117] Interviewee 1, Senior Principle Assistant Director, Consumer Protection Unit, Pharmaceutical Service Division, Ministry of Health. Conducted on 24 September 2010.

earlier chapter. Under Section 15 of the Sale of Drug Act 1952 (Revised 1989),[118] adulteration means:

> For the purpose of this Act any drug shall be deemed to be adulterated if –
>
> (a) it contains or is mixed or diluted with any substance which diminishes in any manner it's the nutritive or other beneficial properties as compared with such article in a pure and normal state and in an undeteriorated and sound condition or which in any other manner operates; or
>
> (b) any substance or ingredient has been extracted or omitted there from and by reason of such extraction or omission the nutritive or other beneficial properties of the article as sold are less than those of the article in its pure and normal state or the purchaser or consumer is any or may be in any manner prejudiced; or
>
> (c) it contains or is mixed or diluted with any substance of lower commercial value than such article on a pure and normal state and in an undeteriorated and sound condition; or
>
> (d) if it contains any substance which renders the drug injurious to health; or
>
> (e) it does not comply with the standard therefore prescribed by any regulations made under this Act."

Drug in this act means "any substance, product or article intended to be used or capable, or purported or claimed to be capable, of being used on humans or any animal, whether internally or externally, for a medical purposes." The act also defines medical purposes as "alleviating, treating, curing or preventing a disease or a pathological condition or symptoms of a disease, diagnosing a disease or ascertaining the existence, degree or extent of a physiological or pathological condition; contraception, inducing anesthesia, maintaining, modifying, preventing, restoring, or interfering with, the normal operation of a physiological function, controlling body weight and general maintenance or

[118] *Sale of Drug Act 1952* at Section 15.

promotion of health or well-being as stated in Section 2 of the Sale of Drugs Act 1952."[119]

When definition is absence, the enforcement of counterfeit medicine became uncertain. It is important for each country to have a specific definition of counterfeit medicine in legal systems. As suggested in the WHO guidelines for the development of measures to combat counterfeit medicine, counterfeit drugs must be mention specifically in legislation and the development of specific regulation in the area must be implemented.[120]

3.3 ENFORCEMENT POWERS OF PHARMACEUTICAL ENFORCEMENT DIVISION

A criminal justice system is considered as failing to protect people from the most serious dangers if it fails to define the dangerous acts and provide appropriate enforcement powers to enforce the laws. The enforcement powers of PED stipulated in different laws which are used to control the counterfeit medicine will be further explained in the following paragraph.

3.3.1 Powers Appointed under Sale of Drugs Act 1952

Sale of Drugs Act 1952 is the Act which is commonly utilised to prosecute cases related to counterfeit medicine. Although no specific definition of counterfeit medicine is stipulated under this Act, the Act does provide the interpretation of adulteration and

[119] *Sale of Drug Act 1952* at Section 2.
[120] Department of Essential Drugs and Other Medicines, above n15, pg10.

provisions on mislabelling, misleading and unregistered products which are commonly used in dealing with the counterfeit medicine cases.[121]

Sale of Food and Drug Ordinance was enacted on 1st November 1952 to regulate both food and drugs. This is the only law existing at that time. In 1983, through a policy decision which demanded that food and drugs are controlled under two divisions, the separation of powers regulating the sale of food from the sale of drugs began as amendments were made. Later, a new regulation which is the Control of Drugs and Cosmetics Regulation 1984 was made by the ministry to further detail the provision.

Revision in 1989 was made to suspend the Sale of Food and Drug Ordinance to become the Sale of Drugs Act 1952. The revision had separated the control of food which is under the control of the Food Safety and Quality Unit of the Public Health division while the sale of drugs falls under the Pharmaceutical Enforcement Division jurisdiction. This Act is related to the sale of drugs and shall be applied throughout Malaysia.

3.3.1.1 Appointment of Analysts, Officers and Inspectors

Section 3 of Sale of Drug Act (SODA) 1952 authorised the Pharmaceutical Enforcement Division officers as Analysts, Officers and Inspectors.[122]

[121] Interviewee 1, above n 117 pg33.
[122] *Sales of Drugs Act 1952* at Section 3.

Section 3 of SODA 1952 stated:[123]

(1) The Yang di-Pertuan Agong may appoint such number of analysts as he may consider necessary for the purpose of this Act

(2) The Chief Minister may appoint such number of officers and inspectors within a State as may be necessary for the purpose of this Act.

(3) The Minister may make regulations for the conduct of the duties of analysts, officers and inspectors under this Act.

(4) The analysts, officers and inspectors appointed under this section shall be deemed to be public servants within the meaning of Penal Code.

3.3.1.2 Power of officers and inspectors to enter, etc.

Section 4(1) of SODA 1952 provides powers for the officers and inspectors to enter and inspect any place at all reasonable time where he has reason to believe that there is any drug intended for sale. The power is also extended to mark, seal, secure, weight, count, or measure and inspects any drug which sale, preparation or manufacture appears to be contrary to the Act.[124]

Furthermore, section 4(2) of SODA 1952 gives the power to the officer to seize any drug, wherever found which appears to be unwholesome or deleterious to health. They may also destroy any drug wherever found which is decayed or putrefied.[125]

[123] *Sales of Drugs Act 1952* at Section 3.
[124] *Sales of Drugs Act 1952* at Section 4(1)
[125] Ibid at Section 4(2)

A wide range of power is provided without the necessity to issue warrant but the power of arrest is not included in the provisions of the Act. Power to deal with obstruction was also not provided under this Act. Power to arrest and deal with obstruction are needed to deal with circumstances where the suspected person may refuse to cooperate or obstruct the duty of the PED.

3.3.1.3 Power to demand, select and take samples

Under section 5(1) of SODA 1952, an appointed officer may at any place demand and select and take or obtain samples of drug for the purpose of analysis. Samples may be taken at point of payment or tender to any person selling or making any drug, or to his agent or servant.[126] This allows PED to obtain samples suspected as adulterated medicines for further analysis or confirmation.

3.3.1.4 Power to call for information

Besides the power to enter a premise and power to demand, select and take samples, officers or inspectors are also provided the power to call for information. If in the opinion of any officer, there is a reasonable ground for suspecting that any person is in possession of any drug or other substance for the purpose of sale or of manufacturing or preparing the same for sale in breach of this Act, he may require such person to produce any books or documents dealing with reception, possession, purchase, sale or delivery of any such drug or other substance.[127] The officer may also make or cause to be made copies of or extracts.[128] Any person who refuses or neglects to comply with any

[126] *Sale of Drug Act 1952* at Section 5(1)
[127] Ibid at Section 9(1)
[128] Ibid at Section 9(2)

requisition made in pursuance of this section commits an offence.[129] Although this provision may be useful in the investigation process, it is only limited to books or documents. The provision does not provide power to call for information on the particular person suspected. Lack of such power may cause incomplete information thus affecting the investigation result.

3.3.2 Powers under Poison Act 1952.

Poison Act was enacted in 1952 as the F.M. Ordinance 29/1952 and was known as the Poison Ordinance 1952. It came into effect in West Malaysia on 1 September 1952 and East Malaysia on 1 June 1978. There have been a number of amendments made in order to fill the loopholes but there is no amendment in regards to counterfeit medicine. The purpose of the act was to regulate the importation, possession, manufacture, compounding, storage, transport, sale and use of poisons. The main roles of this act in controlling counterfeit medicine are related to medicine adulterated with listed poison.

3.3.2.1 Appointed Drug Enforcement Officer

Pharmaceutical Enforcement Division officer is regarded as the Drug Enforcement Officer under the Poison Act 1952. Drug Enforcement Officer means any registered pharmacist in the public service that has been duly authorised in writing by the Licensing Officer under section 31(1) which is stipulated under Section 2 of Poison Act 1952.[130]

[129] *Sale of Drug Act 1952* at Section 9(3).
[130] *Poison Act 1952* at Section 2.

3.3.2.2 Powers of Investigation, Examination and Entry into Premises.

Section 31(1) of Poison Act 1952 stated that the Licensing Officer "may authorise in writing any registered pharmacist in the public service to exercise the powers of a Drug Enforcement Officer under this Act." Officer authorized may have power to investigate the commission of an offence and this provision is stipulated under section 31(2) of the Act.[131]

a. Power to examine orally

Section 31(3) of the Act further provides power to examine orally any person supposed to be acquainted with the facts and circumstances of the case while making an investigation.[132]

b. Power to enter, search and examine premises

Under this Act, too, any Drug Enforcement Officer, any police officer not below the rank of Inspector or any Senior Customs Officer may enter, search and examine premises where there is a reasonable cause to believe that an offence under this Act or any regulation made there under has been or is being committed in any premises or in connection with any business carried on in any premises either by himself or by some other person accompanying him and acting under his instructions with presence of his enter as provided under section 31(8).[133]

[131] *Poison Act 1952* at Section 31(1).
[132] Ibid at Section 31(3).
[133] Ibid at Section 31(8).

c. Power to inspect, remove and detain

Above mentioned authority may also inspect, remove and detain any substance reasonably believed to be or to contain a poison, book, document, equipment, instrument, material or any other article found therein which in his opinion may furnish evidence of the commission of an offence under this Act or any regulation made under. This power is also provided under the Section 31(8) of the Act

d. Power when obstruction occur

Section 31(8) also provides the Drug Enforcement Officer power to break open any outer or inner door of such suspicious premises, any cupboard, chest, trunk, package or other receptacle in case of obstruction by force if necessary, to enter any part of the premises.

e. Remove obstruction and detain person

The Officers may remove any obstruction faced by them in carrying out the procedure above mentioned. They are also given power to detain any person found in the premises until the search was completed.[134] All of these provisions are stipulated under section 31(8) of the Act.

Although the Power to arrest is not provided under this Act, it does have an additional power being compared to SODA 1952. Poison Act 1952 provides the officers power to deal with obstruction and to detain person. In situation where the detained person run

[134] *Poison Act 1952* at Section 31(8).

away of refuse to cooperate, this power may be of little value since the PED is not authorised to touch the detained person-no power of arrest.

3.3.2.3 Power to Prosecute

This Act also provides power to prosecute and conduct prosecutions which is stipulated under Section 34. This section stated that prosecution shall be instituted under this Act or regulation and may be conducted by any registered pharmacist in the public service with authorization in writing by Public Prosecutor.[135]

3.3.3 Powers under the Control of Drugs and Cosmetics Regulations 1984

The Control of Drugs and Cosmetics Regulations 1984 (CDCR 1984) consists of five parts, namely; Preliminary, The Drug Control Authority, Registration and Licensing, Manufacture of Registered Products, and Miscellaneous. The Regulation is to regulate the manufacture, sale, supply, importation, possession and administration of drugs and cosmetics in Malaysia. This would include drugs for traditional medicines as well as herbal medicines and dietary supplements.[136]

This regulation was made by the Ministry of Health in exercising the powers conferred upon him by Section 28(1) of the Sale of Food and Drugs Ordinance 1952. This regulation further details the requirement under the Sales of Drugs Act 1952.

[135] *Poison Act 1952* at Section 34.
[136] Retrived on 27 September 2010 from http://www.globinmed.com/IMRContent/regulationDetail.aspx?id=CTN00465

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[135] *Poison Act 1952* at Section 34.
[136] Retrived on 27 September 2010 from http://www.globinmed.com/IMRContent/regulationDetail.aspx?id=CTN00465

3.3.3.1 Appointed Officer

For the purposes of investigating the commission of any offence under these regulations, any officer is provided power to enter any premises used for or connected with the manufacture, sale, and supply, possess, administer or import of any product for the purposes of inspecting, at all reasonable time.[137] They may inspect the product, the premises and the operations carried out, any license, registration certificate, record or document.

3.3.4 Criticism of Enforcement Powers

The authorities vested under the SODA 1952 and Poison Act 1952 are of a very wide discretion power where officers can enter any place at any reasonable time since no warrant is required to be served. The Limitations that can be seen here is that the power may not be suitable in serious or extreme circumstances where officers do not have power to arrest suspected person. Power to deal with obstruction and to detain a person are given only under the Poison Act and this may not be adequate in dealing with counterfeit medicine crime as the crime is difficult to detect and may also involve an organized criminal party. In addition, suspected person may need to be remanded in order to conduct a thorough and complete investigation.

There are is also no provision to conduct investigation and prosecution under the SODA 1952 and CDCR 1984. Although both statutes (the Act) do not provide power to investigate and conduct prosecution, the current approach taken by the PED is by relying on the provisions under the Penal Code and Criminal Procedure Code to operate

[137] *Control of Drugs and Cosmetics Regulation 1984* at Regulation 26(1)

their duties. Section 21(h) of the Penal Code stated that every Government officer whose duty it is, as such officer, to prevent offences, to give information of offences, to bring offenders to justice, or to protect the public health, safety or convenience. Thus, the PED take full of use this provision to carry their duty since they are Government Servant.[138] The Section 377(b)(3) of the Criminal Procedure Code is used in conducting (to conduct) prosecution which has been mentioned in earlier chapter. Section 377(b)(3) stated that subject to the control and direction of the Public Prosecutor, a person may be given authorization in writing by the Public Prosecutors and this may be any person of any Government department.[139] Thus, it can be said that Lack of enforcement power is one of the weaknesses in the PED legal frameworks.

3.4 OFFENCES

Offences discuss in this chapter include offences that are available and usually utilized by PED in dealing with counterfeit medicine cases. Although there is no specific provision for counterfeit medicine offence but there are provisions stipulated in different laws which can be considered as counterfeit medicine offences.[140] In this situation, the Offences here have a deterrent function since they do not only deter criminals from reoffending but also deter the public from committing the crime.

[138] *Penal Code* at section 21(h).
[139] *Criminal Procedure Code* at section 377(b)(3)
[140] Interviewee 3, above n 108, pg31.

3.4.1 Offences under Sales of Drug Act 1952

It is an offence for any person who sells any adulterated drug without fully informing the purchaser at the time of the sale the nature of the adulteration.[141] It is also an offence for any person who sells any drug in any package which bears or has attached thereto any false or misleading statement, word, brand, label or mark purporting to indicate the nature, quality, strength, purity, composition, weight, origin, age or proportion of the article contained in the package of any ingredient thereof.[142] Section 10 stated:

> Section 10 : Offences and penalty
>
> (1) Any person commits an offence who sells –
>
> (a) Any adulterated drug without fully informing the purchaser at the time of the sale of the nature of the adulteration; or
>
> (b) Any drug in any package which bears or has attached thereto any false or misleading statement, word, brand, label or mark purporting to indicate the nature, quality, strength, purity, composition, weight, origin, age or proportion of the article contained in the package or of any ingredient thereof;

3.4.2 Offences under Poison Act 1952

Poison means any substance specified by name in the first column of the Poison List and includes any preparation, solution, compound, mixture or natural substance containing such substances, other than an exempted preparation or an article or preparation included for the time being in the Second Schedule.[143] Poison list means the

[141] *Sale of Drug Act 1952* at Section 10(1)(a)
[142] Ibid at Section 10(1)(b)
[143] *Poison Act 1952* at Section 2.

Poison List set out in the First Schedule as amended from the time to time in accordance with the power of the ministry with the advice of the Poison Board.[144]

The Poisons Act 1952 is regularly used to charge the offenders who deal with products which do not need to be registered with the DCA which had been classified as food and also product registered but found to be adulterated with poison.[145] NP Trimz is one of the food supplement products claiming to help lose weight which had been detected to contain sibutramine.[146] Sale of food supplement products adulterated with poisonous substances is an offence under section 13 of the Act. Section 13 (a) of the Act provides that possession for sale of poison without license issued under section 26 of the Act is an offence. The act of selling, without a license, of adulterated products with poisonous substances is an offence and can be charged under this provision. Only a pharmacist is licensed to sell a dispensed medicine containing poisons in the country.[147]

Whereas section 13 (b) prohibits any act of sale or supplies of poison which contravene this Act or Regulations. This provision can also be used to charge the licensed pharmacist if the traditional medicines or food products sold in their premises are detected to contain poisons which contravene the requirement under this Act. Therefore, the sale or supply of any adulterated products with any poisons is an offence regardless of the seller, either a licensed pharmacist or any retailer.

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[144] *Poison Act 1952* at Section 2.
[145] Interviewee 3, above n 108, pg31.
[146] "Press release Sale of Unregistered Product. (2007). " NP Trimz, Ministry of Health Malaysia". Retrieved on 23 July 2010 from www.moh.gov.my,
[147] *Poisons Act 1952* at ss 21,22, 26.

3.4.3 Offences under Control of Drugs and Cosmetics Regulation 1984

In Malaysia, only registered products are allowed to be marketed and used.[148] Registered product is a product that is currently registered in accordance with the provisions of CDCR 1984.[149] A registered drug is a drug that is approved by the DCA for sale and use in Malaysia and has been evaluated and tested for its efficacy and safety.[150] Every registered drug is given a registration number, which must be printed on its label or package.[151] Beginning 1985, the DCA, through the National Pharmaceutical Control Bureau (NPCB) as the secretariat, was given the task of ensuring the quality, efficacy and safety of pharmaceuticals through the registration and licensing scheme.[152] It is an offence under Regulation 7(1) of CDCR to manufacture sale, supply, import, posses and administer any product unless it is a registered product and hold an appropriate license under this act. This provision is always facilitated to prosecute counterfeiters for manufacturing offence. It is also applied to any adulterated medicine which is not registered in order to impose higher penalties.

Regulation 7(1A)(e) further explained that no person shall manufacture, sale, supply, import, possess or administer any product which is labelled with any words, symbols or letters purporting to be true but otherwise. This provision can be seen as an alternative to tackle the counterfeit medicine although there is no specific provision available.

[148] National Medicines Policy of Malaysia, Ministry of Health Malaysia.
[149] *Control of Drugs and Cosmetics Regulations 1984* at Regulation 2.
[150] http://www.bpfk.gov.my/, accessed on 3 Julai 2010.
[151] Ibid.
[152] Ibid.

3.4.4 The Criticism on the Offences

There is no specific offence in any law currently enforced by PED. The absence of the provision for counterfeit medicine in legislation can be seen as an obstruction to conduct enforcement duty by PED.[153]

Pharmaceutical Enforcement Division currently rely on the provision for adulterated product under Section 15 SODA 1952, sale of poison without a license under Section 13 of Poison Act 1952 and offences regarding unregistered products under the Regulation 7(1) and 7(1A)(e) of the CDCR 1984. This is another weakness that the PED have in controlling counterfeit medicine.[154]

3.5 PENALTIES

3.5.1 Penalty under Sale of Drugs Act 1952

Provision for penalty is provided under section 12 of this Act. Section 12(1) is penalty for individual who has committed the offence under this Act which stated that any person who commits an offence against this Act or any regulation made under this Act for which no penalty is expressly provided shall be liable on conviction to a fine not exceeding twenty-five thousand ringgit or to imprisonment for a term not exceeding three years or to both, and for a second or subsequent offence he shall be liable on

[153] Interviewee 3, above n 108, pg31.
[154] Ibid

conviction to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding five years or to both.[155]

A body corporate who commits an offence against this Act or any regulations made under it is also liable for penalty which is stipulated under section 12(2) of the Act. This section stated that a body corporate who commits an offence shall be liable on conviction to a fine of not exceeding fifty thousand ringgit and for a second or subsequent offence it shall be liable on conviction to a fine not exceeding one hundred thousand ringgit.[156]

3.5.2 Penalty under Poison Act 1952

Section 32 of the Act states the penalties for offences committed under this. Upon conviction, an offender is liable for punishment with a fine not exceeding three thousand ringgit or by imprisonment for a term not exceeding one year or both. There is a proviso under this section that stated that, if in the opinion of the court, the omission charged will amount to "wilful default or culpable negligence, which endangered human life", the accused will be punished to a fine not more than five thousand ringgit or to imprisonment for a term not exceeding two years. The prosecution has to provide the evidence before the court that the act of adulteration of medicines with poisonous substances will endanger human life due to the adverse effect of the poisonous substances to the human body.[157]

The Poisons Act 1952 under section 32(4) states that the owner of the company is liable to a penalty if such offence has been done by his partner, agent or servant unless he

[155] *Sale of Drug Act 1952* at Section 12(1)
[156] Ibid at Section 12(2).
[157] *Poison Act 1952* at Section 32.

proves that he has taken reasonable precaution to prevent the omission of such thing. This provision can be invoked in the case where the sale of adulterated medicines is done by the workers of the business.[158]

3.5.3 Penalty under Control of Drug Regulation 1984

All the offences convicted under this regulation are liable for penalty under section 12 of SODA 1952.

3.5.4 The Criticism on the Penalties

There was a perception that the penalties imposed were of little deterrence value because the enforcement system was patchy, selective and inefficient. Furthermore, the punishment was uncertain because it was rarely carried out.[159] Although there are provision under SODA 1952 and Poison Act 1952 for the offenders to be liable to imprisonment appoint conviction, but the provisions are rarely practised by court. In fact, according to the respondents, the penalties imposed are extremely low.

There is no provision for minimum sentences provided in current laws, therefore it is under the court discretion to impose minimum penalty based on offender's mitigation factors. Research carried out on the sentences under SODA 9152 also shown that out of 79 cases been prosecuted by PED in Kuala Lumpur and Selangor, 64 cases or 81% imposed-were fine below five thousands ringgit and the imprisonment sentence was

[158] *Poison Act 1952* at Section 32.
[159] Gilling, D., Theories of Crime Prevention I, Crime Prevention, Theory, Policy and Politics, (UCL Press, 1997), pg 26.

never carried out.[160] Based on this study, we have a view that the fine imposed were mostly low compared to the amount provided by the laws.

In comparing to the SODA 1952, the penalties under the Poison Act 1952 are extremely low. Although there is a provision where higher penalty can be imposed if in the opinion of the court, the omission charged will amount to "wilful default or culpable negligence, which endangered human life" the maximum penalty is only five thousand ringgit or imprisonment for terms not exceeding two year appoints conviction. We do belief human life is invaluable, and it is clearly seen here that the penalty provided is not sufficient to deter the criminal. Furthermore, the prosecution has to provide the evidence before the court that the act of adulteration of medicines with poisonous substances will endanger human life due to the adverse effect of the poisonous substances to the human body.[161]

A low sentence is one of the factors that contribute to the ever-rising illegal activities among the counterfeiters. The irresponsible parties will continue to their illegal activities for the profits where the consumer safety issue is neglected. The PED lists this issue as the weakness of the Act that need further action in order to ensure the sentences imposed by the Act have deterrence effect to the offender.[162] Remarked by the respondent:

> "...current law we do not have minimum sentences.....we always used SODA 1952 to imposed higher penalty...."[163]

[160] Ahmad, Z. et al., A Legal Analysis of Cases Prosecuted by the Pharmaceutical Enforcement Division in Kuala Lumpur and Selangor for the year 2006-2007, (Faculty of Law, UiTM Shah Alam, Selangor, 2009), p.40.
[161] *Poison Act 1952* at Section 32.
[162] Interviewee 3, above n 108, pg31.
[163] Ibid.

Deterrence is always a principle of punishment in criminal law to act as a deterrence mechanism to deter the public from committing crime.[164] The Punishment may cause the offender to repent and not repeating the same offence in the future and further serve as an example to the society for not committing the same crime.[165] It is under the classical theory of crime work by Beccaria which explained that in order to prevent crime; punishment should be proportional to the offence in order to react as deterrence.[166]

It is the Judge's discretion to make judgment by taking into accounts all relevant information before imposing any (to imposed) sentences. In *Zainuddin bin Mahmud v PP*,[167] the appellant was charged for criminal intimidation under s 506 of Penal Code which, upon convicted, is liable to an imprisonment not extent to 2 years, or fine or both. Appeal was made for lesser punishment but the appeal judge held that ~~the~~ sentencing is the matter of a trial court decision. He further confirmed the sentence by the learned judge. It was showed here that in cases where minimum sentences were imposed in certain offences, it will leave the court with no choice of low types of punishment, thus deterrence sentence may assumed to be applied.

3.6 REGULATORY BODY

The National Pharmaceutical Control Bureau (NPCB) which acts as a regulatory body was set up in 1978 to implement quality control on pharmaceutical products. It was formerly known as National Pharmaceutical Control Laboratory. NPCB is responsible

[164] Lee Chong Fook and Che Audah Hassan. (2006). "Introduction to Principles & Liabilities in Criminal Law". *Lexis Nexis Malayan Law Journal*,p 37.
[165] Ibid.
[166] Gilling, D., above n 159, pg 50.
[167] Zainuddin bin Mahmud v PP [2010]7 MLJ789

to control the counterfeit medicine in terms of its prevention and through the compliance-building among the pharmaceutical industries.

NPCB was given an international recognition by the World Health Organisation (WHO) as a "WHO Collaborating Centre for Regulatory Control of Pharmaceuticals". It is an acknowledgement from WHO for NPCB's contribution in the regulatory affairs field. In the beginning, NPCB was given the task to ensure the quality, efficacy and safety of pharmaceuticals through the registration and licensing scheme. Till now, NPCB plays an important role in various activities which include registration of drug or medicine marketed in Malaysia; notification of cosmetics; carrying out analytical, pharmaceutical, microbiological, pharmacological and toxicological tests on drugs and cosmetics to ensure quality, efficacy and safety of the products and cosmetics; carrying out surveillance on products in the market to ensure the fulfilment of requirement for products that had been registered or notified; enforcing licensing scheme for manufacturer, importer, wholesaler and also for clinical trial; ensuring all manufacturers follow the Good Manufacturing Practice (GMP) by doing inspection routinely; managing the adverse drug reaction program and participating in the WHO Adverse Drug Reaction Monitoring Program; managing product recall if products found to be of substandard, contaminated or cause harm to the consumers; carrying out research and training; and establishing a reference standard system for local use and neighbouring countries through a scheme of co-operation among ASEAN countries.[168]

The Drug Control Authority (DCA) is the executive body established under the CDCR 1984. The tasks which fall under the jurisdiction of the DCA include ensuring the safety, quality and efficacy of the pharmaceuticals, health and personal care products

[168] National Pharmaceutical Control Bureua. Retrieved on 12 Sptember 2010 from http://www.bpfk.gov.my

that are marketed in Malaysia. These tasks involve four main functions: registration of pharmaceutical products and notification of cosmetics; licensing of premises for manufacturers, importers and wholesalers; monitoring the quality of registered products in the market; and monitoring the adverse drug reactions.[169]

3.6.1 Product Registration

The implementation of the registration scheme by the DCA seems to be one of the alternative ways to avoid counterfeit product to be marketed in Malaysia. Registration of pharmaceutical products which contain scheduled poisons as defined in the Poison Act 1952 was done on 1st November 1985, followed by pharmaceutical products that do not contain scheduled poison, also known as over-the-counter product, other than traditional medicine in 1988. Traditional medicine was then required to be registered only in 1st January 1992 and lastly the cosmetics. Due to the Asian Harmonized Regulatory Scheme, cosmetics registration was replaced by notification. All products marketed in Malaysia will have a registration number starting by MAL followed by 8 digits numbers and end with the product category which are A for product containing control medicine as listed in the First Schedule of Poison Act 1952, X for over-the-counter product and T for traditional product. For cosmetics, the notification number NOT followed by 8 digits number was given for notified cosmetics but there is no compulsory requirement for the number to be printed on the product or packaging. Each registration number is specific to a product. In other word two products will not have the same registration numbers.[170]

[169] National Pharmaceutical Control Bureau, above n 168, pg 53.
[170] Ibid.

Prescribed under regulation 7 of CDCR 1984, no person shall manufacture, sale, supply, import, possess and administer any product unless the product is a registered product and the person holds the appropriate license required and issued under the regulations. License involves are either manufacturer's license, wholesale's license, clinical trial import license or import license. All the licenses are issued by the Director of Pharmaceutical Service who is also a member of Drug Control Authority. The license holder should comply with the entire requirement under the regulations.[171]

3.6.2 Good Manufacturing Practices

Good manufacturing practice regulations were first proposed by the United States government in 1963. It was proposed following the congressional passage of the Kefauver-Harris amendment in 1962 and the thalidomide tragedy in the United Kingdom in 1960-1961[172] in which it is believed that dishonesty and sharp practices by the pharmaceutical industry are among the contributing factors.[173] GMP describes the basic requirements for the manufacturing and packaging and distribution of pharmaceutical products.[174]

Good Manufacturing Practice is part of quality assurance to ensure products are consistently produced and controlled to the appropriate quality standards for their intended use and as required by the marketing authorization. GMP aimed to diminish the risk inherent in any pharmaceutical production. Cross contamination or mix up or false labelling are amongst those inherent during the production. Manufacturers must be held responsible if they put patient at risk due to inadequate safety, quality or efficacy.

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[171] *Control of Drugs and Cosmetics Regulations 1984* at Regulation 7.
[172] Micheal J. Akers, (2010). Good Manufacturing Practice.1st Ed. Informa Healthcare.
[173] The Thalidomide Tragedy: Another Example of Animal Research Misleading Science. Retrieved on 30 October 2010 from http://www.pnc.com.au/~cafmr/online/research/thalid2.html
[174] Micheal J. Akers, above n 172.

Therefore, WHO quality assurance guidelines play an important role in risk assessment due to above situation.[175]

The National Pharmaceutical Control Bureau is a member of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme, both jointly referred to as PIC/S. These are two international instruments between countries and pharmaceutical inspection authorities to provide an active and constructive co-operation in GMP field. Their mission is to lead the international development, implementation and maintenance of harmonized Good Manufacturing Practice standards and quality systems of inspectorates in the field of medical products. Mission is achieved by developing and promoting harmonized GMP standards and guidance documents, training competent authorities, assessing and reassessing inspectorates, and facilitating the co-operation and networking for competent authorities and international organization.[176]

Manufacturers holding the manufacturing license with NPCB should comply with GMP directives. Regular inspection will be done to ensure that the license holders comply with the requirements. Besides that, routine surveillance of products in the market are done to confirm the safety, efficacy and quality and at the same time to detect the counterfeit or adulterated product.

[175] World Health Organization. Production. Retrieved on 30 October 2010 from http://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/index.html

[176] Pharmaceutical Inspection Co-operation Scheme (PIC/S). Retrieved on 1 October 2010 from http://www.picscheme.org/

3.7 HOLOGRAM

Ministry of Health had issued a directive on the use of Hologram Meditag due to concerns in respect of counterfeit, imitation and unregistered products being manufactured or imported and sold. This is also an effort to streamline the manufacture, import and sale of genuine products. The use of Hologram Meditag is used as a device to authenticate and verify that products sold have been duly registered with the Drug Control Authority (DCA) and are not counterfeit medicines. This security label also complement enforcement activities to ensure public safety which is the only means employed by the Ministry of Health. Local manufacturer, including the repackager for the products, and importer are responsible for affixing the security device onto the individual unit packs. Hologram Meditag can only be purchased by the licensed manufacturer and importer with his sole supplier, Mediharta Sdn Bhd.[177]

Directive on the use of the Hologram Meditag security device was made beginning 1st January 2005 involving non-parenterals products which is not in the form of injection. The second phase of the directive involves parenterals or injectables products starting 1st July 2005. Products that required cold chain maintenance such as vaccines and biologicals which are temperature sensitive are exempted.[178]

Hologram issued by Medi Harta Sdn Bhd is in sequential number. The self-adhesive holographic Meditag measures 8x16mm and contains three levels of security features.[179] Diagram techniques are the first level of unaided visual security; the second level of security can only be checked by handheld instruments; and the third level of security

[177] Directive on the Use of the Hologram Security Device (MeditagTM). Retrieved on 22 September 2004 from http://www.pharmacy.gov.my
[178] Ibid
[179] Appendix 3

too, can only be inspected by using a special instrument.[180] Different levels of authentication are for the consumer to recognize and the enforcement team to verify, track and trace registered pharmaceuticals in the market.[181] The features of the Hologram were updated on 2006 not only to strengthen the security but also to increase the ability of the enforcement team to take action.[182]

3.8 THE PROACTIVE AND REACTIVE ENFORCEMENT APPROACH BY PHARMACEUTICAL ENFORCEMENT DIVISION

3.8.1 Inspection and Seized

The value of seizures of counterfeit medicine in the Malaysian market in 2007 amounted to RM 35.8 million compared with RM 25.9 million in 2004.[183] The counterfeit medicine also accounted for about 5.28 per cent of over-the-counter self-medication products in Malaysia.[184]

[180] Hologram Meditag. Retrived on 10 July 2010 from http://www.mediharta.com.my/forms/MeditagFAQ.pdf
[181] About Meditag, Benefits of Meditag, Mediharta Sdn Bhd. Retrieved on 10 July 2010 from http://www.mediharta.com.my/benefits.shtml
[182] Letter from National Pharmaceutical Control Bureau. Reference no: Bil (62)dlm.BPFK/02/5/1.3 dated 15 August 2006. Retrieved on 10 July 2010 from http://www.mediharta.com.my/menaiktaraf.pdf
[183] Editorial. (2008). "New Bill to help curb Counterfeit Medicines". *New Straits Times* 22 September 2008, p.17.
[184] Ibid.

Table 1.1 Seizure of unregistered products (Drug/ medicine) According to State From January 2008 – October 2010.

STATES	2008		2009		Until October 2010	
	Total Item	Worth of Estimation (RM)	Total Item	Worth of Estimation (RM)	Total Item	Worth of Estimation (RM)
CPF HQ	17	52,906	40	204,716	0	0
Johor	2352	397,618	3194	812,327	3336	1,135,221
Kedah	609	299,489	337	105,546	235	252,912
Kelantan	1198	108,136	1063	764,836	1229	994,836
Melaka	507	371,781	580	48,184	714	429,245
Negeri Sembilan	742	68,204	369	133,773	462	75,822
Pahang	383	45,799	309	38,791	889	120,342
Perak	855	171,332	695	295,986	1030	516,850
Perlis	315	192,796	552	78,704	257	106,343
Pulau Pinang	2180	6,119,620	1833	239,436	1293	449,245
Sabah	5214	593,328	3861	394,774	5733	667,243
Sarawak	1702	304,329	2447	606,606	1388	671,419
Selangor	3215	2,288,368	3002	3,509,747	3038	9,726,587
Terengganu	453	28,359	671	173,406	905	167,635
WP Kuala Lumpur	945	623,709	782	2,980,564	596	4,922,949
WP Labuan	29	6,609	29	7,241	175	58,667
TOTAL	**20716**	**11,672,383**	**19764**	**10,394,637**	**21280**	**20,295,316**

Source: Pharmaceutical Service Division Programme[185]

As we can see from the table above, until October 2010, a total of 21,280 unregistered products were seized with total value of RM 20, 295,316.00. As there is no specific definition of counterfeit in Malaysia under the SODA 1952 or CDCR 1984, the data covers all unregistered products, adulterated products, and those which can be considered as counterfeit products under the Malaysian law. Also not shown in the table, are the items and the approximate value of seized items which increased from 2003 to 2007 with a little drop down in 2005 which may be due to the Hologram requirement.[186] With total value of RM6,432,008.63 in 2003, RM20,623,111.50 in 2004, RM9,382,653.44 in 2005, RM7,830,441 in 2006, RM29,302,672 in 2007 and

[185] Headquater Summary. Retrieved on 30 October 2010 from http://www.cornerstone-msc.net/pharmacy_enforcement
[186] Interviewee 1, above n 117 pg33.

continued as in the above table, we can see that although Malaysia seems not to be in serious problems with counterfeit medicine, if we look at the total percentage of medicine in the market, this sizeable number indicates a growing concern that there are a large number of counterfeit medicines available in the market.

Selangor and WP Kuala Lumpur are the two states which showed highest item and value seized with increasing trend from year 2008 to October 2010. WP Labuan is the lowest in term of item and value of unregistered products seized although it is located near the border of Brunei and close to Philippines. This may be due to the small size of the state that reflects small number of population.

Looking into these figures itself actually does not give a true picture of the counterfeit problem in Malaysia where various factors should be considered relating to this data. The frequency of enforcement activity; types or products seized; value of the products; and also the policy made in a particular year may reflect the data. The enforcement activity of each state is different based on the human resources available, the size of the states, output target by each state and also the economic status of the states.

Table 1.2 Seizure of unregistered products (Drug/ medicine) According to Country From January 2008 – October 2010.

STATES	2008		2009		Until October 2010	
	Total Item	Worth of Estimation (RM)	Total Item	Worth of Estimation (RM)	Total Item	Worth of Estimation (RM)
Malaysia	4052	18,083,426	5240	9,173,962	6609	13,165,724
Indonesia	9124	1,390,528	8400	1,585,372	8549	1,513,667
China	2680	6,885, 495	2558	923,736	2033	2,498,073
India	633	131,568	1285	263,511	1385	460,995
Thailand	1134	1,106,833	746	107,644	944	762,988
Filipina	525	75,283	559	240,590	1051	679,190
Others	1141	217,933	894	124,304	1438	304,896
Singapore	130	36,124	111	62,964	235	109,726
Oceania	142	61,726	105	35,645	68	48,761
Middle East	30	1,680	34	92,854	19	551,777
Other parts of Asia	2701	377,178	1744	412,596	2253	2,171,605
Africa	5	890	5	290	4	42
European	768	356,244	465	296,741	615	234,643
Latin America	40	5,760	58	13,464	75	10,107
North America	776	373,819	436	349,287	306	83,671
TOTAL	**20716**	**29,104,487**	**22640**	**10,394,637**	**25584**	**22,595,865**

Sources: Pharmaceutical Service Division[187]

From the above table, we can see that local products contribute a major amount to the statistics. Difficulty in detecting the culprit is due to the false address that was printed on the product packaging. Apart from that, false telephone number, invoice or receipts without proper address worsen the situation.[188]

The seizures of the products are always based on the complaints, regular inspections or regular samplings. Complaints are either from external source, which is the consumer;

[187] Headquater Summary, above n 185, pg55.
[188] Interviewee 2, above n 58, pg19.

or internal source, which is the regulatory body and officers itself. Apart from that, regular random samplings by the officers also contribute to the detection of counterfeit or adulterated products in the market. Surveillance was done to identify the suppliers, dealers or manufacturers.

The diagrams show the complex involvement of a China citizen involved in marketing a product adulterated with Sibutramine.[189] The case was detected upon analysis of the sample from the market that was found to be adulterated with Sibutramine. The outcome of the surveillance by the enforcement officers resulted in a counterfeit medicines syndicate being successfully charged. Although it is a serious case that can cause harm for the consumers who consumed the product as mentioned earlier in Chapter 2 on the effects of Sibutramine, the culprits were only convicted to a fine and not allowed to apply visa to Malaysia.

3.8.2 Investigation

Investigation is a very important element in detecting the supply chain of counterfeiters. From investigations, enforcement officers successfully charged a company which was believed to earn approximately RM39 billion for selling the adulterated medicine within 6 months.[190] This shows that the business of counterfeit medicines is very lucrative.

Counterfeiters always printed false addresses, contact numbers and other information on the packaging label. As mentioned earlier, this problem makes it difficult for the enforcement team to apprehend the culprits. The most important thing that they usually cannot falsify is the company registration. Information from the Companies

[189] Appendix 4.
[190] Interviewee 2. above n 58, pg 19.

Commission of Malaysia is very useful in providing details of the owner of the company or business registration.[191]

3.8.3 Prosecution

There are still no cases being prosecuted under the provision of Section 10(1)(a), section 10(1)(b) of SODA 1952 and Regulation 7(1)(A)(e) CDCR 1984. Most of the cases were charged under the Regulation 7(1)(a) CDCR 1984 offences for unregistered products and Section 12(a) offences for selling poisons without license. We can see here the provision provided is underutilized.[192]

Although there is no provision on sanction to prosecute under the SODA 1952, the conduct of prosecution relies on the general provision laid in Section 377(b)(3) of the Criminal Procedure Code which stated:

> "Subject to the control and direction of the Public Prosecutor, by the following persons who are authorised in writing by the public Prosecutor: An officer of any Government department."

The minute written down by the Deputy Public Prosecutor in the Investigation Paper (IP) is the green light to prosecute.[193] Both Sessions and First Class Magistrate courts have the jurisdiction under the SODA 1952 provided under Regulation 18 of SODA 1952.[194]

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[191] Interviewee 2. above n 58, pg 19.
[192] Interviewee 3, above n 108, pg 31.
[193] Wahab, M.K.A, & Samad, A.A. (2009). A Critical Study on the Extend of the Issues and Challenges Facing the Pharmaceutical Enforcement Officers in the Enforcement of Counterfeit Medicines in Malaysia, with Special Reference to the Position in England and Wales, Faculty of Law, Universiti Teknologi Mara, Selangor.
[194] Sales of Drugs Act 1952 at Regulation 8

3.8.4 Public Awareness

Proactive approaches by the PED through public awareness and education also give a significant effect. The emerging problem of counterfeit medicine is also caused by the lack of public awareness. As discussed earlier, demand from the public is one of the contributory factors to this problem,

Pharmaceutical Services Programme has put together many programmes to educate the public. In fact, a campaign called "Know Your Medicine" was launched by the Ministry of Health jointly organized with the Federation of Malaysian Consumer Association (FOMCA) in 2006. This three-year campaign project which will end in 2008 was done not only due to the wrong use of medicines that can endanger the public health, but also have adverse impact on the economy. The main objective of this campaign are to increase consumers' awareness on the correct use of medicines and consumers' right to information, to provide consumers with information on different issues related to the health and medicines, to ensure that consumers know their medicines, what they should and should not take and why, to improve adverse drug reporting through patient education, to improve knowledge of mothers on their children's medicines and to assist senior citizens on the use of medicines.[195]

The Pharmaceutical Enforcement Divisions plays a role in this campaign where under the Consumer Protection Unit, information and educational pamphlets to the public on control, usage and selling of medicines in the market are disseminated. Many campaigns, talks and exhibitions were done at every levels of community such as rural and urban areas, primary and secondary schools, mainly to strengthen the knowledge of

[195] About The Campaign. Retrieved on 18 July 2010 from http://www.knowyourmedicine.gov.my/index.cfm?&menuid=2&lang=EN

consumer as they have the right to know about the risk of taking the counterfeit medicine. Besides that, those activities were done to give awareness to the public and how to identify the genuine and counterfeit medicines.

The characteristic of the registered products and labels with the Hologram are the main things consumer should consider first before they consume the medicines. The hologram authentication devices were placed in every retail pharmacies all over Malaysia to enable the public to check on the medicines they bought and these are easily accessed. Furthermore, the pharmacist-in-charge can explain and ensure that the consumers are taking the right medicines.[196] Posters and postcards of "Know Your Medicine" campaign have been distributed to the public all over the country through State Pharmaceutical Enforcement Branches. The calendars with information and messages regarding the use of medicines are also distributed every year since 2006. Besides that, information and educational articles are also printed through media such as Sunday Star, Mingguan Malaysia, Sin Chew Daily and Men's Health magazine. Consumer Protection Units together with PED are also involved in the TV3's *Malaysia Hari Ini* slot and radio station to disseminate the information.[197] Although the campaign initially targets three years to educate the public, it is continued till today as the awareness of the public is most important to solve the counterfeit problem and to avoid the risk of dangerous effect of counterfeit medicines.

[196] Interviewee 1, above n 117, pg33.
[197] Ibid.

3.9 CONCLUSION

Based on the discussion above, there is no specific provision in any laws on interpreting the offence for counterfeit medicine. However, there are several provisions in separate laws that can be used to tackle the problem. There are also powers provided by laws allowing the PED to enforce on the counterfeit medicines. Besides PED, there is also a regulatory body under the Ministry of health that plays a part in controlling the counterfeit medicines which is the NPCB. PED also enlists the co-operation of the society by increasing on the public awareness as they are the major group most impacted by counterfeit medicines. Malaysia also has implemented the hologram detection device to differentiate between the genuine and counterfeit products. Even though we have enforcement powers, provisions which can tackle the problem and holograms as the device to detect counterfeit medicines, this may not be adequate to combat counterfeit medicines.

CHAPTER 4

PROBLEMS AND RECOMMENDATIONS

4.0 INTRODUCTION

This chapter will discuss the problems in the Pharmaceutical Enforcement Division (PED) framework in controlling counterfeit medicines and further suggest some recommendations that can be made to improve the weaknesses. A suitable approach recommended can be taken into consideration to strengthen the enforcement of counterfeit medicines.

4.1 ABSENCE OF DEFINITION AND SPECIFIC PROVISION

Absence of counterfeit definition is a major problem faced by PED. One of the interviewee remarked that the legal system is adequate to tackle on the counterfeit medicines because there are provisions available to deal with counterfeit medicines although in different terms. The problem is just the absence of the counterfeit medicine

definition.[198] Due to the absence of the definition, the enforcement of counterfeit medicines became uncertain. As remarked by the interviewee:

> "...we can take action on counterfeit medicines where we have different provisions that can cater to the problem but it just a matter of no definition. Even for the offence of adulterated food, we can use Section 10(1) (b) of SODA 1952. For the time being we use the existing law."[199]

As suggested in the WHO guidelines for the development of measures to combat counterfeit medicine, counterfeit drugs must be mentioned specifically in the legislation and the development of specific regulation in the area must be implemented.[200]

4.2 LACK OF ENFORCEMENT POWER

As discussed in Chapter 3, lack of enforcement power is one of the weaknesses in PED framework. It is an urgent need to have wider power in order to deal with serious or extreme circumstances. Pharmaceutical Enforcement Division is a law enforcement agency which has a large scope of activities outside the spectrum of work connected with specific crime. Law enforcement component can be divided into two components which are prevention/suppression function and investigation/apprehension function.[201] Prevention or suppression function will be discussed in the next sub topic.

Investigation or apprehension function of enforcement officer is the crucial part where criminals will be apprehended and be prosecuted. Counterfeiting medicines is a very dangerous crime which affect the public health. Compared to pirated VCDs or direct

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[198] Interviewee 3. above n 108, pg32.
[199] Ibid.
[200] Department of Essential Drugs and Other Medicines, above n 15, pg9.
[201] Eldefonso, E., Coffey, A. & Grace, R.C. (1968). *Principles of Law Enforcement*. New York: John Wiley & Sons Inc, pg 7

selling offences, the impact to the public was not as serious as counterfeit medicines crime. But the enforcement officers of those units are provided with a tough enforcement power to fulfil their duty.

4.2.1 Power to Access to Computerized Data

Under Section 42, Part VII of the Optical Disc Act 2000 (Act 606), power to access to computerized data is provided under the statutory provisions. The officer can search for data either stored in the computer or otherwise. Access includes being provided with necessary password, encryption code, decryption code, software or hardware and any other means required to enable comprehension of computerised data.[202]

PED may need this authorization power when doing an investigation as presently, almost everyone uses a computer to keep records and a lot of transactions is done online. Important information may be missed out during investigation as due to absence of this power.

4.2.2 Power to Arrest

Under Section 30 of the Direct Sales Act 1993,[203] power to arrest without warrant any person who is believed to commit an offence under the Act is provided. Rationale of this power being provided is to avoid the suspected person going missing during the conduct of the investigation. As counterfeit crime is a serious crime which may involve a bigger scale than what was successfully confiscated during the raid, this power will allow information or interrogation to be taken during investigation. Without arresting,

[202] Section 42 of the *Optical Disc Act 2000 (Act 606).*
[203] Section 30 of the *Direct Sales Act 1993.*

the information is difficult to obtain and the usual investigation may take time. By the time the information is gathered, the criminals may have shut down their activities.

4.2.3 Power to Intercept Phone Conversation

Use of electronic surveillance is useful to penetrate the close society of organized crime.[204] Counterfeit medicines can be linked to organized crime which yields large profits and required manufacture, importation and distribution as mentioned in earlier chapter. Nowadays, a cell phone a cell phone is often used for individuals to keep in touch. Intercept orders is valuable where telephone conversations are an integral part of the criminal activity. Cell phone makes it easier to track down any wireless device user. As intercept order is not purely for intelligence-gathering purpose, where it must be for the purpose of the investigation of specific criminals' violations,[205] it will benefits PED when it is provided in the statutory provision.

4.2.4 Power to Require Evidence

One of potential sources of information that is often overlooked is the suspect or accused. The suspect or accused may need to be in interviewed or interrogate to gain more information.[206] Power to require evidence is important in investigation process. Thus absence of this power cause the potential sources of the counterfeiters are missed. Standard legal requirement or caution must be provided together with the power to avoid any violations of human right or power abused.

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[204] Dowling, J.L. (1979). *Criminal Investigation: Investigation of Organized Crime*. New York: Harcourt Brace Jovanovich Inc, pg 208.
[205] Ibid.
[206] Allen, B.V. (2000). *Criminal Investigation in Search the Truth*. Toronto: Pearson Prentice Hall, pg115.

4.3 LOW PENALTY

Besides definition and specific provision on counterfeit medicines, higher penalty should be introduced to current laws enforced by PED. Penalty should be high due to the concerns on public health and to deter criminals from recidivisms. Minimum sentences should be provided to limits the imposed of extremely low sentences for convicted criminals. Mandatory imprisonment sentence will also help to deter the criminals. As discussed in earlier chapter, although there are provisions for imprisonment sentences, no record show it been imposed to those convicted.

> "...We have the law but the penalty is not a strong deterrent....we suggest penalty is increased with mandatory imprisonment sentence."[207]

Amendment of law seems to be a better approach in tackling the counterfeit medicines.

4.4 DIFFICULT TO DETECT

As discussed in Chapter 2, difficulty in detecting the activities involve in counterfeiting the medicine is among the challenges faced by PED. In terms of analysis, the fast development of the counterfeiters to create new analogues and entity is a challenge to PED. Products may be adulterated by the analogues of the poison involved which are sometimes overlooked by PED when requesting samples analysis. Further, analysis may take time where samples were sent to Department of Chemistry Malaysia, Ministry of Science, Technology and Innovation (MOSTI) for the purpose. Samples cannot be

[207] Interviewee 2, above n 58, pg19.

analysed at the point of search. The counterfeiters may change their product to a different form by the time it was detected by PED. An interviewee explained:

> "....difficulty that we usually faced is to detect the poison in the product where analogue is used by the counterfeiters. For example, the analogues for sildenafil and tadalafil maybe overlooked when we send the sample to the chemistry unit. We also need time to trace the presence of this analogue in the market. Same product will be adulterated with different analogue and maybe the appearance is changed to food or drink for example. This gives us a challenge."[208]

Difficulty in detecting the manufacturer was raised in regards to the issues on false information on the labelled packaging and documents. According to the interviewee, false information of address, contact number, invoice and cash bill caused difficulty to trace the origin of the product.

> "....difficult for us to detect manufacture by illegal manufacturers because the address is different and it is false address printed. The only way to detect is by the company name which they cannot falsify."[209]

4.5 RECOMMENDATIONS

4.5.1 Amendment of Relevant Laws

As identified in Chapter 3, lack of powers in the SODA 1952 and CDCR 1984 exist. It is recommended that the power to access to computerized data, power to arrest, power to intercept phone conversation and power to require evidence are provided to PED to strengthen the enforcement control. Legislation gives appropriate officials the authority to implement or enforce the law. Legislation should be regularly scrutinized and

[208] Interviewee 2, above n 58, pg19.
[209] Ibid.

amended as required to ensure effectiveness.[210] Amendment may be made to current law when urgency is needed. A definition of counterfeit medicine, specific provision for counterfeit offence included sale, supply, manufacture and administered; and also higher penalty provision should be provided in existing law.

4.5.2 Assessment on the Nature and Extent of Counterfeit Medicine

Every effort should be made to identify the sources of counterfeit drugs and to assess their levels in the national drug distribution channels. All reports of counterfeit drugs should be investigated. Workers in the national distribution channels are often favourably placed for early recognition of counterfeit drugs in the market place. These workers should be encouraged to be on the alert of counterfeit drugs and to reports any suspicion of these to the PED, which should in turn to be able to react rapidly and appropriately to these reports, without detriment to the whistle-blowers.[211] Surveillance is important and investigation is a very crucial part and imposes heavy responsibilities. Investigators have responsibility to investigate the crime with every means available.[212]

There should also be a separation of data on counterfeit medicines itself. This would be easier to research on the sources of the problems and the culprits involved. Based on the statistic, we cannot predict the seriousness of the problem in Malaysia as the term used overlapped with other offences, thus making the evaluation process difficult. The scale of the problem must be monitored regularly to ensure that appropriate approaches or measures were conducted.

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[210] Department of Essential Drugs and Other Medicines. above n 15, pg10.
[211] Ibid.
[212] Kinnee, K.B. (1994). *Introduction, Practical Investigation*. London: Techniques.CRC Press, pg 5.

4.5.3 Inter-Agency Partnership

Enforcement alone is not able to combat the counterfeit drugs successfully. Cooperation from all levels is required to ensure the success of the action plan. The parties that should be made involved are the pharmaceutical industry, importers, wholesalers, retailers, health professionals and consumer associations. Cooperation from other enforcement agencies such as the Customs, Ministry of Science, Technology and Innovation; and Ministry of Domestic Trade Co-operatives and Consumerism are also required. Customs help should be enlisted in importation and exportation at the entry point level. All levels of involvement are required to make the action plan on combating counterfeit medicine successful.

4.5.4 Effective Collaboration with Interested Bodies

Closer work with the pharmaceutical industries is required and should deliver both strategic and tactical outcomes ranging from legislative and regulatory review to operational results focused upon safeguarding public health. The pharmaceutical industry has a great part to play in the detection, control and eradication of counterfeiting of drugs as they are the producer or product owner which knows better about the drugs in the market. Legitimate drug manufacturers should be encouraged to develop measures, such as the introduction of security systems including the use of security tags, to prevent counterfeiting of their products. They are also encouraged to secure their own stocks of medicines and packaging materials in order to prevent their diversion to illegal manufacturers and packagers. Regular survey of their own drug distribution channels with a view to detecting the presence of any counterfeiting of their products may help PED in detecting counterfeit medicine crime. Iinformation shared

may be used as evidence in court proceedings, in which they could be witnesses. Manufacture are also advice to avoid promoting drugs in a way that results in demands that cannot be met by their own supply system, thereby leaving a gap which could be exploited by the counterfeiters.[213]

4.5.5 Enhancement of Public Education

Education is one of the prevention or suppression function in law enforcement. The general public should be encouraged to become involved in the fight against drug counterfeiting.[214] Apart from establishment of education and information campaign directed to the public, consumers should be encouraged to report to PED any suspect products and/or illegal unauthorized manufacturer and distributors they may encounter.

Consumers could also be encouraged to report to their prescribers or physicians on any lack of improvement in their health status in spite of their compliance with the prescribed treatment regime. They are also encouraged to reports all adverse reactions experienced during treatment where unexpected adverse reactions might indicate that the drug used was a counterfeit.[215]

4.5.6 Establishing Anti-Counterfeiting Taskforce

WHO has initiated the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) which is the first global initiative comprising of all 193 WHO member states to improve coordination and harmonization across and between countries to cease the production, trading and selling of counterfeit medicines. Members include international

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[213] Department of Essential Drugs and Other Medicines, above n 15, pg10.
[214] Ibid.
[215] Ibid.

organizations, enforcement agencies, national medicine regulatory authorities, customs and police organizations, associations representing pharmaceutical manufacturers and wholesalers, health professionals and patients' groups.[216]

As a recommendation, the Ministry of Health should also establish an Anti-Counterfeiting Taskforce specialized in dealing with counterfeit medicines using the best approach to overcome the problems and challenges.

4.5.7 Training

All enforcement officers should be given appropriate training, especially in the intelligence part. Constrained power by PED may limit the surveillance and investigation. Therefore, a trained and knowledgeable enforcement officer is required in order to trace the origin of the counterfeiters to eradicate the roots of the problems. Successful investigators will invariably possess a high degree of self-discipline, and have knowledge of practice and methods that are legally acceptable. Investigations cannot always be performed perfectly according to the procedures outlined. Therefore, to be successful, investigators must be creative and able to take initiative. Adequate training will prepare enforcement officers toward the required surveillance and investigation officers.

4.5.8 Technological Solution

Technological solution can be considered as prevention or suppression function in law enforcement. Although Malaysia is using the hologram as a tool to detect the genuine

[216] IMPACT International Medical Products Anti-Counterfeiting Taskforce, World Health Organization, online, available at http://www.who.int/impact/events/FinalPrinciplesforlegislation.pdf retrieved on 20 September 2010.

medicine and registered product, there are other technologies that can be considered to be used to combat counterfeit medicine. The radio-frequency identification (RFID) using the X-Ray analysis is one of the good technologies which can be considered to be applied.[217] The ability to non-destructively analyze intact pharmaceutical tablets, without requiring removal from the original blister packaging is the major benefit. The screening can be used to differentiate authentic drugs from counterfeits products or to conduct non-invasive post-production product control.[218]

There is no such thing as a worldwide applicable technology where different approaches are taken based on cost and scale of counterfeit medicine problems in its own country.[219] Consideration on this technology can be made as we may need the device in the future in case the hologram method becomes ineffective.

4.5.9 Public Reporting System

It is important to have public reporting system which would be easy and convenient for them to channel their information or complaints regarding the counterfeit medicines to PED. This system also could assist the PED in their enforcement task whether effective or otherwise.

[217] Spekman, R.E., Sweeney II, P.J. (2006). "RFID: The Concept to Implementation". *International Journal of Physical Distribution & Logistic Management*. Emerald Group Publishing Limited, Vol36, Issue 10, pg736-754.
[218] Mukuth Venkathesan & Grauer, Z. (2004). Leveraging Radio Frequency Identification (RFID) Technology to Improve Laboratory Information Management. American Laboratory.
[219] A white paper from PANalytical, A Technological Solution for Combating Counterfeit Drugs, (American Laboratory, 2004).

4.6 Conclusion

This chapter revealed problems faced by PED in controlling counterfeit medicines. Lack of enforcement power may hinder the enforcement on counterfeit medicine. Therefore, some powers are recommended to strengthen PED's power in regards to the problems. Counterfeit medicines and counterfeiters are also difficult to be detected. Training provided to officers will prepare them to have special skill and knowledge to track down the culprits. Technological solution such as RFID may be useful to enhance the security of hologram. Regular assessment, Inter-agencies partnership and enhancement of public education and also the establishment of Anti-Counterfeiting taskforce may also be useful in improving the control framework on counterfeit medicines by PED.

CHAPTER 5

CONCLUSION

5.0 INTRODUCTION

This chapter represent the concluding remarks of this research.

5.1 CONCLUDING REMARKS

The purpose of this research is to outline and describe the existing methods to curb counterfeit medicines in Malaysia as employed by the Pharmacy Enforcement Division, Ministry of Health:- to evaluate the current response towards counterfeit medicine; and to suggest any suitable improvement in the methods of preventing counterfeit medicines in Malaysia.

Existing weaknesses obstruct the use of the provision in the laws. Absence of counterfeit medicine definition as discussed in Chapter 2 is the major obstruction. The control of counterfeit medicines using other regulatory terms show the uncertainty of the PED as a law enforcement u nitresponsible to tackle the problem. The lack of

counterfeit medicine definition in any statutory provision in the laws enforced by PED also gives the impression counterfeit medicine per se may not be a crime.

In Chapter 3, the Pharmacy Enforcement Division legal frameworks were detailed as the laws used to control the counterfeit medicine. Besides the laws, there is a device known as Hologram Meditag which acts as an identification tool to differentiate between genuine and counterfeit medicine. From the discussion, there are some weaknesses that had been identified, particularly in the area of power, offence and penalty. There are also provisions which is underutilised or over utilised in order to impose harsher penalty to the criminals. Amendment of the law may improve the existing law where specific provision for counterfeit medicine and higher penalty are introduced. PED may need extended power in enforcing counterfeit medicines crime to deal with serious and extreme situation where organized crime is involved. As recommended, a new specific law with adequate power to strengthen the enforcement power increased the capability of PED to deal with the problem.

Although crime is a national problem but it is primarily the responsibility of local government to handle. When crime cannot be dealt with or effectively prevented, there will be negative repercussions. When criminals escape from prosecution, further illegal act or crime is encouraged. With the increasing crime rate, resources to other social needs will be reduced and give rise to another social problem such as inadequate medical care or treatment. It also impacted the public where the society lost their trust in the government as they fail to safeguard the public welfare. The quality of life is also affected.

In conclusion, this research has discovered that the existing legislations in controlling counterfeit medicines are still insufficient to eradicate the counterfeit medicines in the market. These shortcomings need to be addressed to provide a proper comprehensive law in Malaysia. Thus, when the law or policy relating to the control of counterfeit medicines is to be reviewed or enacted by the government, it is proposed that the recommendations set out in this research be considered.

This research is only focused on the SODA 1952, Poison Act 1952 and CDCR 1984 whereby there is another provision involved under the Medicines (Advertisement and Sale) Act 1956, solely related to the offences in the publication of advertisements. Thus, it is recommended for any future research in this area to look into the control on advertisement of counterfeit medicines in news paper, magazines and particularly internet, where in view of present advance technology; most of the transactions and promotions were made online. Last but not least, it is hoped that this research will provide better understanding and information regarding the control of counterfeit medicine in Malaysia. The discussion, findings, solutions and recommendations above indicate that the research question in this study has already been answered.

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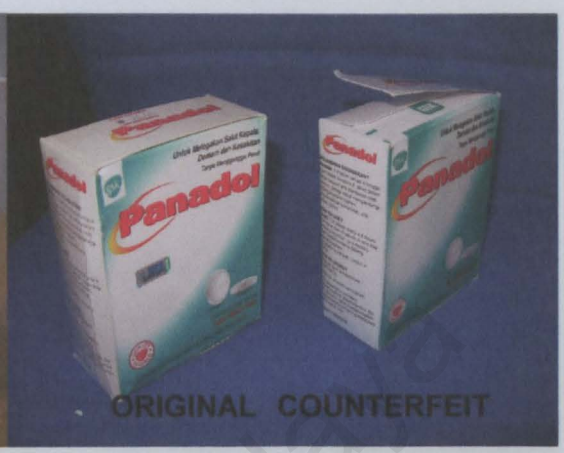
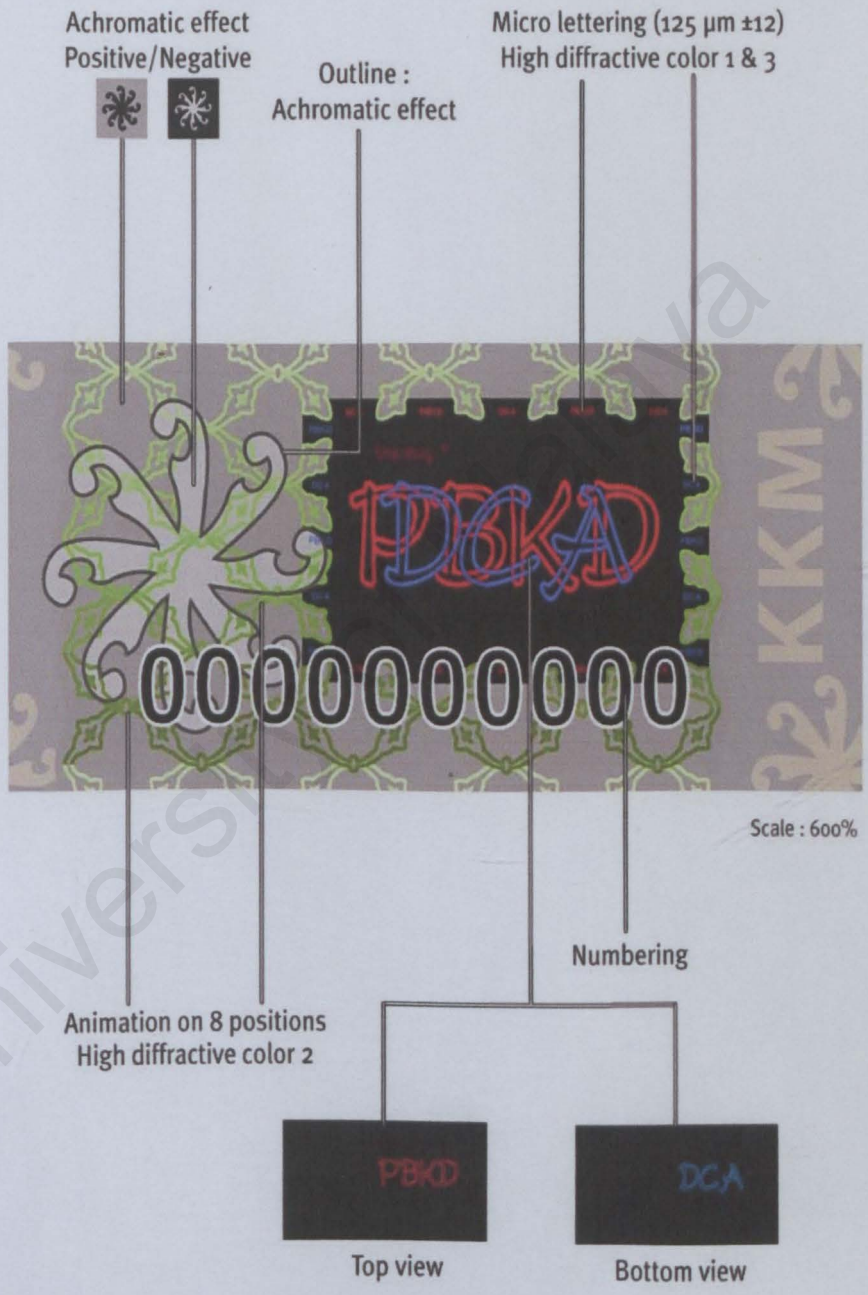
Example of "Ubat Papan"

EXAMPLES OF COUNTERFEIT MEDICINES SEIZED



HOLOGRAM

1st level authentication



DIAGRAM®
Final size : 18 x 8 mm