(R)

UNIVERSITI MALAYA
ORIGINAL LITERARY WORK DECLARATION

RESTRICTED

Name of Candidate: **NURUL HAYATI BINTI BOHARI**

I.C/Passport No: [redacted]

Registration/Matric No: **LGC 090006**

Name of Degree: **MASTER OF CRIMINAL JUSTICE**

Title of Project Paper/Research Report/Dissertation/Thesis ("this Work"):
ISSUES AND CHALLENGES IN THE ENFORCEMENT OF PSYCHOTROPIC SUBSTANCES BY PHARMACEUTICAL ENFORCEMENT DEPARTMENT

Field of Study: **CRIMINOLOGY**

I do solemnly and sincerely declare that:

(1) I am the sole author/writer of this Work;
(2) This Work is original;
(3) Any use of any work in which copyright exists was done by way of fair dealing and for permitted purposes and any excerpt or extract from, or reference to or reproduction of any copyright work has been disclosed expressly and sufficiently and the title of the work and its authorship have been acknowledged in this Work;
(4) I do not have any actual knowledge nor do I ought reasonably to know that the making of this work constitutes an infringement of any copyright work;
(5) I hereby assign all and every rights in the copyright to this Work to the University of Malaya ("UM"), who henceforth shall be owner of the copyright in this Work and that any reproduction or use in any form or by any means whatsoever is prohibited without the written consent of UM having been first had and obtained;
(6) I am fully aware that if in the course of making this Work I have infringed any copyright whether intentionally or otherwise, I may be subject to legal action or any other action as may be determined by UM.

Candidate's Signature [redacted] Date 11/1/11

Subscribed and solemnly declared before,

Witness's Signature [redacted] Date 11/1/11

Name: Dr. Abdul Samad Abd Ghani
Designation: Senior Lecturer
Faculty of Law
University of Malaya

ISSUES AND CHALLENGES IN THE ENFORCEMENT OF PSYCHOTROPIC SUBSTANCES BY PHARMACEUTICAL ENFORCEMENT DEPARTMENT

NURUL HAYATI BINTI BOHARI

A RESEARCH PROJECT SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF CRIMINAL JUSTICE.

2009/2010

ABSTRACT

This research is about the study on the law enforcement of Pharmaceutical Enforcement Department (PED) on the issues and challenges in the enforcement of psychotropic substances. The focus on this study is on the illegal supply of psychotropic substances by the medical practitioners. As the one and only agencies in the enforcement on the illegal supply of psychotropic substances, it is very important to make sure the method and approaches to curb the abuses and diversion which lead to drug addicts and crimes been identified. The research was based on official statistic data on psychotropic substances control by PED and investigation and prosecution cases, interviews with relevant officers in PED on the current control approaches on the supply of psychotropic substances and critical analysis on information gathered from library and internet. In the illegal supply of psychotropic substances, the medical practitioners prone to unlawful practices such as without or improper treatment (doctor shopping), overprescribe, makes compounding, improper records, improper storage, improper labeling and makes false documentation or declaration. The weaknesses of the PED are because the lack of information, difficulty in getting cooperation from the medical practitioner in the investigation cases and insufficient legislation such as definition of terms and the punishment. Hence, in this study found that the crime happened absolutely because of the medical practitioner is only the authorized person to prescribe and dispensed the psychotropic substances. Thus, there is a need to improve the laws, the enforcement approaches such as established an academy for PED, educating the medical practitioners and the policy approaches in psychotropic substances control related to medical practitioners such as dispensing separation, licensing the medical practitioner purchase and supply the psychotropic substance and established prescription and dispensing computerized system.

ABSTRAK

Penyelidikan ini mengenai kajian penguatkuasaan undang-undang oleh Bahagian Penguatkuasa Farmasi (PED) terhadap isu-isu dan cabaran dalam penguatkuasaan bahan-bahan psikotropik. Fokus kajian ini adalah terhadap pembekalan bahan-bahan psikotropik secara tidak sah oleh pengamal perubatan. Sebagai agensi tunggal dalam penguatkuasaan pembekalan bahan-bahan psikotropik secara tidak sah, adalah penting bagi PED memastikan kaedah dan pendekatan-pendekatan dikenalpasti dalam menangani penyalahgunaan dan pemesongan bahan psikotropik yang boleh membawa kepada penagihan dadah dan jenayah. Penyelidikan ini berdasarkan data-data rasmi berkenaan pengawalan bahan-bahan psikotropik oleh PED, kes-kes penyiasatan dan pendakwaan, temuduga pegawai-pegawai yang terlibat berkenaan pendekatan terkini terhadap pengawalan pembekalan bahan psikotropik dan penganalisaan secara kritis terhadap maklumat-maklumat yang dikumpulkan daripada perpustakaan dan internet. Dalam pembekalan bahan-bahan psikotropik secara tidak sah, pengamal-pengamal perubatan didapati cenderung melakukan amalan-amalan yang tidak mengikut undang-undang seperti tidak menjalankan rawatan atau tidak sepenuhnya (doctor shopping), terlebih preskrib, melakukan aktiviti sebatian, tiada menyimpan rekod atau tidak lengkap, penyimpanan bahan psikotropik yang tidak betul, pelabelan yang tidak betul dan melakukan dokumentasi atau pengakuan palsu. Kelemahan-kelemahan PED adalah antaranya kerana kurang maklumat berkenaan pembekalan bahan-bahan psikotropik, sukar mendapatkan kerjasama daripada pengamal–pengamal perubatan terutamanya dalam penyiasatan dan undang-undang yang tidak mencukupi seperti definisi dan hukuman. Oleh itu, kajian ini mendapati jenayah ini berlaku adalah kerana pengamal-pengamal perubatan diberikuasa sepenuhnya mempreskripsi dan membekal bahan-bahan psikotropik. Jadi, penambahbaikan adalah perlu dilakukan terhadap undang-udang yang sedia ada, pendekatan dari segi penguatkuasaan seperti mewujudkan akademi bagi pegawai PED dan memberi pendidikan kepada pengamal-pengamal perubatan dan pendekatan dari segi polisi kerajaan dalam pengawalan bahan-bahan psikotropik yang melibatkan pengamal perubatan seperti pengasingan fungsi-fungsi pemprekripsian dan pembekalan khasnya bahan-bahan psikotropik, melesenkan pengamal-pengamal perubatan dalam membeli dan membekal bahan-bahan psikotropik dan mewujudkan sistem pengkomputeran dalam fungsi preskripsian dan pembekalan.

ACKNOWLEDGEMENT

First of all, I would like to forward the greatest appreciation and gratitude to God for blessing me with the vital health to accomplish my research project.

I would like to express my appreciation to the Ministry of Health for giving me the opportunity to further my study. I also like to thank Faculty of Law, University Malaya for their co-operation and accommodation provided to me with all the equipments and materials concerned.

I also would like to express my grateful thanks to my honored, Dr Abdul Samad Bin Abdul Ghani for endless support, guidance and valuable comments in the preparation and completion of this research.

A special thanks to my greatest boss, Dato' Eisah Bt A. Rahman, to Director of Pharmaceutical Enforcement, En Mohd Hatta Bin Ahmad and Tn Hj Wan Hamid Bin Wan Ibrahim. I also would like to give greatest appreciation to En Dzafarullah Bin Daud for his kindness and cooperation, En Mohd Zawawi Bin Abdullah, Pn Azlinda Bt Mohd Saad and Pn Zurainy Bt A. Samah for giving their view and related information sincerely. Not forgetting to my dearest friends, Pn Shafilliza Bt Samsuri, Pn Rohaya Bt Mahmud and En. Azaruddin Bin Azis for their support, view and advice.

I also would like to portray my millions thanks and loves to my beloved husband Anuar Bin Hamzah, daughters Nuraina Adani and Nuraina Nabila, son Adam Faiz, my mum Maznah Bt Abd Latif, my father Bohari Bin Mohd Yamin and my grandmother Zaitun Bt Ibrahim for their understandings, continuing supports and faith and their never ending love in my lives. This project paper would not be completed without the help and encouragement from each and every one of you. Also not forgotten also to my helpful and thoughtful colleagues of Master in Criminal Justice session 2008/2009 and 2009/2010. Finally, I would like to thank all whom I have forgotten to mention here. I cannot thank you enough for being there for me when I needed you most.

TABLE OF CONTENTS

LIST OF STATUTES

Criminal Procedure Code (Act 593)

Control Drug and Cosmetic Regulations 1984

Dangerous Drug Act 1952 (Act 234)

Dangerous Drug Regulations

Direct Sales Act 1993

Optical Disc Act 2000 (Act 606)

Poison Act 1952 (Act 366)

Poison (Psychotropic Substances) Regulations 1989

Private Healthcare Facilities and Services Act 1998 (Act 586)

Registration of Pharmacist Act 1951 (Act 371)

Registration of Pharmacist Regulations 2004

Sale of Drugs Act 1952 (Act 368)

LIST OF CASES

Barnett v. Chelsea & Kensington Hospital Management Committee (1969) 1 Q.B. 428.

Bolam v Friern Hospital Management Committee (1975) 1 WLR 582.

Leadbetter v Brand (1980) 107 D.L.R (3d) 252.

PP v Gernal Singh a/l Kundan Singh (2004) unreported, Kuala Lumpur Magistrate Court.

PP v Lau Hee Sim, (2003) unreported, Georgetown, Penang Magistrate Court.

PP v Mohamed Amanullah bin Mohamed Ibrahim (2007) unreported, Pulau Pinang Magistrate Court.

PP v Ng Lung Heam (2003) unreported, Kuala Lumpur Magistrate Court.

PP v Ramesh a/l Muniasamy (2005) unreported, Johor Bahru Magistrate Court.

Sang (1979) Cr. App. R. 240.

Sorrrells v U.S 287 U.S 435, 442 (1932).

LIST OF ABBREVIATIONS

ADK	National Anti-Drugs Agency
DDA	Dangerous Drug Act 1952 (Act 234)
DEA	Drugs Enforcement Administration
DEO	Drug Enforcement Officer
DST	Drug Substitution Therapy
GP	General Practitioner
MOH	Ministry Of Health
PED	Pharmaceutical Enforcement Department
PSD	Pharmaceutical Services Division

GLOSSARY

Anti-anxiety	Preventing or reducing a state of apprehension and psychic tension occurring in some forms of mental disorder
Anti-depressive	Mood-stimulating drugs used primarily in the treatment of affective disorders and related conditions such as depression
Diagnosis	The process of determining by examination the nature and circumstances of a diseased condition
Hallucinogen	Subjectively experienced sensations in the absence of an appropriate stimulus, but which are regarded by the individual as real. They may be of organic origin or associated with mental disorders
Tranquilizing	i. To sedate or relieve of anxiety or tension by the administration ii. To have a calming or soothing effect

CHAPTER ONE

INTRODUCTION TO THE RESEARCH

1.0 INTRODUCTION

This chapter discusses the background of study, as well as statement of research, objective of research, significance of study, scope of research, methodology of research, chapters division, and limitations of research.

1.1 BACKGROUND OF STUDY

Pharmaceutical Enforcement Department (PED) is one of the departments under the Pharmaceutical Services Division (PSD), a division under the Ministry of Health, Malaysia (MOH). PED is responsible for control of importation, manufacture, sale, supply and administration of all psychotropic substances in Malaysia.

One of the problems in relation to the control of psychotropic substance by PED is the illegal supply of such substance by medical practitioners. Medical practitioners are permitted under the law, but subject to various restrictions, to prescribe and supply psychotropic substance to their patients, especially those with psychiatric problems. The Pharmaceutical Enforcement Department (PED), Ministry of Health, Malaysia had conducted numbers of raid, audit and inspection each year to control the sale, distribution and manufacturing of psychotropic substances but the existing law is still

inadequate to tackle the problems[1]. However, there is a growing problem of illegal supply of psychotropic substance by some medical practitioners despite high level of control by PED. Current enforcement efforts by PED have shown that some medical practitioner had illegally supplied psychotropic substance to drug abusers. In this way, these illegal practices are contributing to the drug problem in Malaysia as it provides another source of supply to drug addicts.

In Malaysia, crime related illegal supply of psychotropic substances being a serious public concern on how this problem can be tackled. As we know, drug abuse gives a negative impact to the health, safety, security and social issues. At the same time there is a concern that medical practitioners should not be so strictly controlled that they may not perform their medical duties to patients who really need these medicines. PED plays an important role in control the supply of psychotropic substances which in turn may reduce the impact of drug abuse. What is clearly the case is that the problem of illegal supply of psychotropic substance by medical practitioners needs to be tackled more effectively through better enforcement work by the PED. PED faced a very challenging task to control the supply of psychotropic substances by medical practitioner. It is therefore assumed that there are weaknesses in the current enforcement methods by PED which need to be remedied. In order to do so, it is necessary to understand the nature of illegal supply of psychotropic substance by medical practitioners as well as identifying weaknesses in the current enforcement work in this area by the PED.

[1] Mohamad Sabri Yusoh & Che Bakar Che Mat. (2008). *Penyalahgunaan dan Pengedaran Dadah di Malaysia*, (2nd ed.), 31.

1.2 PROBLEM STATEMENT

Weaknesses in the enforcement method of PED could be contributing to the illegal supply of psychotropic substance by medical practitioners. Therefore it is necessary to study the nature of the problem and to find ways of improving the effectiveness of enforcement work by PED in controlling the supply of psychotropic substance by medical practitioners.

1.3 OBJECTIVES OF THE STUDY

a. To describe the nature of illegal supply of psychotropic substances by medical practitioners.

b. To identify weaknesses in the law and enforcement powers of PED in controlling the illegal supply of psychotropic substances by medical practitioners.

c. To suggest improvement in the enforcement powers of PED on illegal supply of psychotropic substances by medical practitioners.

1.4 SIGNIFICANCE OF STUDY

This research will give a significant contribution to the knowledge and better understanding of the control of psychotropic substances. PED is the main agency to control the supply of psychotropic substances, so PED have to know the nature of

illegal supply of psychotropic substances by medical practitioners. The psychotropic substances need to be control to make sure the people who are really sick used the substances. The psychotropic substances also need to be control to avoid evidence of addiction or tolerance. The research also conducted to reflect critically on the implication of psychotropic substance to the public safety and crime control.

1.5 SCOPE OF STUDY

There are provision on importation, manufacture, sale, supply and administration of psychotropic substances in the laws. This study focus on the provision related to the supply of psychotropic substances which are illegitimate. Further, Pharmaceutical Enforcement Department (PED) controls the supply of psychotropic substances by the registered medical practitioners, registered dentists, veterinary surgeons and licensed pharmacists. This study covers only medical practitioners who supply the psychotropic substances in the private clinics.

1.6 RESEARCH METHODOLOGY

This study is based on the library and documentary research. Following are the material and techniques applied to achieve the aims of this project;

a) Academic material

Relevant academic and professional literature by academicians and scholars which published in journals and publication were the sources of theory and information.

b) Official documents

Formal publications such as the statistic importation of psychotropic substances, statistic investigation of medical practitioner cases, annual reports of Pharmaceutical Services Division, and any relevance report and data of related agencies like statistic drug been used by the drug addicts produced by the National Anti-Drug Agency and annual reports of Ministry of Health.

c) Interview session

Interview sessions have been conducted in order to obtain further information regarding the research area. The interviewees are as below;

Interviewee 1: Deputy Director, Pharmaceutical Enforcement Department, Pharmaceutical Services Division, Ministry of Health Malaysia

Interviewee 2: Senior Principle Assistant Director, Prosecution Unit, Pharmaceutical Enforcement Department, Pharmaceutical Services Division, Ministry of Health Malaysia

Interviewee 3: Senior Principle Assistant Director, Licensing Section, Pharmaceutical Enforcement Department, Pharmaceutical Services Division, Ministry of Health Malaysia

Interviewee 4: Senior Principle Assistant Director, Prosecution Unit, Pharmacy Division, Jabatan Kesihatan Wilayah Persekutuan Kuala Lumpur & Putrajaya

d) Others

Others publication such as newspaper, articles, dictionaries, electronic database, etc. were the source of information and facts. From the library and internet research, books, articles and cases which are related to the study are also gathered. Some of the cases are gathered through interview session. In Malaysia, books that specifically discuss the laws that govern the control of drugs and medicines are still lacking.

1.7 LIMITATIONS OF STUDY

Accessibility to the official statistic data was major obstacle where have to go through many people and makes appointment with the interviewee. However, sometimes only manage to get previous year statistics and reports from relevance agencies due to the time constrain and sensitivity of the issue.

1.8 DIVISION OF CHAPTERS

The research contains five (5) chapters altogether. Chapter one is the introductory part of the research explaining the current situation and the problem concerning the control and problem of psychotropic substances in Malaysia, the objective and methodology of the research, besides explaining the limitation and significance of the research.

Chapter two will discuss focus on the nature of illegal supply of psychotropic substances by medical practitioner in Malaysia. The discussion provides an overview of psychotropic substances and statutory or provisions concerned in the illegal supply psychotropic substances by medical practitioner in Malaysia.

Chapter three, will study on the current method applied by PED in combating the psychotropic substances abuse and diversion. The method applied on the current PED activities such as through the quota control, auditing, investigation and prosecution on illegal supply of psychotropic substances by medical practitioner cases. Discussion will be based on the statistics collected by Statistic Department of Pharmaceutical Services related to illegal supply of psychotropic substances by medical practitioner taken through the interview sessions.

Chapter four will discuss on the weaknesses in the Pharmaceutical Enforcement Department on illegal supply of psychotropic substances by medical practitioner.

Chapter five will makes recommendations and conclusion of this study.

1.9 CONCLUSION

From the above discussion, it can be concluded that PED had a serious problem in combating the illegal supply of psychotropic substances by medical practitioner. Weak enforcement was contributed by inadequate understanding of the nature of illegal supply of psychotropic substance by medical practitioners. There are areas where current enforcement methods are insufficient to tackle the problem. Statutory provisions need to be improve/amended in to order to make enforcement work more effective.

Therefore, in this study, I will discuss detail on the nature of illegal supply of psychotropic substances by medical practitioners in the next chapter.

CHAPTER TWO

THE NATURE OF ILLEGAL SUPPLY OF PSYCHOTROPIC SUBSTANCES BY MEDICAL PRACTITIONER

2.0 INTRODUCTION

This chapter discusses the nature of illegal supply psychotropic substances by medical practitioner in Malaysia. The discussion based on the statistics importation, auditing, investigation and prosecution data of Pharmaceutical Enforcement Department on the illegal supply of psychotropic substances by medical practitioners. Also combine with the issues forward through the interview sessions. The understandings of the illegal supply of psychotropic substances in Malaysia in this chapter will illustrate the abuse of the psychotropic substances by medical practitioners.

2.1 CONTROL OF PSYCHOTROPIC SUBSTANCES

By becoming a party to the three treaties, namely the Single Convention on Narcotic Drugs 1961, the Convention on Psychotropic Substances 1971 and the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988, the Government of Malaysia has undertaken all measures to adapt its own legislation on psychotropic substances to ensure that it complies with the provisions of the treaties.[2]

[2] Arnie Fadzilah, et al. (2007). *Legislative Control of Psychotropic Substances in Private Clinics: A Study on the Existing Laws in* Malaysia. Unpublished master's thesis, University of Technology MARA, 32.

Treaty seriously stated that:

> *Addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind.*[3]

In Malaysia, the classification of psychotropic substances is clear and totally separated with dangerous drug. PED controlled on psychotropic substances which are for medicinal purposes under *Poisons Act* 1952 and regulations and bound to be registered products under *Sale of Drugs Act* 1952 and regulations. According to WHO, psychotropic agents include anti-depressive agents, hallucinogens and tranquilizing agents.[4] Fisher et al defined psychotropic drugs as chemicals used to treat mental disorders.[5]

According to the Poisons Act 1952, psychotropic substances is a poison which is categorized as Group B poison under the First Schedule of the *Poisons Act* 1952 where the drug supplied by medical practitioner to his patient for the purposes of medical treatment or prescribed a prescription for the licensed pharmacist dispensed. The psychotropic substances also defined under section 30(1) of the *Poisons Act* 1952 which means any of the substances specified in the Third Schedule of the Act. The Third Schedule of the *Poisons Act* 1952 is divided into three parts. The first part is the list of psychotropic substances regardless whether they are in the raw form or in pharmaceutical dosage (registered medicine which is being prescribed by medical practitioners in the clinic or hospital) form. The second part of the Schedule was

---

[3] *The United Nations Drug Control Treaties.* (2002). Paris: Senlis Council.
[4] *United Nation Report on Convention on Psychotropic Substances 1971* (United Nation).
[5] Fisher G.L. & Thomas C.H. (2000). *Substance Abuse, Information for School Counselors, Social Workers, Therapists and Counselors.* (2nd ed). Allyn and Bacon USA.

included after the amendment was done in 2006. It includes any product or medicine which is registered under the Drug Control Authority and contains any of the following substances specified in this part. The third part of the Schedule stated that all derivatives of psychotropic substances are also considered as psychotropic substances. This means that any chemicals or substances that are related structurally to psychotropic substances or results from the substances are included under this part. The schedules attached to the Act list the psychotropic substances are subject to restrictions.

2.1.1 Psychotropic Substances in Abuse

Illegal supply of psychotropic substances will leads to the diversion and drug abuse. Of course, drug abuse in itself is serious enough. Nobody would deny the great potential for harm in the misuse of chemicals for personal pleasure. In fact, the drug use in abuse and addiction is unpredictable and without any clear links to existing patterns of use. According to the Drug Information 2009 by the National Anti-Drug Agency of Malaysia, the highest use of psychotropic pills by drug addict particularly is in year of 2005. Table 1 is the table to show the drug addicts been used from 2005 to 2009.

TABLE 1: Total Of Drug Addicts According To The Drug Used From 2005 To 2009[6]

(Source: National Anti-Drug Agency)

YEAR	Heroin	Morphine	Candu	Canabis	Syabu	Tablets of ATS*	Psychotropic Pills	Others **
2005	13,914	8,047	20	5,044	3,832	777	752	422
	42.41%	24.53%	0.06%	15.37%	11.68%	2.34%	2.29%	1.29%
2006	7,963	5,889	7	5,275	2,411	454	621	191
	34.91%	25.82%	0.03%	23.12%	10.57%	1.99%	2.72%	0.84%
2007	4,752	4,312	14	3,385	1,235	255	442	94
	32.80%	29.76%	0.10%	23.36%	8.52%	1.76%	3.05%	0.65%
2008	4,974	3,640	9	1,726	1,443	344	145	71
	40.27%	29.47%	0.07%	13.97%	11.68%	2.78%	1.17%	0.57%
2009	5,047	3,386	5	5,207	1,131	167	39	754
	32.07%	21.52%	0.03%	33.09%	7.19%	1.06%	0.25%	4.80%

Note :

* ATS (ecstasy & amphetamine)

** Others (codein / cough mixture & inhalant)

As average, we can see the psychotropic substances used by drug addicts are at sixth of rank among all the drug abuse. While in 2005, the estimated numbers of opium users and heroin users were 8,047 to 13,914 respectively, the number of problem psychotropic substance users was estimated 752 users.[7] Even though the statistics on Table 1 shown that the number of users of psychotropic substances is decreasing but the number of seized pills is increasing with 3,286,427 pills.[8] From the data shows that the psychotropic pills are an alternatives drug for the drug addicts besides getting heroin, morphine, cannabis, ecstasy and amphetamine for their addiction. Psychotropic

[6] Agensi Antidadah Kebangsaan, "Maklumat Dadah 2009", 12. Retrieved 18 October 2010, from http://www.adk.gov.my/pdf/laporandadah/maklumat dadah2009.pdf.

[7] Ibid.

[8] Ibid.

substances not only been used as alternative drug but also to increase the effect of the drug.

The statistic data on importation of psychotropic substances data by PED shown that Malaysia's prominent psychotropic substances imported are benzodiazepines, groups of barbital and phentermine. Chart 1 is the chart showed the importation of psychotropic substances from year 2007 to 2009.

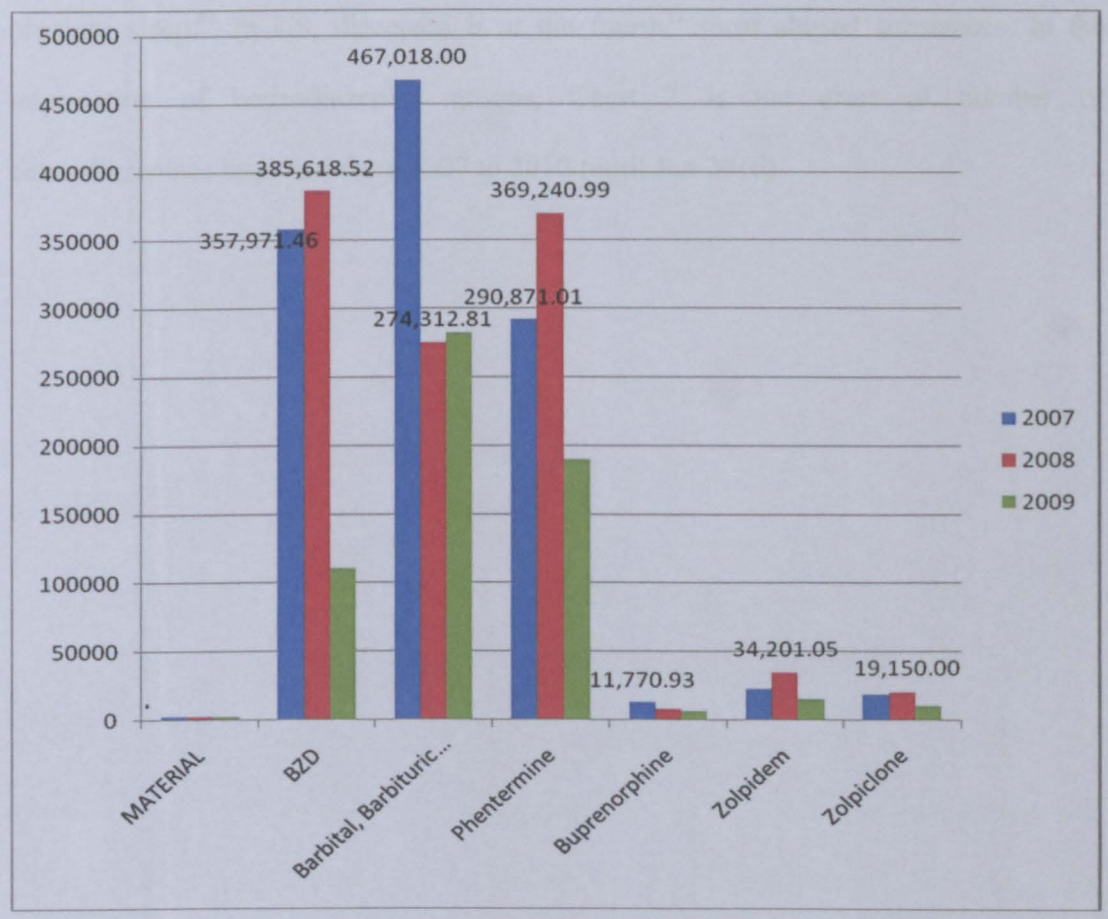


CHART 1: Importation of Psychotropic Substances from Year 2007 to 2009

(Source: Pharmaceutical Services Division)

The well-known psychotropic substances been illegally supplied by medical practitioner or diverted in Malaysia are barbiturate and benzodiazepine groups.[9] These drugs were treatments of choice for insomnia and anxiety are central nervous system depressants[10]. Based on the investigation cases done, the benzodiazepines groups of psychotropic substances are seem as well-known target in the private general practitioner market to be misuse by the motivated offender of medical practitioners. The concern benzodiazepine groups are especially midazolam and diazepam. Benzodiazepines are the group of drugs which are usually prescribed to relieve anxiety and stress or to promote sleep.[11] In US, diazepam is at the fourth[12] most abused substances. In the importation of benzodiazepine groups, Chart 2 is the chart of number of benzodiazepines imported from 2007 to 2010 (until Jun 2010).

[9] Interviewee 1, Deputy Director, Pharmaceutical Enforcement Department, Pharmaceutical Services Division, Ministry of Health Malaysia (Petaling Jaya, 14 October 2010).

[10] Harold Doweiko E. (1993). *Concepts of Chemical Dependency*. (2nd edition). United States, America: Wadsworth Inc., 48.

[11] Drug and Alcohol Services Control. (1995). *Benzodiazepines: Reasons to Stop*, 4. Retrieved 6 August 2010, from http://www.dassa.sa.gov.au/sites/page.cfm .

[12] Manchikanti Laxmaiah. (May 2007). National Drug Control Policy and Prescription Drug Abuse: Facts and Fallacies, *Pain Physician* 10, 400.

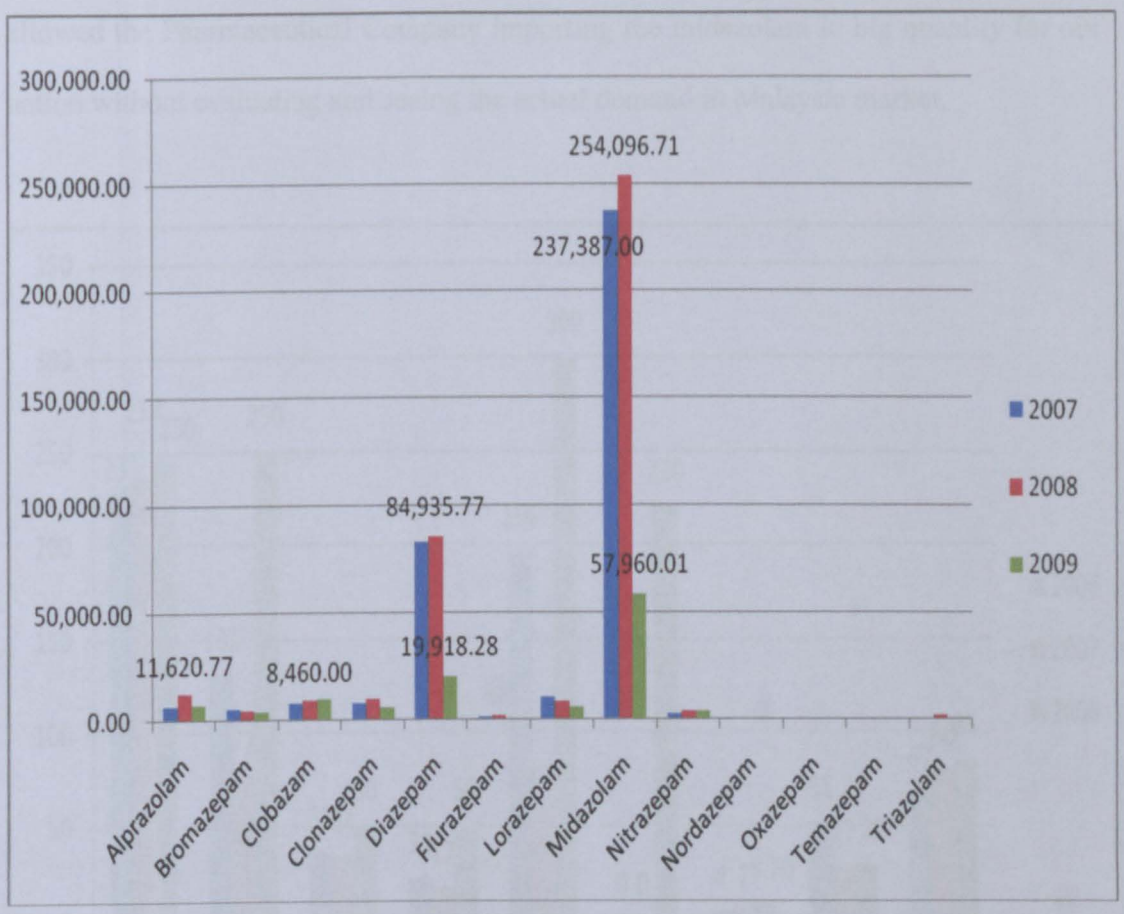


CHART 2: Number of Benzodiazepines Imported From 2007 to 2009

(Source: Pharmaceutical Services Division)

Together with data obtained from the International Narcotics Control Board (INCB) showed an increasing trend[13] of such usage of psychotropic substances in Malaysia and interview 1 reported that Malaysia had been the highest importation of midazolam[14] between other countries such as Indonesia, Japan, Thailand, India, Australia and UK. Chart 3 is the chart of number of midazolam imported for 2006, 2007 and 2008 according to the countries. Interview 1 is comparing the use of midazolam[15] with others country, Malaysia is the highest rate. Unrealizable until 2008, PED had consistently

[13] MOH Pharmaceutical Services Division. (2010). *Curbing The Diversion And Misuse of Psychotropic Substances And Controlled Medicines dated 29 April 2010.* Retrievd 29 July 2010, from http://www.pharmacy.gov.my/newsmaster.cfm?&menuid=134&action=view& retrieveid=210.

[14] Interviewee 1, above n 9.

[15] Ibid.

allowed the Pharmaceutical Company importing the midazolam in big quantity for our nation without evaluating and seeing the actual demand in Malaysia market.

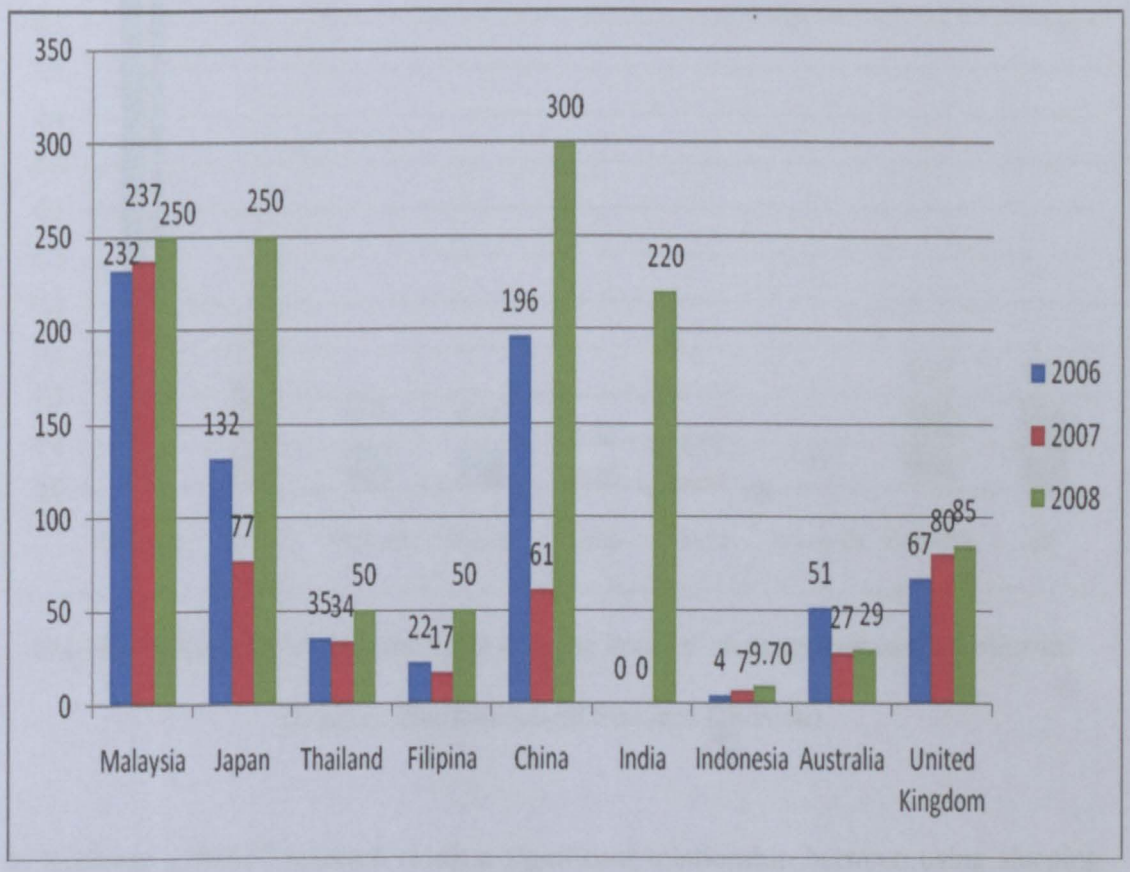


CHART 3: Number of Midazolam Imported for 2006, 2007 And 2008 according to the Countries

(Source: Pharmaceutical Services Division)

Malaysia let the culprit plays the game of crime so called the illegal supply freely and victory without a strict control. In addition, Chart 4 is the ratio of midazolam used with the population according to the countries. Indirectly, it looks Malaysian was full with mental problem specifically depress or anxiety people.

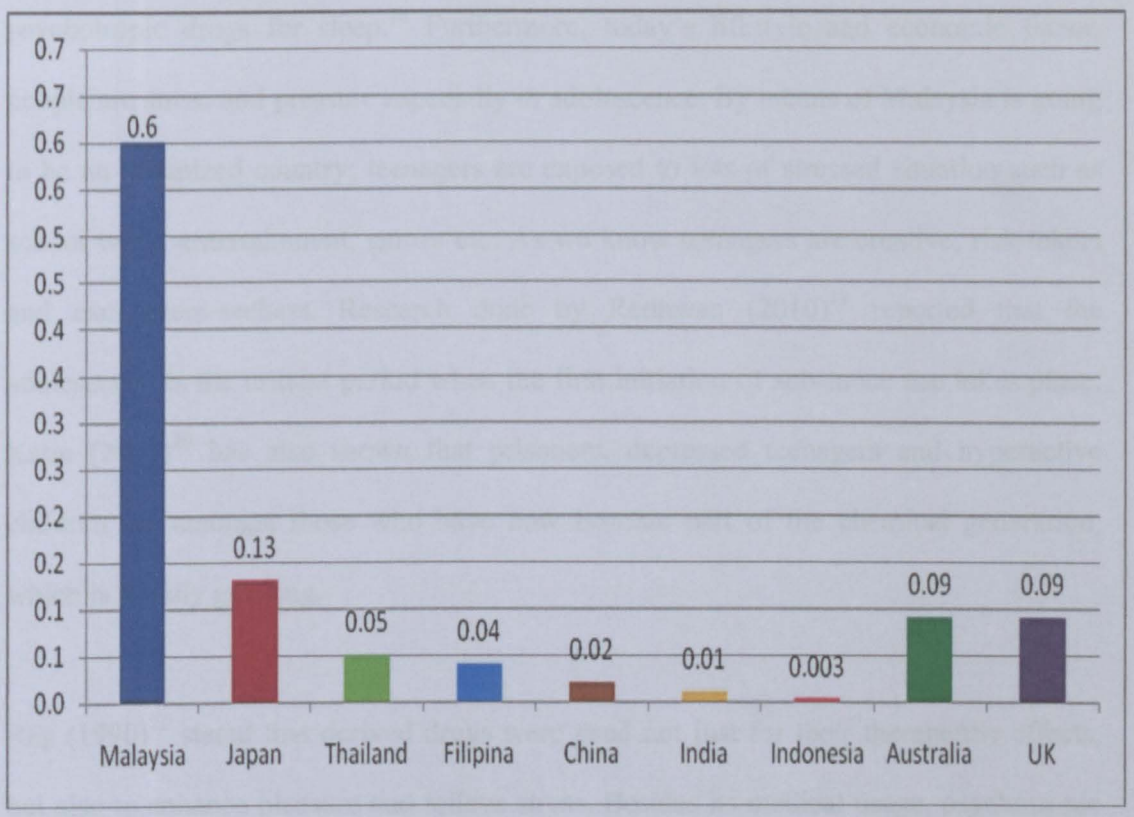


CHART 4: Ratio of Midazolam used with the Population according to the Countries

(Source: Pharmaceutical Services Division)

In Redhwan (2010)[16] research result a significant relationship between using sleeping pills and depression among university students and sleeping pills usage among university students is relatively high. A psychotropic substances use issue is sleeping purposes treatment so called insomnia. For example, a WHO collaborative survey of 25,916 primary care attendees found that 29% of those with sleeping problems had tried medications for sleep.[17] In the US, there are over the counter and prescription medications for sleep aid. Mellinger et al. (1985) reported that 3.1% of the adult population had used over the counter sleeping pills and 4.3% had taken prescribed

[16] Redhwan Ahmed Al-Naggar, Zaleha Mohd Isa & Ramli Musa. (2010). Prevalence and Associated Factors of Sleeping Pills Use Among Students in a Malaysia University. *ASEAN Journal of Psychiatry*, Vol 11, No. 2, 48.

[17] Silva JA, Costa E, Chase M, Sartorius N & Roth T. (1996). Special Report from A Symposium Held by the World Health Organization and the World Federation of Sleep Research Societies: An Overview of Insomnias and Related Disorders - Recognition, Epidemiology and Rational Management. *Sleep*, 19, 412–6.

psychotropic drugs for sleep.[18] Furthermore, today's lifestyle and economic factor, people are stress and pressure especially in adolescence. By means of Malaysia is going to be an urbanized country; teenagers are exposed to lots of stressed situation such as school work, entertainment, games etc. As we know teenagers are creative, risk-takers and excitement-seekers. Research done by Redhwan (2010)[19] reported that the adolescence is the critical period when the first initiation of substance use takes place. Katie (2008)[20] has also shown that prisoners, depressed teenagers and hyperactive children are amongst those who have now become part of the chemical generation, which is rapidly growing.

Ray (1990)[21] stated that derived drugs were used not just for their therapeutic effects, but also to enhance pleasure and relieve stress. Besides its medical usage, psychotropic substances are also used for treating drug dependency and its withdrawal symptoms and it is also known as Drug Substitution Therapy (DST) such as methadone. Aleksandra Bulka et al. (2002), in their research on the use of methadone as a replacement drug, found that the methadone had slower tolerance development than morphine[22] and has less addiction and tolerance effects than opiate[23]. With the side effects, the new drug of methadone became a target drug been abuse by the drug addict. Psychotropic substance affects the brain; therefore, it can change human mood, behavior and perception. The implementation of the DST program contributes such a serious problem to the enforcement on illegal supply of psychotropic substances.[24] Medical practitioner

---

[18]Mellinger GD, Balter MB & Uhlenhuth EH. (1985). Insomnia and Its Treatment, Prevalence and Correlates. *Arch Gen Psychiatry* 42, 225–32.

[19]Redhwan, above n 16.

[20]Katie Ware. (2008). The Chemical Generation: A Critical Analysis of Medical 'Expert' Discourse and the Construction of Mental Illness. *Internet Journal of Criminology*, 22.

[21]Ray O, Ksir C, et al. (eds). (1990). *Drugs, Society and Human Behaviour* (5th ed.). Times Mirror/Misby College Publishing, 6.

[22]Aleksandra Bulka, Aida Plesan, Xiao-Jun Xu & Zsuzsanna Wiesenfeld-Hallin. (2002). Reduced Tolerance To The Anti-Hyperalgesic Effect Of Methadone In Comparison To Morphine In A Rat Model Of Mononeuropathy. *PAIN* 95, 103-109.

[23]Editorial. (18 April 2004). Dadah: Tolak Cadangan YB, Ikut Syor Pakar Perubatan – Forum: Dr Wan Mohd. Rushidi Wan Mahmud. *Utusan Malaysia*.

[24]Interviewee 1, above n 9.

illegally supplied the methadone not for treatment purposes or treats the person not as his or her particular patient.[25]

Grinspoon and Bakalar (1985) they are use the benzodiazepine groups to reduce the experience of insomnia and anxiety and hostility of ecstasy and amphetamine[26] that their taken. Furthermore, reported that many individuals who abuse the amphetamines and cocaine will use depressants either to control some of the side effects of their stimulant use or to "come down" from the stimulants in order to sleep.[27] Typically, media illustrated the term of psychotropic substances as domi[28], stilnox, xanax[29], lexotan[30], inzolam[31], duromine[32], sleeping pills[33], anti-anxiety pills[34], dependence drug, misuse drug, controlled drug etc.

2.2 THE SUPPLY OF PSYCHOTROPIC SUBSTANCES BY MEDICAL PRACTITIONERS IN MALAYSIA

Medical practitioner is authorized in the supply of psychotropic substances in Malaysia. The supply of psychotropic substances is accordance any regulations under *Poison (Psychotropic Substances) Regulations* 1989 and Act under *Poisons Act* 1952. It considered an illegal supply when the medical practitioner breaks any regulations or Act under *Poisons Act* 1952. The misconduct or non compliance of medical practitioner leads to description of drug abuse and diversion.

---

[25] Interviewee 2, Senior Principle Assistant Director, Prosecution Unit, Pharmaceutical Enforcement Department, Pharmaceutical Services Division, Ministry of Health Malaysia (Petaling Jaya, 27 October 2010).
[26] Doweiko, above n 10, 73.
[27] Ibid, 67.
[28] Editorial. (13 May 2007). Doktor jual Pil Khayal. *Kosmo*.
[29] Editorial. (20 July 2007). Doktor Mata Duitan. *Harian Metro*.
[30] Ibid.
[31] Ibid.
[32] Editorial. (30 May 2007). Clinic busted, 52 types of pills seized. *Borneo Post*.
[33] Redhwan, above n 16.
[34] Info Sihat. Isu Penyalahgunaan Dadah. (2010). Retrieved 3 November 2010, from http://www.infosihat.gov.my/penyakit/Remaja/PENYALAHGUNAAN DADAH.pdf.

2.2.1 Supply of Psychotropic Substances by Medical Practitioner

According to the laws, the "registered medical practitioner" means any person who is registered as such under the *Medical Act* 1971 [*Act 50*][35] and who holds a valid practicing certificate[36].

"Supply" includes the supply of commercial samples and dispensed medicines, but does not include the direct administration by or under the immediate personal supervision of a registered medical practitioner or registered dentist of a poison or medicine to his patient in the course of treatment where such administration is authorized.[37] Medical practitioner supplies the psychotropic substances through clinic assistant is an offence.[38] Supply not for medical treatment and to not his or her particular patient is an illegal supply of psychotropic substances.[39]

Under section 19 of *Poisons Act* 1952, the medical practitioner must supply the drug or substance for the purpose of medical treatment and his patient only. The sale or supply of the poison also, under the section 23(1)(c) of the Act, must in the form of dispensed medicine and prescribed by the medical practitioner. Where "dispensed medicine" means a medicine supplied by a registered medical practitioner, registered dentist or veterinary surgeon under and in accordance with section 19 or supplied, for the purpose of the medical, dental or animal treatment, of a particular individual by a licensed pharmacist on the premises specified in his license.[40]

[35] Poison Act 1952 [Act 366], s2 and Private Healthcare Facilities and Services Act 1998 [Act 586], s2.
[36] *Private Healthcare Facilities and Services Act* 1998 [Act 586], s2.
[37] *Poison Act* 1952, s2.
[38] Interviewee 4, Senior Principle Assistant Director, Prosecution Unit, Pharmaceutical Services Division, Jabatan Kesihatan Wilayah Persekutuan Kuala Lumpur and Putrajaya (Kuala Lumpur, 2 November 2010).
[39] Ibid.
[40] See above n 35.

Here, the medical practitioner shall meet the patient and follow routine procedure[41] i.e. acting in accordance with a particular art, as stated by McNair J in the *Bolam*[42] case. Then, doctor should take the standard of duty of care before any incident occurred in supplying of any type of poison especially psychotropic substances. In US, there are many studies done on non-medical use of psychotherapeutic drugs where it shows an illegal supply of psychotropic substances by supplier includes medical practitioner. The type of illicit drugs used in past year among persons aged 12 or older from 1995 to 2005 increased for non-medical use of psychotherapeutic drugs.[43]

Those are authorized are allowed in supply the psychotropic substances such as the pharmacist, medical practitioner, dentist and veterinary. One of the examples is controlling the supply of the psychotropic substances by medical practitioner to their patient. Under regulation 11(1)(a) of *Poisons (Psychotropic Substances) Regulations 1989*, registered medical practitioner is allowed to supply psychotropic substances for the purposes of the medical treatment to his patient only. In 2007 to 2009 PED statistics[44], significant proof shows that 75 to 100% offences on illegal supply of psychotropic substances are done by the medical practitioners. Therefore, the PED faced a very challenging task to control the supply of psychotropic substances by medical practitioner. The enforcement problem is in the investigation on the medical practitioner supplies the psychotropic substances for medical purposes whether to the really sick patient or not where we can say such as drug addicts. PED also difficult to ensure the medical practitioner is treating their patient professionally in duty of care or

[41] Anisah Che Ngah. (7 February 2006). The Medical Profession on Trial: A case comment. Retrieved 21 July 2010, from http://www.malaysianbar.org.my/tort_personal_injury_or_death/themedical_profession_on_trial_a_case_com ment.html.

[42] *Bolam v Friern Hospital Management Committee* (1975) 1 WLR 582.

[43] Rockville, MD. (2006). *Results from the 2005 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-30, DHHS Publication No. SMA 06-4194). Substance Abuse and Mental Health Services Administration. Retrieved 21 September 2010, from www.oas.samhsa.gov/ nsduh/2k5nsduh/2k5Results.pdf.

[44] Statistic Unit, Pharmaceutical Services Division, Ministry of Health, update by 14 September 2010.

for profit-making. The medical practitioners continuously violate the provided laws with smart and professional way of conduct as a perpetrator.

2.2.2 Provision on illegal supply of psychotropic substances by medical practitioner

According to the Regulation 3 of the *Poisons (Psychotropic Substances) Regulations* 1989, registered medical practitioners are allowed to possess or handle psychotropic substances for medical purposes provided they have to follow strictly to the *Poisons (Psychotropic Substances) Regulations* 1989. It is illegal supply, if the medical practitioner is not registered or the authorized in the possession of psychotropic substances. Under Regulation 11, the registered medical practitioners are allowed to sale or supply the psychotropic substances for medical treatment of his patient only. It is illegal if the practitioner supplied or sold not for medical treatment or not for his patient. In the mechanism of supply, the practitioner must go through the method of administer, prescribing, maintain register, storage of the substances, disposal of the substances, labeling and make order if the substances has finish. Considered as illegal supply if the medical practitioner not prescribed as a requirement of prescription under Regulation 11(2). In emergency cases, the illegal supply happened where the psychotropic substances supplied without a prescription more than one day (Regulation 11(6)(b)). The prescription must be kept for a period at least two years (Regulation 11(7)).

The medical practitioner against the Regulation 16 if the administer not for the purpose of medical treatment of a particular patient. In a way to administer or supply, under Regulation 19, the medical practitioner must keep and maintain register called as "Prescription Register For Psychotropic Substance" on the day supplied according to

the stated requirement. Regulation 22 stated that the record must register the quantity supply or sale and total stock in possession. Under Regulation 23 stated that the register must in a bound book or in other form which has the written approval of the Licensing Officer. Apart of illegal supply by medical practitioner, the storage of the psychotropic substances in the room, cabinet, safe or receptacle without locks (Regulation 24(1)). It is strictly which the lock and unlocked only by the authorized person to possess the psychotropic substances and the key must be kept by the medical practitioner (Regulation 24(2)). Regulation 24(3) stated that the store must be constructed with reasonable security measures to prevent theft or diversion.

For some reason, disposal of the psychotropic substances will be a part of illegal supply. Under Regulation 25, any disposal must be in the presence and instruction of the Drug Enforcement Officer. In supply the psychotropic substance, the container of psychotropic substances must have the name of the substance (Regulation 26(1)(a)) and the word "Poison" in red printed (Regulation 26(1)(b)). The container of psychotropic substances supplied also must with stated labeling requirement under Regulation 28. According to the Regulation 12(2)(b)(ii), every medical practitioners required to submit the quantity and frequency of the psychotropic substances in written (so called 'written attestation') based on their patient decalaration to make their order.

In some condition, for the purpose of obtaining any psychotropic substances, the medical practitioner willing to make any false particulars such as register (Regulation 36(b)), document (Regulation 36(c)) and declaration or statement (Regulation 36(e)).

Hence, the illegal supply means the medical practitioners were not comply with the available provisions. Government realized that the misusage of psychotropic substances

is one of the major contributory factors towards street crimes and need to be curbed. The misusage involved the drug users, medical practitioner or doctor and drug company which is supplier in the chain. The drug users always obtain the excessive quantities of psychotropic substances by inducing the practitioners. They may also found, from one clinic to another to get the supply. Their target clinics were practitioners who known for supplying the substances on demand or without adhering to the existing laws.[45]

2.3 THE NATURE OF ILLEGAL SUPPLY OF PSYCHOTROPIC SUBSTANCES BY MEDICAL PRACTITIONER

Article published on page 2 of the Borneo Post on 30 May 2007 under the heading of "Clinic busted, 52 types of pills seized"[46] stated that the clinic suspected to have been supplying the pills to the black market and estimated value of the seized pills was approximately RM1.3 million. Evans and Sullivan[47] study have shown that 50% of the patients seen in emergency rooms are either direct or indirectly because of chemical abuse. Interview 1[48] reported that there are greedy medical practitioners either prone to supplies the psychotropic substances as a drug of choice or purposely for profit making. In Kosmo on 23 January 2008, reports raised an issue that the doctor sold 'pil khayal' where the complaint, surveillance and investigation found that the drug addict had bought the psychotropic substances without consulting their doctor, just through the unqualified clinic's assistant.[49]

---

[45] Dzafarullah Daud & Salimin Adnan. (2004). Control of Psychotropic Substances in Malaysia: Balancing the Demand and Supply. Unpublished report, Pharmaceutical Services Division.
[46] Editorial, above n 32.
[47] Evans, K. & Sullivan, J.M. (1990). *Dual Diagnosis*. New York: The Guilford Press.
[48] Interviewee 1, above n 9.
[49] Editorial. (23 January 2008). Doktor 'Pil Khayal. *Kosmo*.

Before I further, I would like to describe based on the rational choice theory by the Cornish and Ronald (1987)[50] and PED experience through interview session that there are three types perspective of medical practitioner. First, medical practitioner totally avoid to illegal supply. The medical practitioner will screen and examine the patient thoroughly, then prescribed and dispensed the appropriate treatment and medication to the patient. Second, the medical practitioners who are unrealized that he or she treated inappropriately. The medical practitioner doesn't aware on the control of the psychotropic substances, they thought the patients is in emergency condition, they thought the practice is legal, others medical practitioner did the same, they misunderstanding with the information about handling of the psychotropic substances likes claimed that the speaker in Methadone Therapy Program taught that and so on. Third, medical practitioner is really a trafficker. The monetary gain or profit-making[51] is their solely motive for their involvement. They purposely supply the psychotropic substances without or improper treatment, supply over the counter through their clinic assistants, mixing the psychotropic substances with other drugs to increase the 'high' effect (compounding), make the fraud records, false documentation, false declarations, false patient cards, prescribe and dispense excessive amounts (overprescribe), stock in psychotropic substances with huge amounts assume likes doing wholesaler (over storage), supply to the pusher or middle-man besides a patients and so on. The three perspectives is mainly are their professional practice or attitude and update knowledge.

Through auditing experience, PED found that there are medical practitioner without or improper treatment (doctor shopping), overprescribe, makes compounding, improper records, improper storage, improper labeling and makes false documentation or

[50] Cornish Derek B & Ronald V. Clarke (eds.). (1987). *The Reasoning Cnminal: Rational Choice Perspectives on Offending* (New York: Springer-Verlag, 1986); Understanding Crime Displacement: An Application of Rational Choice Theory, 25 *Criminology*, 933.

[51] Wesson, DR and Smith DE. (May1990). Prescription Drug Abuse-Patient, Physician and Cultural Responsibilities, In Addiction Medicine and the Primary Care Physician [Special issue], *West J Med*, 613.

declaration. The nature of the illegal supply will be identified through related criminology theory.

2.3.1 Improper Treatment (Doctor shopping)

Physicians who are dispense prescription without a thorough examination or screening being a target to the persons practicing doctor shopping[52]. Hence, doctor shopping scenario shown that the medical practitioners treat patient inappropriately and away of patient care. It has been reported that individuals may collect thousands of pills during a one-year period and sell on the street.[53] According to Lawrence Cohen and Marcus Felson (1979)[54], presence of suitable target and motivated offender increases the likelihood that a predatory crime will take place.

In Malaysia, there are some medical practitioner treats the patient not according to the standard protocol or guideline given. Interviewee 1 stated that the medical practitioner simply prescribed without screening the patient thoroughly and supplied the drug unethically.[55] He also added with specialist statement which said that it is normally happened to the medical practitioners who aim for profit gain[56] only. He[57] also stated that survey done in government clinics surrounding Wilayah Persekutuan Kuala Lumpur found that medical practitioner in government clinics were done legitimately where only use antihistamine, instead of midazolam unless the patient come again and still not cured[58]. Hence, the practice of some private general practitioner is absolute

---

[52] Kraman P. 'Drug Abuse in America – Prescription Drug Diversion' (April 2004) The Council of State Governments. Retrieved 15 October 2010, from www.csg.org.
[53] Ibid.
[54] Cohen Lawrence and Marcus Felson. (1979). Social Change and Crime Rate Trends: A Routine Activities Approach. *American Sociological Review* 44, 588-608.
[55] Interviewee 1, above n 9.
[56] Ibid.
[57] Ibid.
[58] Ibid.

disjunction and illegitimately. The practice of medical practitioner in private clinic is difficult to detect by PED unless there are public or negative auditing reports.

Philips (1953)[59] stated that the doctor must have a certain readiness in his treatment likes frequent visits and be especially careful in his examinations, countering things in which he has been deceived by changing phases of the illness. Hence, the use of midazolam for insomnia treatment is actually not the only drug of choice. Since, the interviewee 1 stated that there are others choice of drug[60] in treating insomnia which is antihistamine group with no tolerance and dependence side effects. Moreover, Dzafarullah (2004)[61] reported with the existing laws, a medical practitioner enjoys a great degree of professional freedom and discretion to determine the choice of psychotropic substances to be prescribed to their patients. Malaysia PENGASIH Society's president, Mohd. Yunus Pathi reported in newspaper on 18 September 2010,[62] patient must undergo for urine test screening before bought methadone to make sure illegal drug use. Unluckily the private clinic purposely skips the urine test screening for profit[63] gain only. Even, some private clinic asks to buy dormicum pills before buying the substitution drug, methadone.[64] Most horrible, the medical practitioner sells the methadone and dormicum pills to the young youths who are not involved to the drug abuse yet. They just do it for profit-making[65]. In rationality is tells the medical practitioner had assess the risks and the benefits before he engage to the criminal conduct.

---

[59] Philips ED. (Jun 1953). Doctor and Patient in Classical Greece. *Greece & Rome*, Vol. 22, No. 65, 74.
[60] Interviewee 1, above n 9.
[61] Dzafarullah, above n 45.
[62] Ku Mohd. Ridzuan Ku Abdul Rahman. (18 September 2010). Beli Dormicum Baru Dapat Metadon. *Kosmo.*
[63] Ibid.
[64] Ibid.
[65] Ibid.

The medical practitioner rationalized the criminal act as a good act. Do not see it as 'bad' because they thought their deed is significant for their families, friends, other business growth and contributing to the country economy. They will think the further examine is not their responsibility. As in the rational choice theory by the Cornish and Ronald (1987)[66] argued that the decision to commit an offense is negatively related to the perceived costs of crime and positively related to the perceived rewards of crime. Perceived risk of punishment may deter some potential and active criminal offenders but only if they doubt that they can make a "big score" from committing a crime.[67]

There are neutralization theory introduced by Sykes and Matza in 1957[68] where a condition of the unscrupulous medical practitioner will 'drift' from illegitimate to legitimate lifestyles such as "It wasn't my fault", "I thought can", "I don't know the restricted amount", "They are the one who coming to meet him" and "They are in need of my help, what was I going to do?". As a medical practitioner should not make unsubstantiated assumptions about the patient's condition[69] where before diagnosing; he must conduct an adequate anamnesis. This entails a thorough physical examination of the patient.[70] Efforts should be made to elicit candor from the patient, though if a patient's response to questions are inaccurate, the physician who assumes them to be true in the absence of any contraindications is not negligent.[71]

In tackling the illegal supply to doctor shopping, the test buy by the agent provocateur have been done by PED. The medical practitioner hold up the doctor shopping by sells and supply through clinic assistant[72] over the counter. However, the successful raids is

---

[66] Cornish, above n 50, 933.
[67] Alex Piquero & George Rengert. (1995). Studying Deterrence with Active Residential Burglars. *Justice Quarterly* 16, 451-462.
[68] Sykes G and Matza, D. (1957). Techniques of Neutralization: A Theory of Delinquency. *American Sociological Review* 22, 664-670.
[69] *Barnett v. Chelsea & Kensington Hospital Management Committee* [1969] 1 Q.B. 428.
[70] Wood v Thurston. (25 May 1951). *The Times*.
[71] *Leadbetter v Brand* (1980) 107 D.L.R (3d) 252.
[72] Interviewee 4, above n 38.

depend to the successful of test buy by the appointed agent provocateur (AP). On the 25th April 2007 paper reported that PED had conducted an operation throughout the country and one of the successfully raid is at a clinic in Rompin, Pahang supplied Suboxone and Dormicum to the AP over the counter. Clearly, the sale and supply the psychotropic substance is not for medical treatment purposes which proof the doctor shopping situation. Then, PED had seized 900 pills of Dormicum and others psychotropic substances from the clinic.[73]

High demand of psychotropic substances by drug addicts has created a profitable business especially to private clinics. According to Cohen and Felson (1979)[74] stated that presence of suitable targets and motivated offender will contribute to crime. In this case, the suitable targets could be the availability of drug addicts[75] who in need the psychotropic substances, the availability of middle-man or drug pusher who offered the medical practitioner with high profit and makes them as accomplice[76], the availability of socialized people likes adolescence and teenagers and any patient who are in pain or with mental health problem may also be their target. Psychotropic substances from legitimate sources are heavily sought for the reasons that they are guaranteed in terms of safety, quality and efficacy. Furthermore, the cost of obtaining the substances from clinics is far less compared to the cost from illegal sources. According to Felson, there are always impulsive, motivated offenders who are willing to take the chance, if conditions are right, of committing crime for profit. The motivated offender is a person who is motivated enough to commit a crime[77]. Here, the motivated offender is the unscrupulous medical practitioner who would like to earn more and more money.

---

[73] Editorial. (25 April 2007). Dadah 'Power. *Harian Metro*.
[74] Cohen, above n 54.
[75]Interviewee 3, Senior Principle Assistant Director, Licensing Section, Pharmaceutical Enforcement Department, Pharmaceutical Services Division, Ministry of Health Malaysia (Petaling Jaya, 5 October 2010).
[76] Interviewee 2, above n 25.
[77]Ronald Akers L. & Christine S. Sellers. (2004). *Criminological Theories: Introduction, Evaluation, and Applications*, 33.

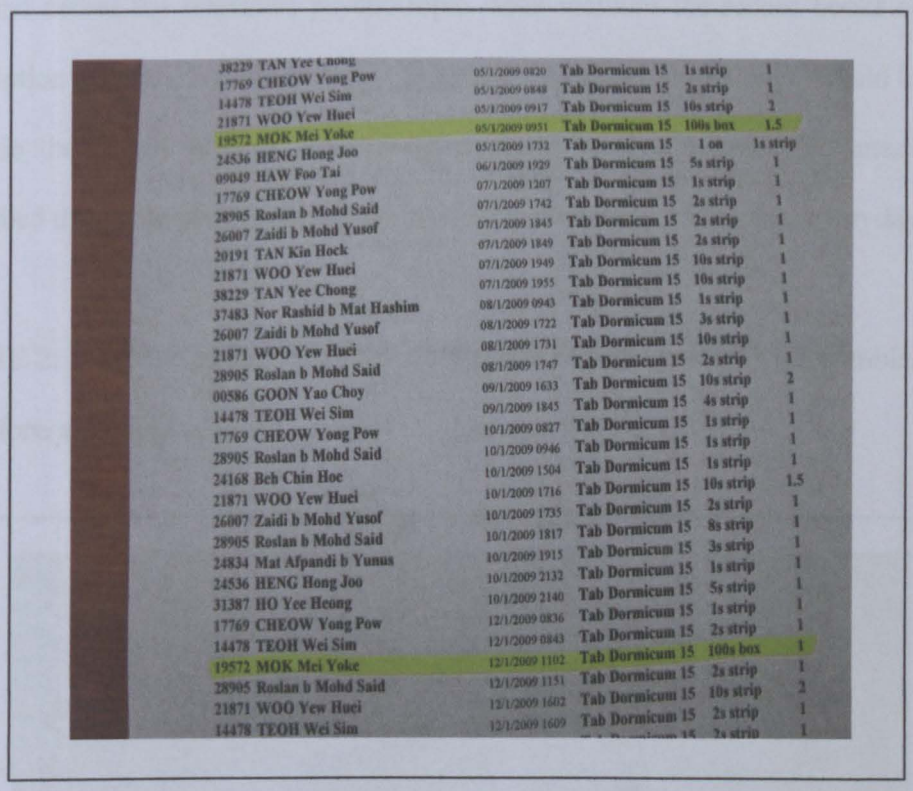
2.3.2 Overprescribe

The illegal supply illustrated clearly through the implementation of Methadone Therapy Program, the issues regarding the supply and handling of the methadone in private clinics is still in crucial. Interviewee 1[78] mentioned that through auditing, the most private general practitioner (GP) are prescribing midazolam 2 to 6 tablets daily for minimum of 3 months. He quoted that according to specialist in private hospital[79], the midazolam is not advisable to take daily because tolerance will develop after 2 weeks and it is a great offence and unethical to prescribe midazolam to those patients who are on opiate agonist treatment because this practice will worsen the condition of the patient more than the addiction to heroin and can led to death. He further quoted the specialist in Psychiatric Department of Hospital Kuala Lumpur[80] reported that midazolam has no role in treatment of addiction and did suggest that midazolam not be prescribed in the outpatient clinics especially by private general practitioner (GP).

Through the PED auditing also, the supply record (figure 1) showed the patient received treatment for 150 tablets for 1 week. The treatment and supplied of the medical practitioner (GP) is extremely suspiciously and unethically. It is really shown that the medical practitioner supplied with the motive of profit-making and ignored the patient care. Neutralized medical practitioner would say that "He doesn't know the restricted amount" or "I thought I can supply with that amount" and so on. Perhaps there are loopholes in the legislation.

[78] Interviewee 1, above n 9.
[79] Ibid.
[80] Ibid.

FIGURE 1: Prescription Register for Psychotropic Substance Overprescribed and Supplied



38229	TAN Yee Chong	05/1/2009 0820	Tab Dormicum 15	1s strip	1
17769	CHEOW Yong Pow	05/1/2009 0848	Tab Dormicum 15	2s strip	1
14478	TEOH Wei Sim	05/1/2009 0917	Tab Dormicum 15	10s strip	2
21871	WOO Yew Huei	05/1/2009 0951	Tab Dormicum 15	100s box	1.5
19572	MOK Mei Yoke	05/1/2009 1732	Tab Dormicum 15	1 on	1s strip
24536	HENG Hong Joo	06/1/2009 1929	Tab Dormicum 15	5s strip	1
09049	HAW Foo Tai	07/1/2009 1207	Tab Dormicum 15	1s strip	1
17769	CHEOW Yong Pow	07/1/2009 1742	Tab Dormicum 15	2s strip	1
28905	Roslan b Mohd Said	07/1/2009 1845	Tab Dormicum 15	2s strip	1
26007	Zaidi b Mohd Yusof	07/1/2009 1849	Tab Dormicum 15	2s strip	1
20191	TAN Kin Hock	07/1/2009 1949	Tab Dormicum 15	10s strip	1
21871	WOO Yew Huei	07/1/2009 1955	Tab Dormicum 15	10s strip	1
38229	TAN Yee Chong	08/1/2009 0943	Tab Dormicum 15	1s strip	1
37483	Nor Rashid b Mat Hashim	08/1/2009 1722	Tab Dormicum 15	3s strip	1
26007	Zaidi b Mohd Yusof	08/1/2009 1731	Tab Dormicum 15	10s strip	1
21871	WOO Yew Huei	08/1/2009 1747	Tab Dormicum 15	2s strip	1
28905	Roslan b Mohd Said	09/1/2009 1633	Tab Dormicum 15	10s strip	2
00586	GOON Yao Choy	09/1/2009 1845	Tab Dormicum 15	4s strip	1
14478	TEOH Wei Sim	10/1/2009 0827	Tab Dormicum 15	1s strip	1
17769	CHEOW Yong Pow	10/1/2009 0946	Tab Dormicum 15	1s strip	1
28905	Roslan b Mohd Said	10/1/2009 1504	Tab Dormicum 15	1s strip	1
24168	Beh Chin Hoe	10/1/2009 1716	Tab Dormicum 15	10s strip	1.5
21871	WOO Yew Huei	10/1/2009 1735	Tab Dormicum 15	2s strip	1
26007	Zaidi b Mohd Yusof	10/1/2009 1817	Tab Dormicum 15	8s strip	1
28905	Roslan b Mohd Said	10/1/2009 1915	Tab Dormicum 15	3s strip	1
24834	Mat Afpandi b Yunus	10/1/2009 2132	Tab Dormicum 15	1s strip	1
24536	HENG Hong Joo	10/1/2009 2140	Tab Dormicum 15	5s strip	1
31387	HO Yee Heong	12/1/2009 0836	Tab Dormicum 15	1s strip	1
17769	CHEOW Yong Pow	12/1/2009 0843	Tab Dormicum 15	2s strip	1
14478	TEOH Wei Sim	12/1/2009 1102	Tab Dormicum 15	100s box	1
19572	MOK Mei Yoke	12/1/2009 1151	Tab Dormicum 15	2s strip	1
28905	Roslan b Mohd Said	12/1/2009 1602	Tab Dormicum 15	10s strip	2
21871	WOO Yew Huei	12/1/2009 1609	Tab Dormicum 15	2s strip	1
14478	TEOH Wei Sim				

2.3.3 Makes Compounding

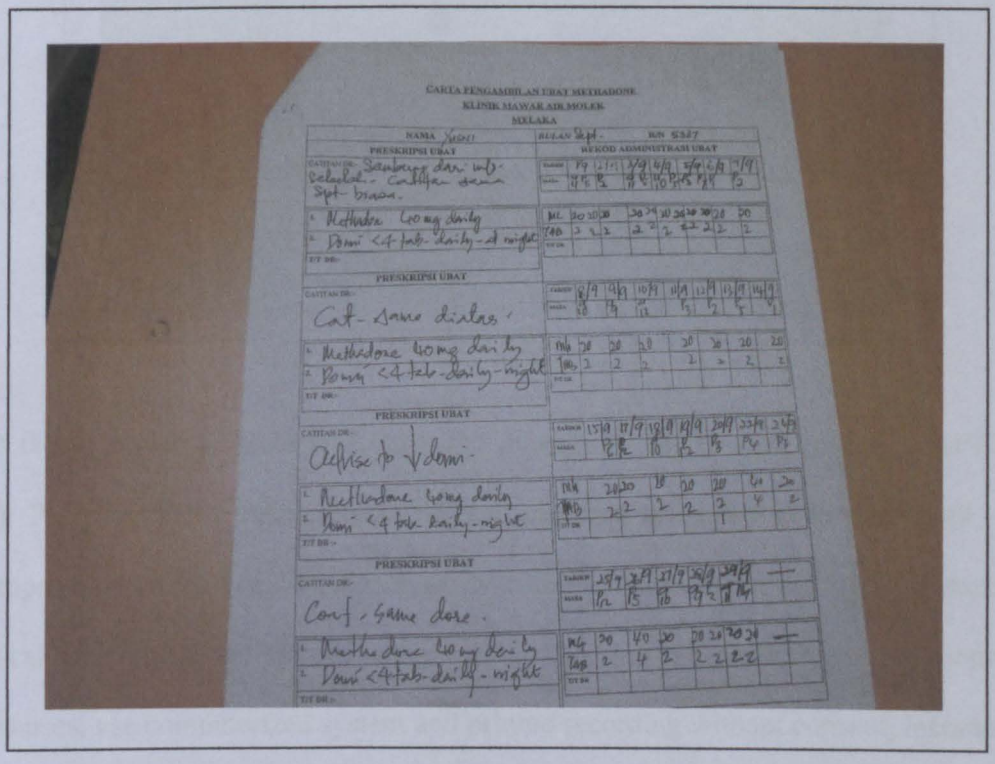
According to the interviewee 4[81], it is common the private general practitioner makes a compounding. But psychotropic substances, the medical practitioners are not allowed to make any compounding unless for administer to their patient. So, the preparation of mixing between methadone and antihistamine is an offence under regulation 17 of *Poison (Psychotropic Substances) Regulations* 1989. The medical practitioner will claimed that "he doesn't know that cannot", "others medical practitioner do the same" and "I prepared earlier, easy to administer when the patient arrives" and so on.

[81] Interviewee 4, above n 38.

2.3.4 Improper Record Books

PED had seized the relevance psychotropic stock includes the record books so called Prescription Register for Psychotropic Substance. Medical practitioner should keep and maintain the supply records. Records in figure 2 showed that medical practitioners prescribed their patient with combination of methadone and midazolam everyday.

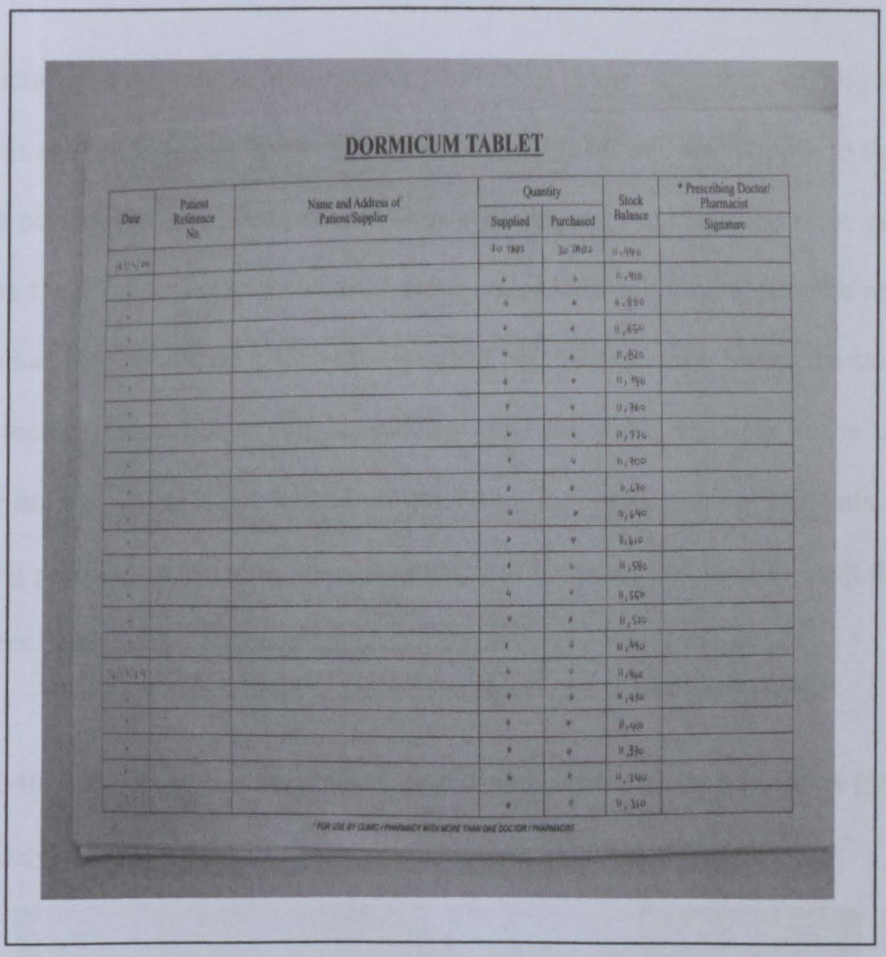
FIGURE 2: Prescription Register for Psychotropic Substance shows the combination of methadone and midazolam



Other cases, PED found the record book is pre-recording (figure 3). This situation show that the medical practitioner sales of midazolam are rampant and for profit gain only[82].

[82] Interviewee 1, above n 9.

FIGURE 3: Prescription Register for Psychotropic Substance Pre-recording



DORMICUM TABLET

Date	Patient Reference No.	Name and Address of Patient/Supplier	Quantity		Stock Balance	* Prescribing Doctor/ Pharmacist
			Supplied	Purchased		Signature
			30 TABS	30 TABS	11,990	
			0	0	11,910	
			0	0	11,890	
			0	0	11,650	
			0	0	11,820	
			0	0	11,790	
			0	0	11,760	
			0	0	11,730	
			0	0	11,700	
			0	0	11,670	
			0	0	11,640	
			0	0	11,610	
			0	0	11,580	
			0	0	11,550	
			0	0	11,520	
			0	0	11,490	
			0	0	11,460	
			0	0	11,430	
			0	0	11,400	
			0	0	11,370	
			0	0	11,340	
			0	0	11,310	

* FOR USE BY CLINIC / PHARMACY WITH MORE THAN ONE DOCTOR / PHARMACIST

PED faced lots of problem with improper records by the private general practitioner (GP). Perhaps PED's enforcement still not adequate and need to be improved. The improper records includes unbalance of psychotropic substances in stock and records, medical practitioner not records every supplied, makes pre-recording of psychotropic substances, use computerized system and printed recording without consent, incomplete information such as patient's name, quantity receive, quantity supplied and supplier's name in Prescription Register for Psychotropic Substance and incomplete information in patient's card such as patient's particular information and diagnosis in particular date of treatment.

2.3.5 Improper Storage

The unscrupulous medical practitioner will buy huge amounts of psychotropic substances and stock in one room. They too busy with the sell and supply to the doctor shopping patient so called drug addict, they will forget to manage the store especially make sure the room or cabinet so called store under lock and key. Under the regulation 24(2) the key also should be kept by the medical practitioner only. Since, the store is too big, the medical practitioner will inclined to keep the small amounts in the improper locker or drawer which is not locked. In other condition, too much of amounts, the will have a big problem in keeping the psychotropic substances and tend to keep the drugs with others item (Figure 4(a) and 4(b)).

FIGURE 4(a): Psychotropic Substances stored with other non-poison items (not under lock and key)

FIGURE 4(b): Psychotropic Substances stored with other non-poison items (not under lock and key)

2.3.6 Improper Labeling

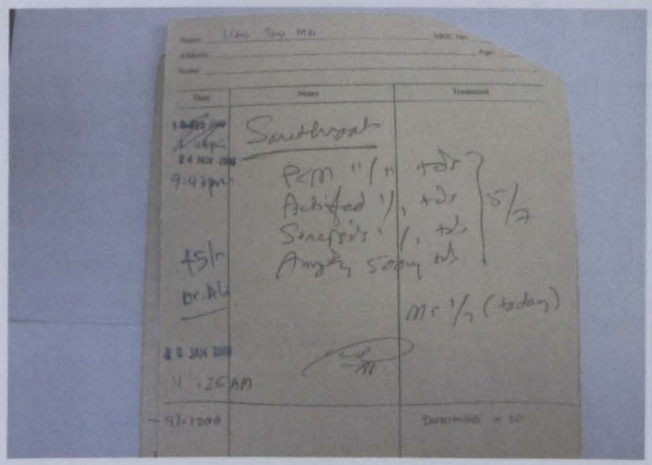
Starting 2010, according to the interviewee 3[83], PED inclined to charge the illegal supply of psychotropic substances by medical practitioner to the labeling offences under regulation 28 *Poison (Psychotropic Substances) Regulations* 1989. This offence is a clear provision where in need of labeling requirement for purposes of medical treatment. The unscrupulous medical practitioners are not aware of the labeling requirement and function because they not examine and diagnose the patient entirely.

[83] Interviewee 3, above n 75.

2.3.7 False Documentation or Declaration

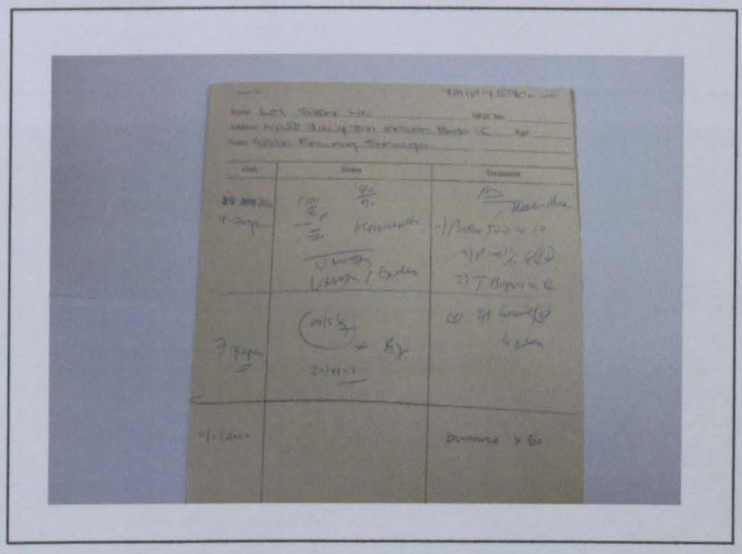
In auditing, Interviewee 1 stated that patient card written by clinic's assistant. He added that the clinic's assistant wrote it purposely[84] to balance the psychotropic substances in stock. Figure 5(a) and 5(b) shows the patient cards with different hand-writing of "Duromine x 60" to balance the phentermine in stock. Furthermore, the patient cards are without diagnosis and proof of treatment been given where no such of complaint stated for the particular date. In the case of *PP v Ng Lung Heam* (2003), Dr Wan Mazlan B Wan Rushdi[85] in the trial statement, usually patient card should written patient complaints, result of physical examines, any plan of action and listing the treatment/medication given. He also highlighted in his statement, clinic assistant[86] only can assist the medical practitioner but not take over the practitioner's job.

FIGURE 5(a): Patient Cards with different Hand-Writing of "Duromine x 60"



[84] Ibid.
[85] *PP v Ng Lung Heam* (2003) unreported, Kuala Lumpur Magistrate Court, 60.
[86] Ibid, 61.

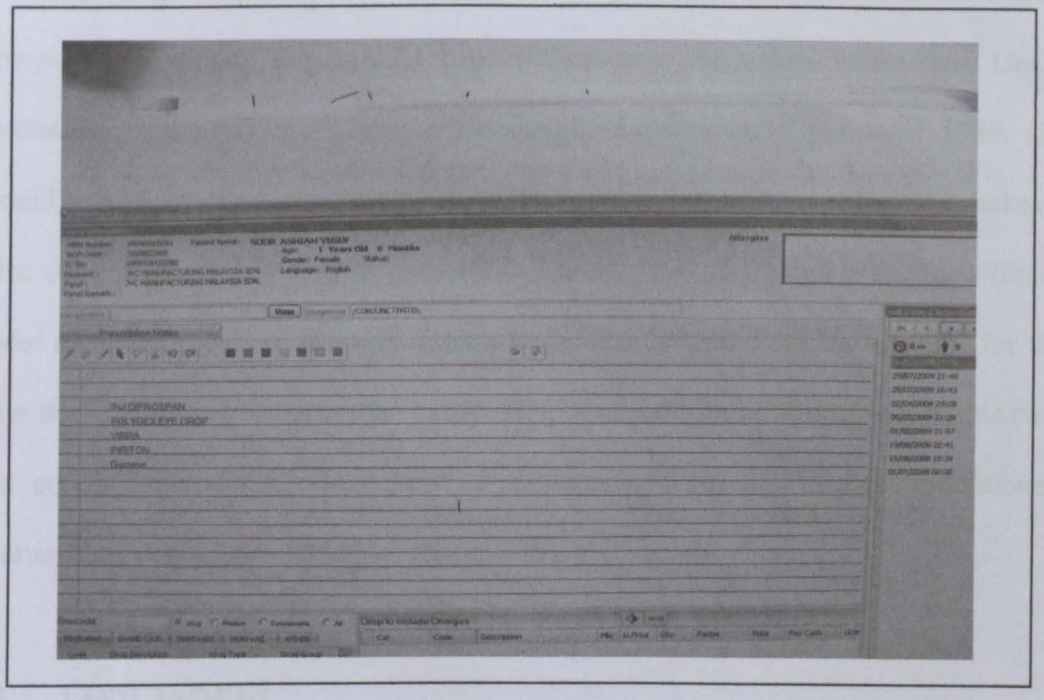
FIGURE 5(b): Patient Cards with different Hand-Writing of "Duromine x 60"



He confirmed[87] that the patient cards (figure 6) wrote by clinic's assistant purposely to balancing the psychotropic substances in stock where they wrote on the infant or baby's card. The clinic's assistant just did it without unrealized it the patient card is owned by infant or children 1 year old. Interviewee 1[88] said that practices really unlawful and a sort of abuse. Dzafarullah[89] stated that the unlawful practices include supply not for medical treatment, failure to maintain records and not having proper storage leads to inconsistent prescribing, willful mis-prescribing for abuse and self prescribing.

[87] Ibid.
[88] Ibid.
[89] Dzafarullah, above n 45.

FIGURE 6: Patient Cards stated supplied "Duromin" to patient age children below 2 years (1 year and 6 months)



The minimal requirements of information that should be recorded – the date of each consultation and any prescribed drug treatment.[90] It is a nature of general practice that there will be occasional lapses even in these minimal requirements, but a consistent pattern of failure to record these fundamentals is highly suggestive of a low standard of medical care.

There are many innovative motivated offender as mentioned by Merton (1938)[91] where the medical practitioner accept the dominant goals to achieve wealth, reject the legitimate means and pursue illegitimate means. The medical practitioner willingly to create the false documentation or declared wrongly. For example, in the case of PP v *Dr Ina Harlina Bt Mohd Ali & Nor Aida Bt Kamarudin* (2008) where the case pharmacy enforcement officer audited and found that the clinics doesn't stocked any suspicious

[90] Charles Lewis J. (1995). *Medical Negligence: A Practical Guide* (3rd ed.). Great Britain: Tolley, 96.
[91] Merton R. (1938). Social Structure and Anomie. *American Sociological Review*, Vol 3, 676.

amount of psychotropic substances because according to medical practitioner's statement and confession that the substances actually is bought for the 'middle-man'. She only keeps documents of invoice which purchase from the Pharmaceutical Company but sold to the 'middle-man' without any documents transaction. Under regulation 12(2)(b)(ii) of *Poisons (Psychotropic Substances) Regulations* 1989, she should submit a written attestation before she could purchase but confess she makes a false declaration on the written attestation. Hence, PED charged her for the offence under regulation 36(e) of *Poisons (Psychotropic Substances) Regulations* 1989 for the false declaration and statement her made. PED find a difficulty to investigate this case and collecting evidence where need a corporation from the medical practitioner, pharmaceutical company and other related party.

2.4 CONCLUSION

Based on the above discussion, there is no doubt that the abuse and illegal supply of psychotropic substances by medical practitioner does exist. There is various nature of illegal supply of psychotropic substances by medical practitioner. The medical practitioner is an important source in supply of psychotropic substances which need to be control. In this chapter, we can see that the government needs to monitor meticulously and strengthen the control of illegal supply of psychotropic substances by medical practitioner either loophole on the laws or the method of the enforcement.

The enforcement of current degree of illegal supply of psychotropic substances by medical practitioner is thought to be sufficient. Therefore, the study is very important to determine the weaknesses in the control of psychotropic substances. The next chapter will discuss on the current system and method in enforcement of psychotropic

substances by PED. Further discuss on the investigation and prosecution cases in emerging the issue and challenges.

CHAPTER THREE

PHARMACEUTICAL ENFORCEMENT DEPARTMENT ON THE ILLEGAL SUPPLY OF PSYCHOTROPIC SUBSTANCES BY MEDICAL PRACTITIONER

3.0 INTRODUCTION

This chapter will study on the current method applied by PED in combating the psychotropic substances abuse and diversion. The method applied on the current PED activities such as through the quota control, auditing, investigation and prosecution on illegal supply of psychotropic substances by medical practitioner cases. Discussion will be based on the statistics collected by Statistic Department of Pharmaceutical Services related to illegal supply of psychotropic substances by medical practitioner taken through the interview sessions.

3.1 CURRENT STRATEGY OR APPROACH ENFORCEMENT ON ILLEGAL SUPPLY OF PSYCHOTROPIC SUBSTANCES BY MEDICAL PRACTITIONER

Pharmaceutical Enforcement Department (PED) is a part of the law enforcement. As law enforcement, PED is a part of the criminal justice system besides the courts and corrections agency. In criminal justice, the system of practices and institutions of governments directed to upholding social control, deterring and mitigating crime, and sanctioning those who violate laws with criminal penalties and rehabilitation efforts.

PED are empowered on the *Poison Act* 1952 and *Poison (Psychotropic Substances) Regulations* 1989 which have been regulated in enforcing the psychotropic substances.

Enforcement of laws has a major impact to the society. Every strategies or systems taken by the enforcement affected to the nations. Kishore[92] reported that there are two issues in the enforcement of public law. The first is whether the system of inspections and penalties set by the regulator is effective. The second is whether a better system of inspections and penalties can be designed, given the institutional constraints under which the regulator must function.[93] So, it depends to the enforcement agency to use the better approach or strategies in curbing the specific crime. In curbing this problem, PED have taken various approach since 2004 either administrative approach or technical approach.

3.1.1 Administrative Approach

The Pharmaceutical Enforcement Department (PED), Ministry of Health PED controls the licensed seller and supplier which are registered pharmacists. PED also controls the medical practitioners, dentists and veterinary who are dealing with the psychotropic substances. Due to the role, PED control from the point of the importation until the supply of the psychotropic substances to the particular patient or animal.

Arnie (2007)[94] stated that the weaknesses of the enforcement strategy and system are the main factors contributing to the abuse of psychotropic substances in private clinics. Since 1990, constrain of man power due to PED control the psychotropic substances as reactive approach. In 2005, PED transform to proactive approach where put the focal

[92] Kishore Gawande & Alok K. Bohara. *Agency Problems in Law Enforcement: Theory and Application to the US Coast Guard.* Retrieved 21 July 2010, from www.mansci.journal.informs.org/.
[93] Ibid.
[94] Arnie, above n 2, pg. 71.

point controls the psychotropic substances to curb the abuse and diversion such as established the quota system[95], recruited written attestation[96] and upscale the auditing monitoring method[97].

i) Quota System

PED is the main enforcement agency control the importation of the psychotropic substances. The importer is a person who is authorized to import the psychotropic substances in Malaysia by Licensing Officer. Every year the pharmaceutical companies have to submit the application of quantity of psychotropic substances sales to PED whereby the enforcement strongly urged the manufacturers, importers and main distributors to be responsible for the control of supply and sale of these preparations.[98] Although the PED monitored the supply and distribution of psychotropic substances and put the maximum limit or approved quota on their application but yet they exceed the limit.

PED control the quota of importation of psychotropic substances to the importer. Statistics showed it became greater demand by supplier year by year. Any reasonable suspicion on importation and purchasing of psychotropic substances, PED will scrutinize and identify the matter.

In 2009, PED starting had restricted the importing quantity of midazolam from 254,096g to 57,960g and diazepam from 84,935g to 19,918g.[99] Consequence of it,

---

[95] Interviewee 1, above n 9.
[96] Ibid.
[97] Interviewee 3, above n 75.
[98] Pharmaceutical Services Division. *Press Statement by Director General of Health, Ministry of Health of Malaysia on Abuse in Supply of Psychotropic Substances dated 23 April 2008*. Retrieved 12 August 2010, from www.pharmacy.gov.my.
[99] Ibid.

interviewee 4 reported this situation has created a 'panic situation'[100] in the public sector whereby there are no such problem or alleviated supply in private sector. PED knew that is a Pharmaceutical Company's tactic for increase their restricted quota. In US, an evaluation of prescription drug monitoring programs performed on 1 September 2006 showed that Prescription Drug Monitoring Programs (PDMP)s manage to reduce the per capita supply of prescription pain relievers and stimulants and in so doing reduce the probability of abuse of these drugs.[101]

3.1.2 Technical Approach

i) Scheduled Auditing

The supply of psychotropic involved of the drug users, medical practitioner and Pharmaceutical Company which need to have constant guard and strict control to avoid the diversion and abuses. Even though, PED empowered with absolute powers and laws, there is a clear that is not enough if they don't have effective and comprehensive method. Hence, besides the statutory, PED with a view that in order to make sure the control on illegal supply of psychotropic substances is efficient and effective is through proper and firm controlling the supply and distribution of psychotropic substances until the end user.[102]

In 2005, PED circulated to product holder about the obligation[103] to appoint appointed wholesaler for marketed their psychotropic's product. This requirement is purposely to

---

[100] Interviewee 4, above n 38.
[101] Manchikanti, above n 12, 408.
[102] Interviewee 1, above n 9.
[103] Official Letter by Pharmaceutical Services Division with Reference No.dlmKKM-55/203/001/04Bhg3(43) date 30 November 2005.

control of selling, supplying and distribution of the psychotropic substances through the appointed wholesaler by the product holder.

From the Annual Report 2008, they have done two steps of approach whereby through "A-MORE" and "Hands-on" approach. The approaches are as below;

a. "A-MORE" Approach[104]

The implementation of the diversion audit activities where combined together with monitoring and research elements. Increase the monitoring of registered products such as dangerous drugs (methadone), psychotropic substances (buprenorphine, benzodiazepines, dihydrocodiene and zolpidem) and controlled medicine (dextromethorphan and pseudophedrine).

b. "Hands-on" Approach[105]

This approach is through the implementation of a Prescription Drug Diversion course. The objective of this course is to give exposure for the enforcement officers of the latest approaches to overcome the problems arising from the prescriptions drugs diversions. Hence, the importation data showed that midazolam is the serious of psychotropic substances used in Malaysia. Interviewee 1 reported that PED found the top 20 clinic usage of psychotropic substances is in Klang Valley area.[106] Chart 5 below showed the comparison usage of midazolam between investigated clinics.

[104] Pharmaceutical Services Division. (2008). *Annual Report Pharmaceutical Services Division, Ministry of Health Malaysia*, 2008, 28.
[105] Ibid.
[106] Interviewee 1, above n 9.

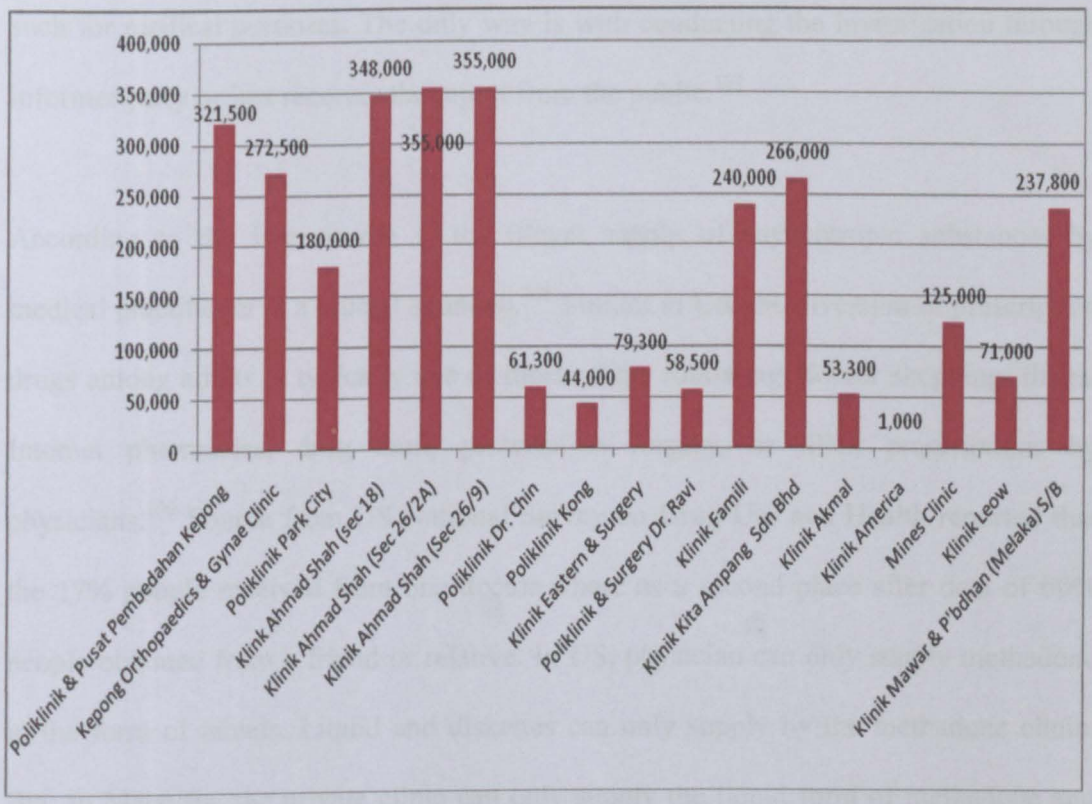


CHART 5: Comparison usage of Midazolam between investigated clinics

(Source: Pharmaceutical Services Division)

According to the system, PED are checking routinely and closely monitoring the practice and procedure of the wholesaler and retailer of pharmacy but selectively for the private clinic. Private clinics are selected randomly, based on the follow up purposes or for the case of higher purchasing of psychotropic substances. This situation happened because the number of private clinic is more than the capacity of PED's officers. The cooperation of medical practitioners also is a problematic factor to PED in performs their duty. With the selective method, showed the control is quite loose.

In term of enforcement, the problem is in the investigation on medical practitioner whether they are provides the treatment to their patient either ethically and professionally or profit-making. Law enforcement really needs deliberated investigation

to prove this offence. Since, medical practitioner is authorized to supply any poison as such for medical purposes. The only way is with conducting the investigation through informer party or just receives the report from the public.[107]

According to the interviewee 1, the illegal supply of psychotropic substances by medical practitioner is a crucial situation.[108] Similar in US, the diversion of prescription drugs among adults is typically one or more of the following: doctor shopping, illegal Internet pharmacies, drug theft, prescription forgery, or illicit prescriptions by physicians.[109] Source from US National Survey on Drug Use and Health reported that the 17% people received from one doctor where as a second place after data of 60% people obtained from a friend or relative. In US, physician can only supply methadone in the form of tablets. Liquid and diskettes can only supply by the methadone clinic. But, in Malaysia, the private clinic can only supply the liquid form of methadone and tablet form is been banned in the market.[110]

ii) Written Attestation

As a step towards strengthening and making control more effective, the requirement of "written attestation" as provided in Regulation 12(2)(b) of the *Poisons (Psychotropic Substances) Regulations* 1989 for all psychotropic substances have been enforced to curb misuse and diversion.[111] With the proactive approach, in Feb 2006, interviewee 1[112] reported that PED circulated an official letter to inform every Pharmaceutical Company dealing with wholesale of psychotropic substances strictly have to followed the Written Attestation requirement. Current strategies, in 2009, PED have taken a

---

[107] Ibid.
[108] Ibid.
[109] Manchikanti, above n 12, 410.
[110] Interviewee 4, above n 38.
[111] Editorial, above n 98.
[112] Interviewee 1, above n 9.

tough stand in strengthening the provision on written attestation through officially circulating the official letter[113] to inform the Pharmaceutical Company (supplier) and Medical Practitioners the official standard format of the written attestation which have to be submitted by the supplier to PED.

In Malaysia, there are thirty-one (31) authorized companies[114] involved in the importation of psychotropic substances and applied for the quota from PED in 2010. From these importer companies, the psychotropic substances will be distributed to the wholesale or/and retail pharmacy and private clinics. In the supplying procedure of psychotropic substances, the distributor/importer of the psychotropic substances will ask for written attestation from the purchaser according to the directive format. Licensed retail pharmacist can supply or dispense the psychotropic substances if they receive prescription from the patient or customer. Registered medical practitioners are allowed to supply the substances after they treated the patient so called prescribing and dispensing power.

3.2 CURRENT OUTCOME OF THE ENFORCEMENT ON ILLEGAL SUPPLY OF PSYCHOTROPIC SUBSTANCES BY MEDICAL PRACTITIONER

Followed statistic data of audits, raids, investigates and prosecutes cases showed the status on illegal supply of psychotropic substances by medical practitioner in Malaysia.

[113] Official Letter by Pharmaceutical Services Division with Reference No.(12)dlmKKM-55/207/002/04Bhg date 30 December 2009.
[114] Interviewee 3, above n 75.

3.2.1 Number of clinic been audited

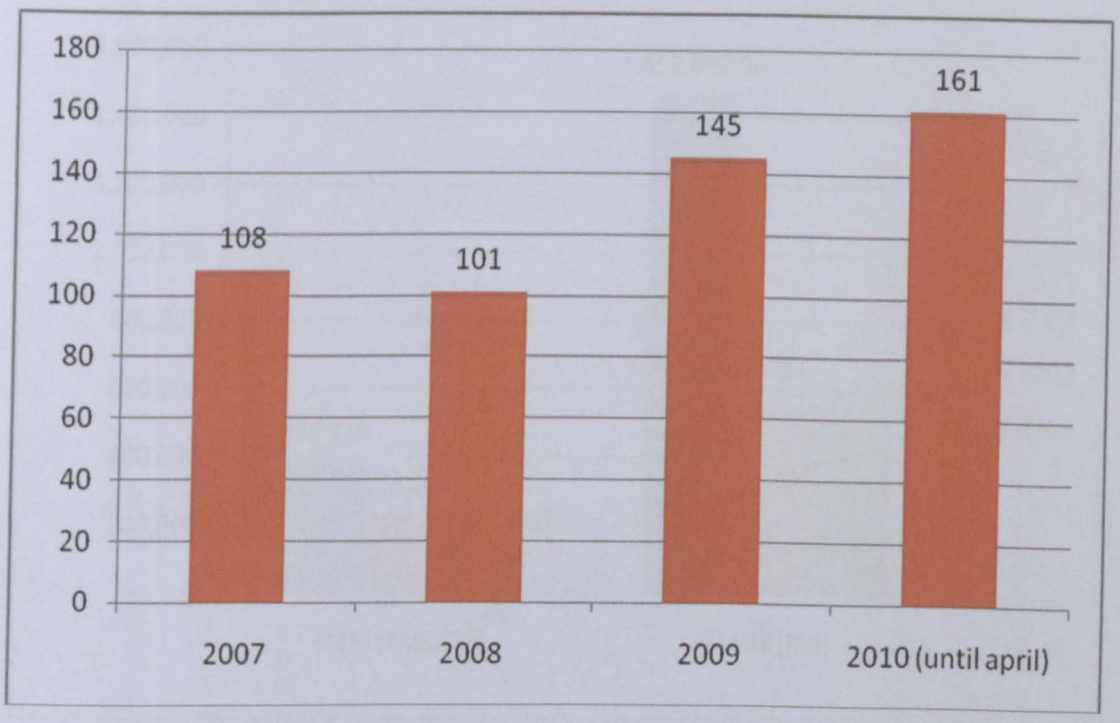


CHART 6: Number of clinics audited year 2007 to 2010 (until April)

The number of monitoring on clinics highest purchase of psychotropic substances is increased. This shows the PED slowly scaling-up their strategy and skill in reducing the non-compliances among medical practitioners. In 2007, the Diversion Control Unit under the Pharmaceutical Enforcement Department has started using A-MORE[115] approach where means monitor and research. Products like methadone, ketamine and dihydrocodeine which are scheduled as psychotropic substances since September 2006 has been monitored closely together with other controlled medicines.[116]

[115] Pharmaceutical Services Division. *Annual Report 2007*. Retrieved 5 October 2010, from www.pharmacy.gov.my.
[116] Ibid.

3.2.2 Number of Psychotropic Substance been seized

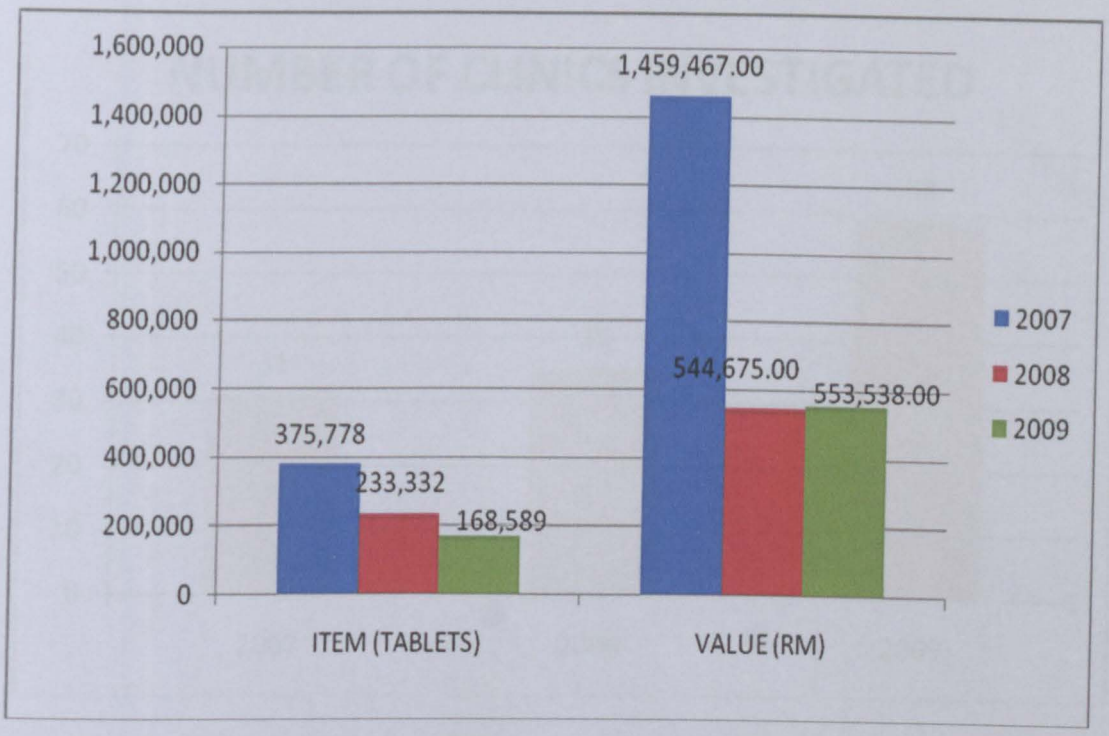


CHART 6: Number of psychotropic substances been seized year 2007 to 2009

From the chart, the seized and value numbers is decreasing. These are because PED are taking proactive approach and strengthen up their monitoring on target clinics.[117] Besides, the medical practitioners now are smarter and trying to protect their profession. Previous method of enforcement such as test-buy in the counter no more sufficient[118] because the medical practitioner knew there are PED's officer will try to buy. Therefore, PED needs to look this challenge with the new method.

There are medical practitioners smart where they not stock psychotropic substances in the clinic but at home or other places. This problem contributes to the weaknesses of PED in controlling the illegal supply of psychotropic substances.

[117] Interviewee 3, above n 75.
[118] Ibid.

3.2.3 Number of clinic been investigated and investigation cases

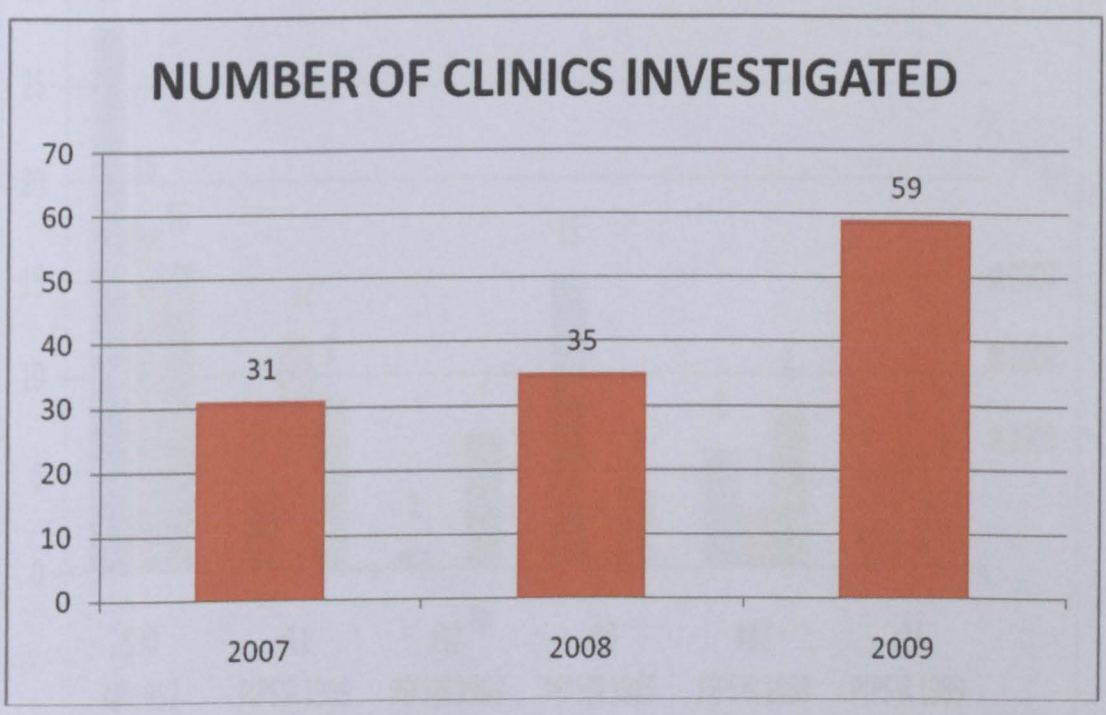


CHART 6: Number of clinics investigated year 2007 to 2009

According to the interviewee 3, data collected by Diversion Control Unit[119] showed that the number of clinics been investigated is increasing since 2004. The trend of offences is still the same likes previous years offences supplying over the counter (contravention to regulation 11), not maintaining records (contravention to regulation 22) and not keeping psychotropic substances under proper storage (contravention to regulation 24).[120] It shows like PED approach is still inadequate and need to be improved. Nowadays, the medical practitioners are smart and it really gives a challenge to enforcer to look into the new strategy and investigation method.[121]

[119] Ibid.
[120] Ibid.
[121] Ibid.

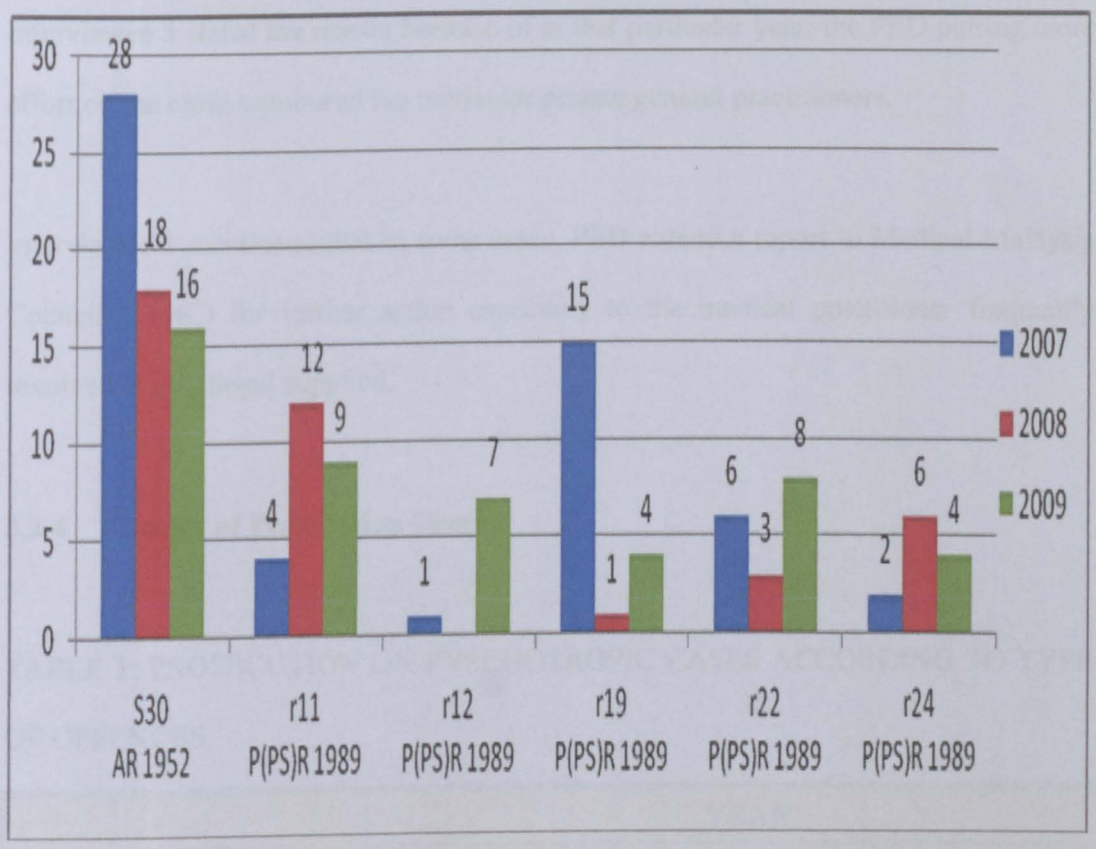


CHART 7: Number of investigation cases according offences year 2007 to 2009

Average, the investigation paper year 2007 to 2009, most of the offence is against the section 30 *Poisons Act* 1952 regarding the import, export, manufacture, compound, mix, dispense, sell, supply, administer, possess or use any psychotropic substances offence. In order, the offence on regulation 11 *Poison (Psychotropic Substances) Regulations* 1989 is at the second place.

So far, in whatever method that PED used, the illegal supply or non-compliance by the medical practitioner is still occurred. In 2008, 101 licensed premises that have been investigated, 35 or 35% were found associated with various offences under the *Poisons Act* 1952.[122] The increased of 6% than previous years where 29% premise is investigated, showed that there are growth of non-compliance medical practitioner.

[122] Pharmaceutical Services Division. *Annual Report 2008*. Retrieved 5 October 2010, from www.pharmacy.gov.my.

Interviewee 3 stated the reason because of at that particular year, the PED putting more effort on the close monitored the particular private general practitioners.

Interviewee 1 mentioned that in some cases, PED extend a report to Medical Malaysia Council (MMC) for further action especially to the medical practitioner frequently involved in the illegal supplied.

3.2.4 Number of Prosecution Cases

TABLE 1: PROSECUTION ON PYSCHOTROPIC CASES ACCORDING TO TYPE OF OFFENCES

NO.	TYPE OF OFFENCES	YEAR					
		2007		2008		2009	
		No	%	No	%	No	%
1	r11 P(PS)R 1989	6	15	4	7	6	14
2	r19 P(PS)R 1989	3	7	0	0	3	7
3	r22 P(PS)R 1989	6	15	14	25	6	14
4	r24 P(PS)R 1989	5	12	9	16	8	19
5	S 30(1) PA 1952	21	51	28	51	20	47
	Jumlah	**41**	**100**	**55**	**100**	**43**	**100**

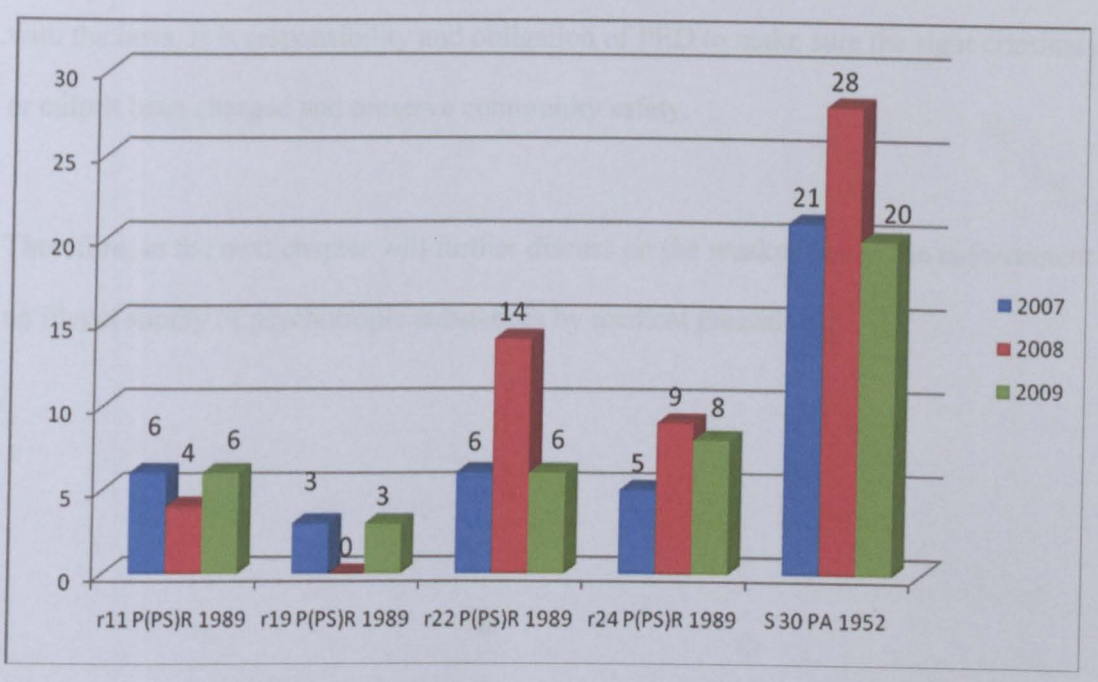


CHART 8: Number prosecution cases according offences for year 2007 to 2010(Jan-Jun)

In prosecution cases is means the investigation paper mentioned in court for year 2007 to 2009, the most cases is also section 30 *Poisons Act* 1952. The second offences turn to regulation 22 *Poison (Psychotropic Substances) Regulations* 1989, where the medical practitioner not maintain and keep their Prescription Register For Psychotropic Substance properly. Approximately, we can say that offences on regulation 11 *Poison (Psychotropic Substances) Regulations* 1989, at fourth place, respectively.

3.3 CONCLUSION

As a conclusion, there are medical practitioners violate the laws. Indeed, the enforcement on illegal supply of psychotropic substances by medical practitioner is still inadequate and need to be strengthening up. There are loophole and weaknesses that need to be identified and improved. Those loopholes and weaknesses need to be clear

out and go through deliberately to make sure the medical practitioner aware and comply with the laws. It is responsibility and obligation of PED to make sure the right criminals or culprit been charged and preserve community safety.

Therefore, in the next chapter will further discuss on the weaknesses in the enforcement on illegal supply of psychotropic substances by medical practitioner.

CHAPTER FOUR

WEAKNESSES IN PHARMACEUTICAL ENFORCEMENT DEPARTMENT ON ILLEGAL SUPPLY OF PSYCHOTROPIC SUBSTANCES BY MEDICAL PRACTITIONERS

4.0 INTRODUCTION

This chapter will discuss the weaknesses in the Pharmaceutical Enforcement Department on illegal supply of psychotropic substances by medical practitioner which as a contributing factors in the law enforcement. The weaknesses are determined based on the discussion done at previous chapter which about the nature of the illegal supply of psychotropic substances by medical practitioner and method taken by PED.

4.1 LACK OF CAPABLE GUARDIAN

According to Cohen and Felson on the routine activity theory, the medical practitioners supply the psychotropic substances without guardians are most likely to commit crimes where there is presence of criminal opportunities. There are opportunities for the motivated offender who is medical practitioner to violate the law. The practitioner can prescribed as what he thought is right or follow as what patients wants without anyone will stop or questioned on him or her decision. In US, skyrocketing drug use in 1980s created an excess of motivated offenders and rates of some crimes, such as robbery, increased dramatically. But, fallen crime rates in 1990s because a robust economy

decreased the pool of motivated offenders, and the growing number of police officers increased guardianship.[123]

Here, the guardian by the Pharmaceutical Enforcement Department (PED) officers is very important to make sure the medical practitioner obey the laws. There are several problems faced by PED including lack of resources and the migration of experienced senior officer to another department due to their promotion.[124] In 2008, the man power[125] of the whole Pharmaceutical Enforcement Department of Malaysia is 274 officers. Meanwhile, private clinic in Malaysia is 6,371 clinics in 2008[126]. Based on the capacity, PED critically hardly to control and monitor closely the supply of psychotropic substances in the private clinics. PED faced a tough time and situation to curb this kind of problem. Moreover, PED officers are not only combating this particular statute but also others statutes such crime in unregistered pharmaceutical product, medicinal advertisement against the laws, pharmaceutical product adulterated poison and so on.

There are medical practitioners with profit gain only. They never care about the patient care and proper treatment. They will do anything so called tactics to avoid detection by law enforcement on their dirty works such as putting paper cutting (figure 8(a) and 8(b)) in front of the door to show that they are decent practitioners.[127]

---

[123] Simha Landau and Daniel Fridman. (1987). The Seasonality of Violent Crime: The Case of Robbery and Homicide in Israel. *Journal of Research in Crime and Delinquency* 30, 468-478.
[124] Arnie, above n 2, 77.
[125] Annual Report, above n 104, 6.
[126] Ministry of Health, Malaysia. (2008). *Annual Report 2008*, 180.
[127] Interviewee 1, above n 9.

FIGURE 8(a): Advertisement in front doctor's door

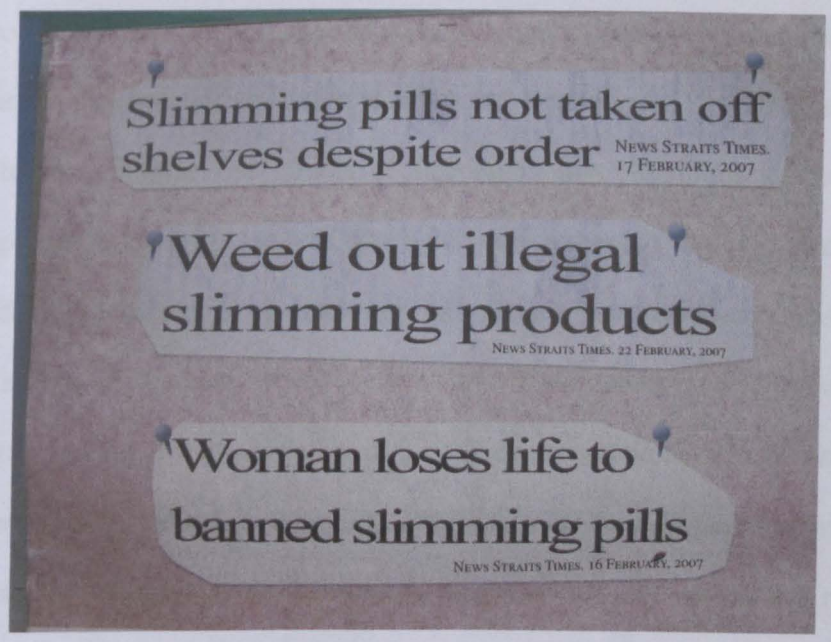
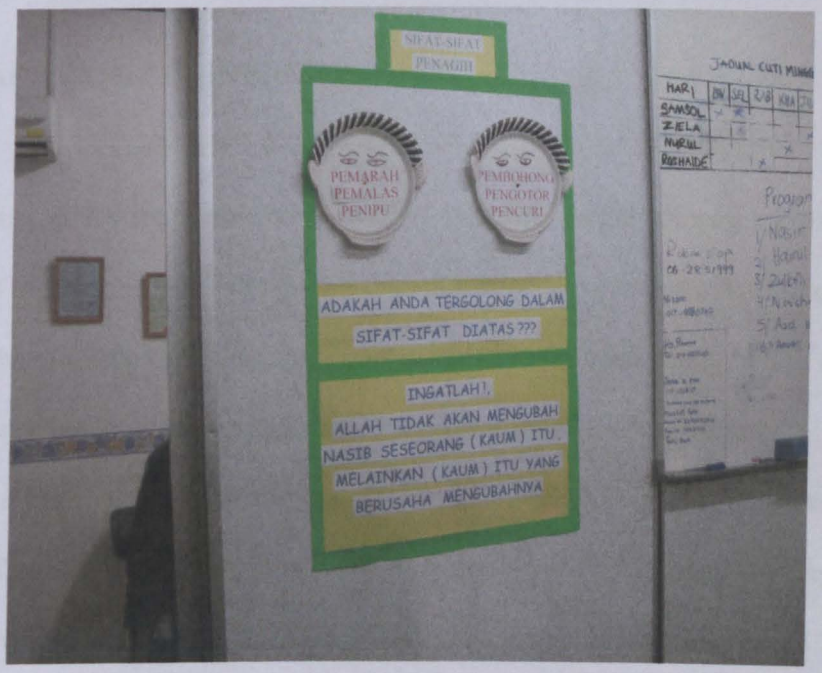


FIGURE 8(b): Advertisement in front doctor's door



Gallo (1998)[128] also agree with creation of audit programs and suggested that healthcare institutions should have created internal codes of conduct and hired compliance officers to monitor compliance with relevant statutes and regulations. Yet, the medical even daringly to makes false declaration or documentation pertaining to purchase the psychotropic substances. PED should take a prevention measure to avoid an opportunity to the medical practitioner to channel their patient care business to enterprise business so called as a profit-making. Many medical practitioner and people in general, view financial gain as one of the motivators in their lives. Everyone likes to feel appreciated and recognized for what they accomplish, and money is the most tangible proof of that appreciation and recognition. Some medical practitioners who choose this route often become more miserable than ever! They are more likely to think of patients as numbers or as potential litigants.

4.2 LACK OF DETERRENCE

The medical practitioner involved in this type of illegal supply of psychotropic substances might think their deeds is a common procedure and standard knowledge on what they have learned and does not know it is wrong. In other hand, before deciding to commit the crime, individuals must decide whether they have the perquisites to commit a successful criminal act including the proper skills, motives, needs and fears.[129] They do not realize also the consequence of his or her act will give negative impact to the country. Even though, some of the medical practitioner has been charged before but there are future offences by him or others medical practitioners.

---

[128] Gallo John N. (1998). Effective Law-Enforcement Techniques for Reducing Crime. *The Journal of Criminal Law and Criminology (1973-) Vol. 88, No. 4, Symposium: Why is Crime Decreasing?*. Summer, 1480.

[129] Siegel Larry J. (2006). *Criminology*. (9th ed.). Thomson Wadsworth, 93.

As a rational, person decides to risk violating the law after considering both personal factors such as for money, revenge and entertainment and also situational factors such as how well the target is protected and the efficiency of the local police force. One of the medical practitioner in PED's case owned a mercedez benz car, playing golf every week and frequently having an oversea trip where he stay in a luxury lifestyle. So, to accommodate his lifestyle, he had to make sure his enterprise crime is succeeded. This might be one of the personal factors that the criminal rationalized him or herself. Plus with the situational factors where psychotropic substances are not enough protected and enforced by the authority makes him or her proceed to commit the crime. Hence, the medical practitioner also becomes more attractive when he becomes convinced that it will result in excessive profits with few costs. Then makes the rational offender likes unscrupulous medical practitioner weighs the costs and benefits of a criminal act in deciding takes the course of action. The medical practitioners are desperate people who suffer from personality disorders that impair their judgment and render them incapable of making truly rational decisions. This theory showed that the deterrence effects from the statutory laws are not sufficient and not immediate effect to them.

In terms of greedy, some medical practitioners are immune to deterrent effects because they believe the profits from crime are worth than the risk of punishment; it may be their only significant chance for gain and profit. This situation will give the greedy medical practitioners an opportunity to break the laws.

4.2.1 Low Punishment

It is found that the penalty provided in the *Poisons Act* 1952 seems inadequate to deter the offender. In practice, the court normally imposes a low fine to the offenders. For example, in an unreported case in Pulau Pinang, the accused was charged under section 30 of the *Poisons Act* 1952 for supplying psychotropic substances not for medical treatment. [130] The accused who is a medical practitioner pleaded guilty to the charge and was fine only five hundred ringgit. In another case in Pulau Pinang, the medical practitioner who pleaded guilty as fined two thousand ringgit only for the three offences of supplying psychotropic substances not for medical treatment.[131] The penalties provided under section 30 of the *Poisons Act* 1952 are generally a fine and or imprisonment. Under this section, the magistrates however cannot exceed ten thousand ringgit or imprisonment of four years. Nowadays, the medical practitioners should be owed a higher liability towards their patients. Especially, to the unscrupulous medical practitioner who found as a drug trafficker should be treated differently with others non-compliances medical practitioners. The fine and imprisonment should be increased so that the punishment will serve as an example and threat to others, as a consequence of their crimes. The purpose of a deterrent punishment is to create a higher awareness among medical practitioners in exercising their duties and responsibilities relating to the act.

---

[130] *PP v Mohamed Amanullah bin Mohamed Ibrahim* (2007) unreported, Pulau Pinang Magistrate Court.
[131] *PP v Lau Hee Sim*, (2003) unreported, Georgetown, Penang Magistrate Court.

4.2.2 No Immediate Impact to the Medical Practitioner

In unreported case in Kuala Lumpur, *PP v Gernal Singh a/l Kundan Singh* (2004)[132], the medical practitioner were charged with two offences of supplying psychotropic substances not for medical treatment and improper storage. Even though, the case is proceed to the court but the medical practitioner is still allowed to supply the psychotropic substances before the case settled after six years. This extremely showed the inefficient on our legal system. As a result, some unscrupulous medical practitioners believe they will not be severely punished for their acts and consequently have little regard for the law's deterrent power.

In other unreported case in Kuala Lumpur, *PP v Teoh Boon Hooi* (2007)[133], the medical practitioner was charged with two offences of not maintaining records (contravention to regulation 22) and not keeping psychotropic substances under proper storage (contravention to regulation 24). This case is the second offences, where the medical practitioner still being in the highest purchaser of psychotropic substances and supply to the drug addicts under treatment. The medical practitioner knows the loophole of the law where the enforcement will hardly to convict him on supply the psychotropic substances for not medical treatment. Our surveillance officer couldn't make it to test buy through the counter anymore likes the first offences. But, until today the medical practitioner is still allowed to supply the psychotropic substances.

It is really looks not much of impact to the medical practitioner on what he or she previous strictly wrong deeds. The plan of power immediate action to the unscrupulous

---

[132] *PP v Gernal Singh a/l Kundan Singh* (2004) unreported, Kuala Lumpur Magistrate Court.
[133] *PP v Ng Lung Heam* (2003) unreported, Kuala Lumpur Magistrate Court.

medical practitioner should be made as examples suspend the particular practice maybe on the handling of psychotropic substances only for a purpose to create a deterrent punishment which lead them scale-up their duties and responsibilities in patient care.

This case uses an agent provocateur to test buying the psychotropic substances which is 10 tablets of midazolam over the counter through the clinic assistant. Prior to this case, there are 4 times test-buy been done by the same agent but in different dates to verified the public complaint.

4.3 LACK OF INFORMATION

The medical practitioner makes the false declaration and documentation contributes to the weaknesses in PED. PED control the supply and distribution through the provision where the medical practitioner need to send the written attestation but been manipulated. PED faced a hard time to get the information on the supply of psychotropic substances. PED have to instruct the pharmaceutical company submitting their supply reports and the written attestation. PED are dealing with human. Human beings are viewed as a rational actor. Based on the rationality, the decision making process is based on the weighing of the potential benefits and consequences of risk. So, if the risk of punishment is not deterred, the medical practitioner will proceed with the crime act or re-offend. They will manipulate the laws. The information regarding the supply and distribution of psychotropic substances is not immediate and might not the fact.

4.4 DIFFICULTY IN GETTING COOPERATION FROM MEDICAL PRACTITIONER

In raiding, sometimes PED takes almost one hour to meet the medical practitioner. While meeting, the medical practitioners will be giving very much excuses and reason such as "he is my regular patient and no need to examine thoroughly", "he is not my patient", "my clinic assistant supplied, not me", "I am having my lunch" and so on. Neutralization theory by Sykes and Matza explained that they are denial to their responsibility. Cooperation by medical practitioner is very difficult to get especially in raiding and investigation.

Sometimes, the medical practitioner stocked the psychotropic substances at their house. In the raiding and investigation, PED also do examine the house of the unscrupulous medical practitioner. Why the medical practitioners become innovative? According to the Strain Theory[134] by Merton, it is because the inability to achieve high social expectation may result in business organizations experiencing anomie or strain. Through the professional perspective, the strain mentioned is they want to get achievement or expectation with minimal effort. Nowadays, the private general practitioners are competing between each other. This situation will create strain and anomie. In worst situation, the medical practitioner are dealing with a middle-man or drug pusher, where this so called a trafficking.

[134] Merton, above n 91.

4.5 WEAKNESSES IN THE LAW

The laws to regulate psychotropic substances are sufficient to curb the problem pertaining to the illegal supply of psychotropic substances by medical practitioner. However, there seems to be a few weaknesses in the punishment and definition of term in the existing law.

The Prosecution Unit in the Headquarters of Pharmaceutical Enforcement Department has been in operation since March 2004. The Prosecution Unit is focused on any prosecution cases that can convict the accused charged with offences under the Pharmaceutical Services Division, Ministry of Health. This Unit is in charge of the prosecution of cases registered in court by the Department. It is also responsible for assigning prosecuting officers to cases referred by the State Pharmacy Enforcement Branches for trial purposes. There are increases of trial cases especially involving the medical practitioners, makes the State level are lack of skill and experience man power to prosecute the case.[135] There are many issue been issue out in the prosecution level but we know that the psychotropic substances been diverted[136].

In prosecution, there are no denials or no doubt of medical practitioners is supplying psychotropic substances for abuse.[137] It is really difficult to prove the medical practitioner "abuse" towards the patient because they are authorized.[138] The medical practitioners are the only authorized person to supply the psychotropic substances. PED have constrained for in proving the psychotropic substances illegal supply. Interviewee

[135] Interviewee 2, above n 25.
[136] Ibid.
[137] Ibid.
[138] Ibid.

2 reported that provision is not strong enough, PED go on accountability where in proving on how much they stocked and how much they supplied.[139] Addition to the report, for not medical treatment offences, PED cannot manage to the conviction and lead to choose to recording offences.[140]

4.5.1 No Standard Or Limitation in The Supply Of Psychotropic Substances Amounts

Excessive amounts in supplying the psychotropic substances will lead to drug abuse and diversion. The diversion means of the supply to the drug pusher or 'middle-man". There is no standard or limitation requirement in the supply of psychotropic substances by medical practitioner. The laws not stated any legitimate amounts can be supplied. So, the medical practitioner can stock any amounts that they want and can supply any amounts that they want. Restriction in limiting the purchasing and supplying of psychotropic substances is very vital to curb this problem.

4.5.2 Difficulty in proving "for medical treatment"

In addition, there is a lacuna in the law in which the definition of "medical treatment" is not defined clearly.[141] The *Poisons Act* 1952 defines "medical treatment" as the treatment of human ailments.[142] Due to this, it is difficult to prove the ingredients of the charge involving the medical treatment. For instance, in a recent case in Johor, there is an issue raised by the counsel in a cross examination to an expert witness pertaining to

---

[139] Ibid.
[140] Ibid.
[141] Arnie, above n 2, 71.
[142] See above n 37.

the definition of "medical treatment".[143] In this case, the accused who is a medical practitioner was a charged under the *Poisons Act* 1952 for selling psychotropic substances not for medical treatment. An expert witness testified that "medical treatment" means that the medical practitioner must see a patient, must ask for his complaint, must do diagnosis and must give prognosis or treatment. However, the counsel says that selling of psychotropic substances by the medical practitioner definitely refers as medical treatment, although the medical practitioner did not examine the patient physically. Thus, even though the expert witness is called to testify, it is still disputable since the term is not defined clearly in the *Poisons Act* 1952 and there are different opinions by different experts.[144]

4.5.3 Difficulty in proving "Particular Patient"

In PP v *Gernal Singh a/l Kundan Singh* (2004) also issuing the term of 'particular patient' to the use of agent provocateur that we used. The defendant neutralized the charge with stand that the "particular agent is not their patient". The medical practitioner does not treat the agent and supply the psychotropic substances through the clinic's assistant. The court accepts the argument and no prima facie case.

In case *PP v Teoh Boon Hooi* (2007)[145], where PED agent provocateur hardly to buy the psychotropic substance through counter likes previous technique's raid, so now it really showed that the medical practitioner learned the crime where applied the differential association theory by the Edwin H. Sutherland. In the criminal justice concerned also, agent provocateur is an issue of unjust and subject to entrapment.

---

[143] *PP v Ramesh a/l Muniasamy* [2005] unreported, Johor Bahru Magistrate Court.
[144] Arnie, above n 2, 71.
[145] *PP v Teoh Boon Hooi* (2007) unreported, Kuala Lumpur Magistrate Court.

An agent provocateur has been defined as "a person who commits an offence or seeks to encourage another to commit an offence in order to detect or obtain evidence of the commission of the offence by that other and to secure his conviction".[146] Agents are usually law enforcement officers. Here, comes the issue on the "entrapment" which the term applied in the United States for situations where members of the law enforcement agencies are largely or partly responsible for the commission of offences by other persons who are eventually charged. A distinction must be drawn between offering the occasion for the commission of a crime to a person who has already formed the intention of committing it and inciting a person who has not formed such an intention to commit a crime in order to have the basis for prosecution against him. Naturally, the latter attracts greater objections.

However, there are an issues of entrapment will come up. In United States, the defense of entrapment is available and acquittal may be awarded where the intention to commit the offence has been implanted by law enforcement officers.[147] In the Australia also, the defense of entrapment is available because to them entrapment is "inducing the commission of an offence which the person induced would not otherwise have committed on the occasion in question either with the entrapper or anyone else".[148] In England, the Law Commission thought that entrapment should only be a mitigating factor.[149] This view was raised by the Court of Appeal in *Sang* and endorsed by the House of Lords when the case went to appeal.

---

[146] Oxford Companion to Law.
[147] *Sorrrells v U.S* 287 U.S 435, 442 [1932].
[148] Australia, Law Reform Commission, Report No. 2 Interim: Criminal Investigation (1975), 108; hereinafter referred to as Interim Report: Criminal Investigation.
[149] *Sang* [1979] Cr. App. R. 240.

In *PP v Ng Lung Heam* (1999)[150] case, the use of an agent provocateur to test buying the psychotropic substances which is 10 tablets of midazolam over the counter through the clinic assistant. Prior to this case, there are 4 times test-buy been done by the same agent but in different dates to verified the public complaint. Is this case will be entrapment issue? Maybe this also will be the weaknesses in the PED enforcement approach.

4.6 CONCLUSION

It is important to note that weaknesses of the enforcement are the main factor contributing to the problem of illegal supply of psychotropic substances by medical practitioners in Malaysia. The Pharmaceutical Enforcement Department is the only agency in controlling the supply of psychotropic substances by medical practitioner in Malaysia. However, there is a need for improvement in certain areas of prevention approaches which means proactive approach such as the definition of terms and strengthen the punishment of deterrence effect and policy approach.

The next chapter will discuss further on the recommendation and conclude this study.

[150] *PP v Ng Lung Heam* (2003) unreported, Kuala Lumpur Magistrate Court.

CHAPTER FIVE

RECOMMENDATIONS AND CONCLUSION

5.0 INTRODUCTION

This chapter will highlight on the recommendations to improve the control on illegal supply of psychotropic substances by medical practitioner in Malaysia. In line with the aim to improve in the enforcement of the laws, a few suggestions could be implemented by the Pharmacy Enforcement Division.

5.1 RECOMMENDATIONS

The illegal supply of psychotropic substances by medical practitioner in Malaysia is on the rise each year. There is a need to curb this problem as it can create more drug problems and this is bad for the country in the long run. Thus, in this chapter in order to curb this problem and to improve the laws relating the psychotropic substances, the recommendations are proposed based on the weaknesses at previous chapter. The recommendations staggered in this chapter according to the administration approach, legal improvement and policy approach.

5.1.1 Administration Approach

Besides employ more officers, PED need to establish the proactive monitoring approach. Hence, in a way to develop and being solid law enforcement, PED should

enhance their man power and activities such as strengthen their enforcement learning skills through own academy and cooperation with other enforcement agencies. With this academy, indirectly the man power in PED will be expanded. Even, in US the Drug Enforcement Administration (DEA) increased the amount of resources and manpower dedicated to investigating the diversion of controlled pharmaceuticals.[151] Evidence also suggested that states which are proactive in the approach to regulation are more effective in reducing the illegal supply.

5.1.1.1 Training Academy

The enforcement agency is created in order to enforce the law. As discussed before, the Pharmacy Enforcement Division is the main agency that enforced the laws which controls the psychotropic substances. The increase in the number of pharmacy officers for Pharmaceutical Services since 2001-2007 has been very encouraging especially when the Government introduces the compulsory service. Currently, all Pharmacy Enforcement Officer undergo in-house training, short courses and work based on their senior officers' experience and guides when they start working as Pharmacy Enforcement Officer. In short, the official training as the Pharmacy Enforcement Officer is not provided by the Department. As a result, their knowledge is different based on where they get their unofficial training.

Thus, in order to uniform their skill and knowledge, it is suggested to have a pharmacy's training academy like the police and custom training academy, be established. The Enforcement Training Academy's aim is to provide law enforcement

[151] Manchikanti, above n 12, 408.

training, study the criminology of the pharmacy enforcement's cases and education which will ensure that the public are protected and served by officers that are capable, well prepared and confident. It is also to provide the highest caliber of instruction and to ensure that the officers leave the training program equipped with fundamental enforcement knowledge, skills and abilities and are sensitive and responsive to the communities they may serve.

Therefore, it is suggested that all newly recruited Pharmacy Enforcement Officers are required to undergo an intensive training in the academy for a certain period of time whenever they have officially been appointed as the Pharmacy Enforcement Officer. In the academy, the officers will be given a full course related to their duties as the Pharmacy Enforcement Officer such as inspection of the licensed premises, raiding, investigation and prosecution. All laws enforced by the Pharmacy Enforcement Division will be explained such as the *Poisons Act* 1952, the *Poisons (Psychotropic Substances) Regulations* 1989, the *Sales of Drugs Act* 1952, the *Control of Drugs and Cosmetics Regulations* 1984 and others. In addition, courses on the leadership and professionalism should also be taught at the academy to help the Department produce a competent Pharmacy Enforcement Officer. As a result, all officers are going to be well trained before they start working as the Pharmacy Enforcement Officers and they will have full knowledge and skills for good performance in their jobs. In other words, the implementation of this academy is hoped to strengthen the workforce and manpower of the Division.

5.1.1.2 Coordination with other Enforcement Agencies

There are a few enforcement agencies that involve in controlling the abuse of psychotropic substances such as the Pharmaceutical Enforcement Division, the National Anti Drugs Agency, the Royal Malaysian Custom and the Royal Malaysian Police. Each agency plays an important role in controlling the psychotropic substances abused as it may led to social problems like theft, robbery, house breaking and so on. Although the Pharmacy Enforcement Division is the most active agency in controlling the abuse of psychotropic substances, it is important to have coordination between these agencies. The authorities involved shall link themselves at all level whether at the interagency level (national or international) or at the inter-sectoral level (private sectors), in order to overcome the problem of lack of information exchange and coordination between agencies. Having adequate information will help authorities to enhance their capacity to investigate and take necessary action to combat the problem of abuse of psychotropic substances. Furthermore, the coordination will strengthen the enforcement agencies in enforcing the laws. For example the Pharmacy Enforcement Division needs the power of arrest of the police during raiding at the private general practitioner from absconding.

In addition, the coordination will help the agencies in sharing information about the laws, procedures and activities. Lack of coordination between enforcement agencies will affect the government's aim which is to reduce or combat the problems of abuse of psychotropic substances.

5.1.1.3 Educate the Medical Practitioners and Public

Education is required at all levels including medical practitioner, pharmacists, and public. Education is important to understand the functions and the role of the PED, the functions and role of monitoring programs, the appropriate prescription of opioids, deleterious effects of opioid use and abuse, and the management of chronic pain with non-opioid techniques. In US, surveys have shown that less than 40% of physicians have received any training in medical school in identifying prescription drug abuse or drug diversion.[152] Representatives of the medical and pharmaceutical communities should be called together to develop concerted and effective strategy of change to address this public health problem. This should encourage medical professionals, pharmacists, and pharmaceutical companies to take a leading role in educating medical practitioners and patients as to the importance of retaining control of prescription medications with abuse liability. The educational efforts should reach not only the people who are preaching to the community, resulting in increases in drug abuse, but also to all the medical practitioners either private or public sector. PED should take this recommendation as a proactive approach in control the problem in the illegal supply of psychotropic substances by medical practitioners.

5.1.2 Legal Improvement

Existing law should be amended or added, in a way to improve the deterrence, loophole in the provision such as the definition or interpretation and the standard of amounts of psychotropic substances supplied. Therefore, there are few recommendations for

[152] Ibid, 420.

improvement need to be made to the existing laws in order to control the problem on illegal supply of psychotropic substances by medical practitioners.

5.1.2.1 Punishment

As noted earlier in Chapter Four, section 30 of the *Poisons Act* 1952 covers the punishment for offences related to psychotropic substances. Addition, from the Rational Choice Theory showed that the medical practitioners not deter with the current penalty. Especially, in the current situation where profit of the medical practitioners earns are more beneficial than the punishment by the Act. Offences relating to the psychotropic substances should be considered as serious as the offences concerning dangerous drugs. PED should be given a power to suspend the medical practitioner who committed any laws under *Poisons Act* 1952 or *Sale of Drugs Act* 1952 on handling psychotropic substances. A deterrence sentence should be imposed to all offences to the psychotropic substances. The aim of deterrence is that the threat of punishment will deter individuals from committing a further crime as a result of his unpleasant experience.[153] In addition, the punishment of offender serves as an example and a threat to others of what will happen to them if they commit crime.[154] The court may pass exemplary sentences which means a sentence which is higher than that which would usually be proper for the offences concerned in order that others would be dissuaded in the future from committing offence of a similar kind.[155] In US, the medical practitioner was sentenced to 60 months in federal prison followed by three years supervised release and ordered to pay an assessment of $600 and a fine of $7,500 for the one count of conspiracy to illegally dispense controlled substances and five counts of illegally dispensing

[153] Lee CF & Che Audah Hassan. (2006). *Introduction to Principles & Liabilities in Criminal Law*. Lexis Nexis Malaysia.
[154] Ibid.
[155] Ibid.

controlled substances such as xanax.[156] In the DEA's cases, there are medical practitioner license or practice been suspended, surrender and revoked.[157] Furthermore, it is proposed that any medical practitioner who has been found guilty by the court to be suspended from the register, therefore they are not allowed to practice.

5.1.2.2 Notification of Conviction in Newspaper

A notification of the name and occupation of any person who has been convicted of any offence against this Act together with his place or places of business, the nature of the offence and the fine, forfeiture, or other penalty inflicted shall, if the court so orders, be published in any newspaper circulating in Malaysia or in any part thereof, and the cost of such publication may be recovered from such person as a civil debt. The deterrence effect is only on the name of the offender but not the stigma effect of their photo. Furthermore, it is proposed that any medical practitioner who has been found guilty by the court to be notified and published in the newspaper or even in the official website to create the deterrence effect.

5.1.2.3 Enhancement the Power Enforcement Drug Officer

Investigation or apprehension function of enforcement officer is the crucial part where criminals will be apprehended and be prosecuted. Impact of the psychotropic substances crime contributed negative impact to the nation. Since, the enforcement officers of those units are provided with a tough enforcement power to fulfill their duty. Here, I would like to suggest the power of enforcement drug officer should be enhanced with power of

[156] Drug Enforcement Administration, U.S Department of Justice. Cases Againts Doctors. Retrieved 21 September 2010, from http://www.dea.diversion.usdoj.gov/crim_admin_actions/admin_2003.htm.

[157] Ibid.

accessed to computerized data, power of arrest and power of intercept phone conversation and require evidence.

i) 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 computerized data.[158] Nowadays, the medical practitioners are smart and used multiple gadget of supply method in supplying of psychotropic substances illegally.

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.

ii) Power to Arrest

Under Section 30 of the Direct Sales Act 1993,[159] 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 psychotropic substances crime is a serious crime which

[158] *Optical Disc Act 2000 (Act 606)* s42.
[159] *Direct Sales Act 1993*, s30.

may involve a bigger scale of communities and act as a high profile case which involved professional's misconduct, this power will allow information or interrogation to be taken during investigation. Without arresting, 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.

iii) Power of Intercept Phone Conversation

Use of electronic surveillance is useful to penetrate the close society of organized crime.[160] Psychotropic substances crime 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,[161] it will benefits PED when it is provided in the statutory provision.

iv) 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.[162] Power to require evidence is important in investigation process.

---

[160] Dowling, J.L. (1979). *Criminal Investigation: Investigation of Organized Crime*. New York: Harcourt Brace Jovanovich Inc, 208.
[161] Ibid.
[162] Allen, B.V. (2000). *Criminal Investigation in Search the Truth*. Toronto: Pearson Prentice Hall, 115.

Thus absence of this power cause the potential sources of the psychotropic substances illegal supplied is missed. Standard legal requirement or caution must be provided together with the power to avoid any violations of human right or power abused.

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 amended as required to ensure effectiveness.[163] Amendment may be made to current law when urgency is needed.

5.1.2.4 Definition Terms

The definitions need to be included are the definitions of medical treatment and particular patient.

i) For Medical Treatment

It is also found that the definition specifically designed for the term of "medical treatment" is not stated clearly in the *Poisons Act* 1952 or any other Act related to the psychotropic substances. When the definition of "medical treatment" is not stated clearly, it might create uncertainty to define it and therefore gives a wide discretionary power for the court to make an interpretation. The interpretation provision is always a vital part for the court before it starts analyzing the fact of every case. Without the

[163] Department of Essential Drugs and Other Medicines. above n 15, 9.

comprehensible definition of the term "medical treatment" it is difficult for the prosecution to prove the ingredient of the charge in cases relating to supply of psychotropic substances not for medical treatment.

This is due to the argument by the defense counsel that all medicines includes the psychotropic substances, which is supplied by the medical practitioners are meant for treatment of human ailments even though the medical practitioner did not see the patient. However, there is an argument by the expert in the medical field that "medical treatment" means the medical practitioner are obliged to see and examine the patient before supplying any medicines. Therefore, it is proposed that the definition of "medical treatment" should be defined clearly in the *Poisons Act* 1952.

ii) Particular Patient

The term of 'particular patient' have been argued by the defense counsel in the case of agent provocateur had been used as a patient. The agent provocateur clearly is not a patient because they come, buy and go without a proper treatment. The 'particular patient' according to the regulation 11 of *Poisons (Psychotropic Substances)* 1989 is the particular person who are coming and meeting the medical practitioner for a treatment and been prescribed the prescription with the medical practitioner owned choice of drug. In PED's raid, there are private general practitioners (GP) sell and supply the drugs through the counter without getting the medical practitioner's treatment especially psychotropic substances.[164] Therefore, it is proposed that the terminology of the

[164] Interviewee 2, above n 25.

'particular patient' should be defined clearly in the *Poisons Act* 1952 or been replaced to the word 'person'.

5.1.2.5 Standard on the limitation on the Amounts of Psychotropic Substances can be Supplied

Here, recommended to make the limitation standard in three level of control of the supply of psychotropic substances which at (1) the purchase level, (2) the supply level and (3) the stock level. The provision should be stated the minimal amount and maximum amount of psychotropic substances can be purchase, keep and supply. The proposal should be according to the particular psychotropic substances regulatory regime. The standard of limitation must be based on the safety and effectiveness of the psychotropic substances and make sure the amounts are not hurdle the medical practitioner to perform their duties. The specific nature of prescription drugs minimizes the impact of other complicated issues of exposure and causation.

5.1.3 Policy Approach

It is suggested that a few key policy changes should be taken to improve problem in collecting information and getting corporation of medical practitioner. As the responsible agency in charge of psychotropic substances in GP, it is important to have a constant guard and limitation against a lack of diligence by the medical practitioners in handling the psychotropic substances.

5.1.3.1 Separation of Psychotropic Substances Prescribing and Dispensing Procedure

Along this while, the medical practitioner is wearing a two hat in their services. The medical practitioners are wearing a hat for treatment and a hat for dispensing. The separation between the dispensing and treatment procedure should be separated. The separation of the procedure is important to make sure controlling the abuse and diversion of psychotropic substances.

We should let the medical practitioner going through the treatment procedure thoroughly and end up with the prescribing the patient with the result of professional and unbiased treatment. Dispensing separation would improve the level of healthcare delivery and would benefit patients as medical practitioners could focus on their clinical, diagnosing, counseling and prescription, while pharmacist could focus on educating patients on how best to optimize the usage of psychotropic substances prescribed. Nowadays, medical practitioners make additional money by dispensing medicine. They tend to prescribe drugs that will give them a better profit, including dispensing psychotropic substances not for medical treatment.

The implementation of the dispensing separation in the public sector appears the positive impact where the pharmacists and medical practitioners are working together and hand in hand towards the patient benefits and care. Any problems regards to the prescribing procedure will be noticed and screened by the secondary level of healthcare which by pharmacist. Therefore by separating the prescribing and dispensing of drugs specifically the controlled drug of psychotropic substances, reform aimed to reduce the

overuse and misuse of drugs, improve the quality of the consumption of prescription drugs, and enhance the patients' right to know about their medication.[165]

With separation of function between private clinics and pharmacies, Malaysia will join the ranks of other developed countries around the world which separate the role of medical practitioners and pharmacists. In the last 30 years. Asian countries like Japan, South Korea, Taiwan, the Philippines and Indonesia have implemented the separation with varying degrees of success. In Korea, drug prescribing and dispensing separation has much important policy implications than the simple division of labor between physicians and pharmacists. Korean previous healthcare system are worst than Malaysian but now acknowledged with the dispensing separation policy benefits in the new health care system. This suggestion policy is very effective and lies with the application of our government future National Health Insurance Policy. In the policy, the major roles of the government could strictly set the reimbursement price for medical care and pharmaceuticals. Evidence showed with the prescribing and dispensing separation policy[166] will reduce pharmaceutical prices and gain a social benefit[167] of pharmaceuticals and as a good first step towards the effective government policy[168] for pharmaceuticals.

---

[165] Soonman Kwon. (2003). Pharmaceutical Reform and Physician Strikes in Korea: Separation of Drug Prescribing and Dispensing. *Social Science & Medicine* 57, 530.

[166] Danzon, P., & Chao, L. W. (2000). Cross-National Price Difference for Pharmaceuticals: How large and why?. *Journal of Health Economics* 19(2), 159–195.

[167] Kwon, above n 158, 537.

[168] Ibid, 536.

5.1.3.2 Licensed the Medical Practitioner in Purchase and Supply the Psychotropic Substances for Medical Purpose

The medical profession bears an important responsibility for appropriate prescribing of psychotropic substances because they have privilege granted by the law to determine the choice of drug, its dosage, duration and termination and ultimately the availability of a particular psychotropic substance for a given patient. The supply of drugs especially for narcotic drugs and psychotropic substances should correspond to medical needs as closely as possible and, therefore, it is important to assess those needs as accurately as possible because their abuse potential and the risk that they may be diverted into the illicit markets. Licensing the medical practitioner who handles psychotropic substances is an effective measure in curbing their abuse and diversion. This method will allow the authorities to check for multiple supplies and overprescribing by the medical practitioners. Their licenses also can be withdrawn if they have been found not law abiding.

5.1.3.3 Registration of Substitution Drug Therapy Program

In the expand to the implementation of Drug Substitution Therapy Program (DST), under the harm reduction program launched by the government in order to prevent or reduce negative health consequences associated with drug addiction. The program needs to be strengthened because the program involves the regular prescription and administration of psychotropic substances pursuant to the *Poison (Psychotropic Substances) Regulations* 1989. Therefore, a close co-operation between physicians and the authorities needs to be realized and individual treatment plan have to be designed for

each single patient in order to control the potential of abuse of the psychotropic substances.

Further to DST program has to be undertaken in a holistic manner wherein the support from government, immediate family members, non-government Organizations, employers as well as the public is vital to make the program a success. The potential for diversion and abuse of this program must always be a cause of concern for responsible members of the treatment community. The treatment community's diligence and accountability in the dispensing of psychotropic substances is absolutely crucial in maintaining the security of these treatment drugs and to ensure that they are not abused by unscrupulous parties for mere profit. Therefore it is suggested that medical practitioner who are involved in the DST program be registered separately and to restrict the treatment of drug addiction to the government institution.

By doing this, it can protect public health from improper, incompetent and unlawful practices by the medical practitioners. Besides that it is also to ensure there is no patient who will receive substitution substances from other medical practitioners, fails to participate in necessary accompanying treatment and care, uses substances that endanger the purpose of substitution treatment, or uses the substitute in a manner that is prohibited by law.

Furthermore, it is also suggested that all medical practitioners seeking to provide drug-substitution treatment need special authorization issued by the Malaysian Medical Council (MMC) and they must provide evidence of having participated in pharmacology and drug addiction training program handled by the government. In

addition, treatment providers have to constantly guard against a lack of diligence in enforcing treatment standards and ensure patient compliance with program guidelines in order to maintain the respect and avoid problems with this medication treatment. Thus by registering the medical practitioners it will require the medical practitioner to institute practices and procedures that will protect against inappropriate, illegal prescribing or illegal supplied of psychotropic substances.

5.1.3.4 Computerized System

Telemedicine and internet prescribing may greatly facilitate access to medical practitioners and patients. At the same time, the potential for errors and intentional misuse is considerable particularly in relation to the diagnosis of psychiatric disorders and the prescription of psychotropic substances. Efforts to regulate this quickly developing technical area require close cooperation among the enforcement agencies and the private general practitioner (GP). Therefore it is recommended to establish a computerized information system to tracks distribution of many psychotropic substances to the GP level by the enforcement agencies in order to allow identification of unusual patterns of use which may, upon audit of the required records, be found to involve diversion. These tools are intended to provide the government with the information to detect leaks from the drug distribution pipeline into the illicit market and the authority to hold individual or medical practitioners responsible for diversion. In US, they manage to reduce the cost of paper prescription forgery and alteration and the reduction in diversion and abuse of controlled substances, with all of its consequences

for public health and safety.[169] For the sake of public safety and health, this recommendation is much recommended in this study.

5.1.3.5 Continuous Public Awareness and Protection

Focus on the public awareness on the importance of the laws is needed, in order for the enforcement agency to enforce the laws effectively.[170] A lot of problem will occur if the public is ignorance of the existing laws. A social illness will rise and the professional attitude will be damage.[171] The number of offences that had been detected will not reflect on the actual number of offences. The public should get involved in controlling the abuse of psychotropic substances in private general practitioners. For instance, the public should always inform the enforcement agencies of any misconduct done by the medical practitioners such as selling psychotropic substances to the drug addicts.

Apparently, there is a lot of publicity on the issue of abuse of psychotropic substances by medical practitioners in Malaysia. Local newspaper has always highlighted on the raiding being conducted by the Pharmacy Enforcement Division.[172] However, it seems that the public are not taking this issue seriously. This is due to the fact that medical practitioners has always been perceived as an honorable profession, thus public will always put a higher respect on them and will not accept anything against them.

---

[169] Drug Enforcement Administration, U.S Department of Justice. *Economic Impact Analysis of the INTERIM Final Electronic Prescription Rule* (March 2010), 2. Retrieved 21 September 2010, from http://www.deadiversion.usdoj.gov/crim_admin_actions/admin_2003.htm.

[170] Arnie, above n 2, 82.

[171] Interviewee 3, above n 75.

[172] Ibid.

For example, in the Harian Metro, it was reported that four medical practitioners were detained for selling psychotropic substances to drug addicts in Kuala Lumpur.[173] Meanwhile, the Borneo Post reported that a clinic has been raided in Kuching where fifty two types of psychotropic substances have been seized.[174] In this case, the medical practitioner of the clinic is suspected to be involved in the illegal supply of psychotropic substances.

There is news on the abuse of psychotropic substances in private general practitioners. However, public participation in curbing the problem is not encouraging. It seems like the news does not give enormous impact to the public. Therefore, the role of the Pharmacy Enforcement Division to educate the public on implications of psychotropic abuse by private general practitioners it is very important to prevent the problem from escalating. Hence, I recommend for the PED to continuously create the awareness and protection to the public and specifically to the medical practitioners.

5.2 CONCLUSION

In conclusion, I can say that the crime happened absolutely because of the medical practitioner is only the authorized person to prescribed and dispensed the psychotropic substances. The weaknesses in the PED are much depending to the ethic and professionalism of the medical practitioner in their practice. There is a need to improve the laws, the enforcement activities towards proactive approaches and policy approaches towards crime prevention on the illegal supply of psychotropic substances by medical practitioner. As a member of the international conventions of psychotropic

[173] Editorial. (19 May 2007). 4 Doktor Ditahan. *Harian Metro*.
[174] Editorial, above n 32.

substances, it is PED responsibility to have a comprehensive legislation and social structure systems in controlling the psychotropic substances that is parallel with the conventions. Therefore, it is hoped that the recommendations given will strengthen the laws that control the supply of psychotropic substances in private general practitioners. Finally, it is hoped that the suggestions will be able to reduce the problem in the illegal supply of psychotropic substances by medical practitioners.

BIBLIOGRAPHY

Books

Allen, B.V. (2000). *Criminal Investigation in Search the Truth.* Pearson Prentice Hall: Toronto.

Charles, Lewis J. (1995). *Medical Negligence: A Practical Guide* (3rd ed.). Great Britain: Tolley.

Dowling, J.L. (1979). *Criminal Investigation: Investigation of Organized Crime.* HarcourtNew York Brace Jovanonich Inc: New York.

Evans, K. & Sullivan, J.M. (1990). *Dual Diagnosis.* New York: The Guilford Press.

Fisher, G.L. & Thomas C.H. (2000). *Substance Abuse, Information for School Counselors, Social Workers, Therapists and Counselors.* (2nd ed). Allyn and Bacon USA.

Harold, Doweiko E. (1993). *Concepts of Chemical Dependency.* (2nd edition). United States, America: Wadsworth Inc.

Lee Chong Fook & Che Audah Hassan. (2006). *Introduction to Principles & Liabilities in Criminal Law.* Lexis Nexis Malaysia.

Mohamad Sabri Yusoh & Che Bakar Che Mat. (2008). *Penyalahgunaan dan Pengedaran Dadah di Malaysia,* (2nd ed.).

Pharmaceutical Services Division. (2007). *Annual Report Pharmaceutical Services Division, Ministry of Health Malaysia* 2007.

Pharmaceutical Services Division. (2008). *Annual Report Pharmaceutical Services Division, Ministry of Health Malaysia* 2008.

Ray, O, Ksir C, et al. (eds). (1990). *Drugs, Society and Human Behaviour* (5th ed.). Times Mirror/Misby College Publishing.

Ronald, Akers L. & Christine S. Sellers. (2004). *Criminological Theories: Introduction, Evaluation, and Applications.*

Siegel, Larry J. (2006). *Criminology*. (9th ed.). Thomson Wadsworth.

Parliamentary, Committee and Other Reports

Daud, Dzafarullah & Salimin Adnan. (2004). Control of Psychotropic Substances in Malaysia: Balancing the Demand and Supply. Unpublished report, Pharmaceutical Services Division.

Ministry of Health, Malaysia. (2008) *Annual Report 2008*.

Official Letter by Pharmaceutical Services Division with Reference No.(12)dlmKKM-55/207/002/04Bhg date 30 December 2009.

Official Letter by Pharmaceutical Services Division with Reference No.dlmKKM-55/203/001/04Bhg3(43) date 30 November 2005.

Journal Articles and Conference Papers

Aleksandra, B, Aida Plesan, Xiao-Jun Xu & Zsuzsanna Wiesenfeld-Hallin. (2002). Reduced Tolerance To The Anti-Hyperalgesic Effect Of Methadone In Comparison To Morphine In A Rat Model Of Mononeuropathy. *PAIN* 95.

Arnie Fadzilah, et al. (2007). *Legislative Control of Psychotropic Substances in Private Clinics: A Study on the Existing Laws in* Malaysia. Unpublished master's thesis, University of Technology MARA.

Cohen, L and Marcus F. (1979). Social Change and Crime Rate Trends: A Routine Activities Approach. *American Sociological Review* 44.

Cornish, Derek B & Ronald V. Clarke (eds.). (1987). *The Reasoning Cnminal: Rational Choice Perspectives on Offending* (New York: Springer-Verlag, 1986); "Understanding Crime Displacement: An Application of Rational Choice Theory", 25 *Criminology.*

Danzon, P., & Chao, L. W. (2000). Cross-National Price Difference for Pharmaceuticals: How large and why?. *Journal of Health Economics* 19(2).

Feighner, J. P. (1987). Impact of Anxiety Therapy on Patient's Quality of Life. *American Journal of Medicine, 32* (Supplement A).

Gallo, John N. (1998). Effective Law-Enforcement Techniques for Reducing Crime. *The Journal of Criminal Law and Criminology (1973-) Vol. 88, No. 4, Symposium: Why is Crime Decreasing?*. Summer.

Gillin, J.C. (1991). The Long and the Short of Sleeping Pills. *New England Journal of Medicine, 324.*

Katie, W. (2008). 'The Chemical Generation: A Critical Analysis of Medical 'Expert' Discourse and the Construction of Mental Illness'. *Internet Journal of Criminology.*

Manchikanti, L. (May, 2007). 'National Drug Control Policy and Prescription Drug Abuse: Facts and Fallacies', *Pain Physician* 10

Mellinger GD, Balter MB & Uhlenhuth EH. (1985). 'Insomnia and Its Treatment, Prevalence and Correlates'. *Arch Gen Psychiatry* 42.

Merton, R. (1938). Social Structure and Anomie. *American Sociological Review*, Vol 3.

Philips, ED. (Jun 1953). Doctor and Patient in Classical Greece. *Greece & Rome*, Vol. 22, No. 65.

Piquero, A & George R. (1995). Studying Deterrence with Active Residential Burglars. *Justice Quarterly* 16.

Redhwan Ahmed Al-Naggar, Zaleha Mohd Isa & Ramli Musa. (2010). Prevalence and Associated Factors of Sleeping Pills Use Among Students in a Malaysia University. *ASEAN Journal of Psychiatry*, Vol 11, No. 2

Silva, JA, Costa E, Chase M, Sartorius N & Roth T. (1996). Special Report from A Symposium Held by the World Health Organization and the World Federation of Sleep Research Societies: An Overview of Insomnias and Related Disorders - Recognition, Epidemiology and Rational Management. *Sleep*, 19.

Simha, L and Daniel F. (1987). The Seasonality of Violent Crime: The Case of Robbery and Homicide in Israel. *Journal of Research in Crime and Delinquency* 30.

Soonman Kwon. (2003). Pharmaceutical Reform and Physician Strikes in Korea: Separation of Drug Prescribing and Dispensing. *Social Science & Medicine* 57.

Sykes, G, and Matza, D. (1957). Techniques of Neutralization: A Theory of Delinquency. *American Sociological Review* 22.

Wesson, DR and Smith DE. (May1990). Prescription Drug Abuse-Patient, Physician and Cultural Responsibilities, In Addiction Medicine and the Primary Care Physician [Special issue], *West J Med.*

International Instruments

Australia, Law Reform Commission, Report No. 2 Interim: Criminal Investigation (1975), 108; hereinafter referred to as Interim Report: Criminal Investigation.

The United Nations Drug Control Treaties. (2002). Paris: Senlis Council.

United Nation Report on Convention on Psychotropic Substances 1971 (United Nation).

Internet Materials

Agensi Antidadah Kebangsaan, "Maklumat Dadah 2009", 12. Retrieved 18 October 2010, from http://www.adk. gov.my/pdf/laporandadah/maklumat dadah2009.pdf.

Anisah Che Ngah. (7 February 2006). The Medical Profession on Trial: A case comment. Retrieved 21 July 2010, from http://www.malaysianbar.org.my/tort_ personal_injury_or_death/themedical_profession_on_trial_a_case_com ment.html.

Drug and Alcohol Services Control. (1995). *Benzodiazepines: Reasons to Stop*, 4. Retrieved 6 August 2010, from http://www.dassa.sa.gov.au/sites/page.cfm .

Drug Enforcement Administration, U.S Department of Justice. Cases Againts Doctors. Retrieved 21 September 2010, from http://www.deadiversion.usdoj.gov/crim_admin_actions/ admin_2003.htm.

Drug Enforcement Administration, U.S Department of Justice. *Economic Impact Analysis of the INTERIM Final Electronic Prescription Rule* (March 2010), 2. Retrieved 21 September 2010, from http://www.dea diversion.usdoj.gov/crim_admin_actions/admin_ 2003.htm.

Info Sihat. Isu Penyalahgunaan Dadah. (2010). Retrieved 3 November 2010, from http://www.infosihat.gov.my/ penyakit/Remaja/PENYALAHGUNAAN DADAH.pdf.

Kishore, G & Alok K. Bohara. *Agency Problems in Law Enforcement: Theory and Application to the US Coast Guard.* Retrieved 21 July 2010, from www.mansci.journal. informs.org/.

Kraman, P. 'Drug Abuse in America – Prescription Drug Diversion' (April 2004) The Council of State Governments. Retrieved 15 October 2010, from www.csg.org.

MOH Pharmaceutical Services Division. (2010). *Curbing The Diversion And Misuse of Psychotropic Substances And Controlled Medicines dated 29 April 2010.* Retrievd 29 July 2010, from http://www.pharmacy.gov.my/newsmaster.cfm?&menuid=134&action=view&retrieveid=210.

Pharmaceutical Services Division. *Press Statement by Director General of Health, Ministry of Health of Malaysia on Abuse in Supply of Psychotropic Substances dated 23 April 2008*. Retrieved 12 August 2010, from www.pharmacy.gov.my.

Rockville, MD. (2006). *Results from the 2005 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-30, DHHS Publication No. SMA 06-4194). Substance Abuse and Mental Health Services Administration. Retrieved 21 September 2010, from www.oas.samhsa.gov/nsduh/2k5nsduh/2k5Results.pdf.

Newspaper Reports

Borneo Post. (30 May 2007). Clinic busted, 52 types of pills seized.

Harian Metro. (25 April 2007). Dadah 'Power'.

Harian Metro. (19 May 2007). 4 Doktor Ditahan.

Harian Metro. (20 July 2007). Doktor Mata Duitan.

Kosmo. (23 January 2008). Doktor 'Pil Khayal'.

Kosmo. (13 May 2007). Doktor jual Pil Khayal.

Ku Mohd. Ridzuan Ku Abdul Rahman. *Kosmo.* (18 September 2010). Beli Dormicum Baru Dapat Metadon.

The Times. Wood v Thurston. (25 May 1951).

Utusan Malaysia. (18 April 2004). Dadah: Tolak Cadangan YB, Ikut Syor Pakar Perubatan – Forum: Dr Wan Mohd. Rushidi Wan Mahmud.

Miscellaneous

Information gathered from Interviewee 1, Deputy of Director, Pharmaceutical Enforcement Department, Pharmaceutical Services Division, Ministry of Health Malaysia in an interview conducted on 14 October 2010.

Information gathered from Interviewee 2, Deputy of Director, Prosecution Unit, Pharmaceutical Enforcement Department, Pharmaceutical Services Division, Ministry of Health Malaysia in an interview conducted on 27 October 2010.

Information gathered from Interviewee 3, Senior Principle Assistant Director, Diversion Control Unit, Pharmaceutical Enforcement Department, Pharmaceutical Services Division, Ministry of Health Malaysia in an interview conducted on 5 October 2010.

Information gathered from Interviewee 4, Principle Assistant Director, Prosecution Unit, Pharmaceutical Services Division, Jabatan Kesihatan Malaysia, Kuala Lumpur and Putrajaya in an interview conducted on 2 November 2010.

APPENDICES

POISONS (PSYCHOTROPIC SUBSTANCES) REGULATIONS 1989

Incorporating latest amendment - P.U.(A) 19/99
Publication in the Gazette : 2nd March 1989
Date of coming into operation : 15th April 1989

ARRANGEMENT OF REGULATIONS

PART VII - REGISTERS

PART VIII - STORAGE AND DISPOSAL OF PSYCHOTROPIC SUBSTANCE

PART IX - LABELLING OF PSYCHOTROPIC SUBSTANCE

PART X - POWER OF MINISTER TO MAKE PROHIBITORY ORDER

PART XI - GENERAL

FIRST SCHEDULE

SECOND SCHEDULE

THIRD SCHEDULE

FOURTH SCHEDULE

Preamble

IN exercise of the powers conferred by section 30 of the Poisons Ordinance 1952 [29/52], the Minister makes the following regulations :

Regulation 1. Citation and commencement.

These Regulations may be cited as the Poisons (Psychotropic Substances) Regulations 1989 and shall come into force on the 15th April 1989.

Regulation 2. Interpretation.

In these Regulations, unless the context otherwise requires -

"competent authority" means the national authorities empowered to issue certificates and authorisations recognised by the Government of Malaysia, for the import and export of psychotropic substances;

"Convention" means the Convention on Psychotropic Substances that was adopted for signature at Vienna on the 21st February 1971;

"export" , with its grammatical variations and cognate expressions, means to take or cause to be taken out of Malaysia by land, air or water, otherwise than in transit;

"import", with its grammatical variations and cognate expressions, means to bring or cause to be brought into Malaysia by land, air or water, otherwise than in transit;

"in transit" means taken or sent from any country and brought into Malaysia by land, air or water, whether or not landed or transhipped in Malaysia, for the sole purpose of being carried to another country either by the same or another conveyance;

"name of the psychotropic substance" means the International Non-proprietary Name (INN) of the psychotropic substance or, in the absence of the INN, the chemical name of the psychotropic substance;

"Ordinance" means the Poisons Ordinance 1952;

"senior officer of Customs" shall have the meaning assigned to it in the Customs Act 1967 [Act 235].

Regulation 3. Prohibition on possession of psychotropic substance.

(1) No person shall have in his possession any psychotropic substance unless -
  (a) he is authorised to be in possession of such psychotropic substance under these Regulations; and
  (b) the psychotropic substance in his possession is -
    (i) for a lawful purpose; and
    (ii) obtained in accordance with the provisions of these Regulations.

(2) For the purposes of paragraph (a) of subregulation (1), the following persons or class of persons shall be authorised to be in possession of psychotropic substance:
  (a) a licenced pharmacist;
  (b) a registered medical practitioner;

(c) a regiatered dentist Division I;
(d) a veterinary surgeon;
(e) the holder of a permit issued under regulation 15;
(f) a person employed in any hospital at which human ailments are treated and for the time being in charge of any ward, operating theatre or of other sections of such hospital who possesses psychotropic substance for use in such ward, operating theatre or sections;
(g) a person concerned with scientific education or research or chemical analysis in a department, university or institution wholly maintained by the Government or approved by the Director General of Health;
(h) a pharmacist in the public service;
(i) an officer of Customs, police officer or an officer of the Postal Department when acting in the course of his duty as such;
(j) a Drug Enforcement Officer;
(k) a person engaged in the delivery of any psychotropic substance from a lawful supplier to a person authorised to have it in his possession, for such period as in the circumstances of the case is reasonably sufficient to enable the delivery to the recipient to be effected;
(l) a person lawfully supplied with such psychotropic substance--
  (i) by a registered medical practitioner, registered dentist Division I or a veterinary surgeon; or
  (ii) in accordance with a prescrption lawfully given by a registered medical practitioner, registered dentist Division I of a veterinary surgoen;
(m) a person acting on behalf of the class of the persons mentioned in paragraph (1);
(n) a person possessing psychotropic substance for administration to a patient or animal in accordance with the direction of a registered medical practitioner, registered dentist Division I or a veterinary surgeon, as the case may be.

Regulation 4. Control of import and export of psychotropic substance.

(1) Except as otherwise provided in these Regulations, no person shall import or export any psychotropic substance unless--

(a) he has in his possession a valid and subsisting import or export authorisation, as the case may be, relating to such psychotropic substance; and
(b) such import or export is in accordance with the terms and conditions specified in the import or export authorisation relating thereto.

(2) The provisions of subregulation (1) shall not apply to -

(a) any person arriving in or leaving Malaysia who carries as part of his personal luggage and solely for his personal use or for the use of his family, a prepared or packaged medicine containing any psychotropic substance, not exceeding such quantities as may be reasonably required for one month's use by one person, which has been lawfully supplied to such person by or on the prescription of a qualified medical practitioner; or
(b) the international carriage by ships, aircrafts or other forms of international public transport entering or leaving Malaysia of such limited quantities of any psychotropic substance as may be required during their journey or voyage for first aid purposes or emergency cases.

Regulation 5. Application for an import authorisation.

(1) An application for an import authorisation in respect of any psychotropic substance shall be made to the Licensing Officer in Form A in the First Schedule.

(2) Upon receipt of an application under subregulation (1), the Licensing Officer may in his discretion issue an import authorisation in Form B in the First Schedule subjet to such terms and conditions as may be imposed by such Licensing Officer.

(3) The Licensing Officer shall prepare the import authorisation in triplicate and shall--

(a) issue two copies to the intending importer who shall forward one copy thereof to the person from whom the psychotropic substance is to be obtained; and
(b) send the third copy direct to the competent authority of the country from which the psychotropic substance is to be imported.

Regulation 6. Application for an export authorisation.

(1) An application for an export authorisation in respect of any psychotropic substance shall be made to the Licensing Officer in Form A in the First Schedule.

(2) Upon receipt of an application under subregulation (1), the Licensing Officer may, upon the production of an import authorisation or an approval of import certificate duly issued by the competent authority of the country to which the psychotropic substance is to be exported, in his discretion issue an export authorisation in Form C in the First Schedule subject to such terms and conditions as may be imposed by such Licensing Officer.

(3) The Licensing Officer shall prepare the export authorisation in triplicate and shall -

(a) issue two copies to the exporter who shall send one copy with the psychotropic substance to which it refes when such psychotropic substance is exported; and
(b) send the third copy direct to the competent authority of the country into which the psychotropic substance is to be exported.

Regulation 7. Fee for import or export authorisation.

The fee for an import or export authorisation shall be one hundred ringgit.

Regulation 8. Furnishing of information to Drug Enforcement Officer, etc.

At the time of importation or exportation of any psychotropic substance, the importer or exporter shall produce to a Drug Enforcement Officer or any proper officer of Customs the import or export authorisation relating thereto, and such other evidence as such officer may require to satisfy him that the psychotropic substance is being imported or exported lawfully and in accordance with the terms and conditions of such authorisations.

Regulation 9. Import or transit of psychotropic substance specified in the Second Schedule.

Every psychotropic substance specified in the Second Schedule which is imported into Malaysia, or brought to Malaysia in transit, from a country which is a party to the Convention shall be accompanied by a valid and subsisting export authorisation duly issued by the competent authority of the country from which it is exported; and the person having the possession or control of such psychotropic substance shall, on demand by any Drug Enforcement Officer, any police officer not below the rank of Inspector or any senior officer of Customs, produce such export authorisation for his inspection.

Regulation 10. Control of psychotropic substance in transit.

No psychotropic substance while in transit shall be subjected to any process which would change the nature of such psychotropic substance and the packing shall not be altered without the written consent of the Licensing Officer.

Regulation 11. Control on the sale and supply of psychotropic substance for medical or dental treatment of a particular patient or animal treatment of a particular animal.

(1) No psychotropic substance shall be sold or supplied for the purposes of medical or dental treatment of a particular patient or animal treatment of a particular animal except by -

(a) a registered medical practitioner for the purposes of the medical treatment of his patient only;
(b) a registered dentist Division I for the purposes of the dental treatment of his patient only;
(c) a veterinary surgeon to his client for the purposes of animal treatment only;
(d) a licensed pharmacist upon a prescription prescribed by a registered medical practitioner or a registered dentist Division I or a veterinary surgeon;
(e) a pharmacist who is for the time being employed in a hospital, clinic or dispensary wholly maintained by the Government, or in an institution approved by the Director General of Health at which human ailments are treated, upon a prescription prescribed by a registered medical practitioner or a registered dentist Division I or a veterinary surgeon;
(f) any of the persons mentioned in paragraphs (a) to (e) of this regulation and paragraph (f) of subregulation (2) of regulation 3 to a person authorised to administer psychotropic substance, upon a prescription prescribed by a registered medical practitioner or a registered dentist Division I or a veterinary surgeon.

(2) Every prescription for any psychotropic substance prescribed by a registered medical practitioner, registered dentist Division I, or veterinary surgeon shall -

(a) be in writing, signed and dated by the prescriber thereof;
(b) state the full name, address and telephone number of the prescriber;
(c) state the age, full name and address of the patient or, in the case of a prescription by a veterinary surgeon, the full name and address of the person to whom such psychotropic substance is to be delivered;

(d) indicate the total amount of psychotropic substance to be supplied and the dose; and
(e) specity the number of times (not exceeding three) the psychotropic substance may be supplied and, if supplied more than once, at what intervals.

(3) No person shall sell or supply any psychotropic substance on a prescription -

(a) which does not comply with all the requirements of subregulation (2);
(b) which contravenes the provisions of subregulation (5);
(c) otherwise than in accordance with the terms of such prescription; or
(d) which is presented to him more than ninety days after date of the prescription.

(4) Every person selling or supplying any psychotropic substance on a prescription shall, at the time of selling or supplying the same, endorse upon the face of the prescription above the signature of the prescriber, his name and address and the date on which such psychotropic substance was sold or supplied.

(5) No prescription for any psychotropic substance shall be written wholly or partly in code or in such manner that it is not readily decipherable and capable of being dispensed by any pharmacist.

(6) Notwithstanding any provisions to the contrary, if it shall appear to the seller or supplier that any psychotropic substance is required urgently in cases of emergency and that it is imposssible without unreasonable delay to obtain a prescription complying with the requirements of paragraph (d) or (e) of subregulation (1), it shall be lawful for the seller or supplier, after making an entry to that effect in his prescription register for psychotropic substance, upon the verbal or telephoned instructions of a registered medical practitioner, registered dentist Division I or veterinary surgeon, personally known to him, to sell or supply such psychotropic substance without a prescription:

Provided that in every such case the seller or supplier --

(a) shall take all necessary steps to obtain, and the prescriber shall deliver, a prescription as required in paragraph (d) or (e) of subregulation (1) within one day of the date of such sale or supply;
(b) shall not sell or supply more than one day's supply of such psychotropic substance; and
(c) shall take such reasonable steps to ascertain the authenticity of the person who gave the instructions.(7) Every prescription for the sale or supply of psychotropic substance shall be kept for a period of at least two years from the date of sale or supply.

Regulation 12. Control on the sale and supply of psychotropic substance for purposes other than medical or dental treatment of a particular patient or animal treatment of a particular animal.

(1) Subject to subregulation (2), no psychotropic substance shall be sold or supplied for purposes other than medical or dental treatment of a particular patient or animal treatment of a particular animal except by a licensed pharmacist or a pharmacist in the public service to--

(a) another licensed pharmacist or pharmacist in the public service;

(b) a registered medical practitioner, registered dentist Division I or veterinary surgeon for the purpose of medical, dental or animal treatment;
(c) a person concerned with scientific education or research or chemical analysis in a department, university or institution wholly maintained by the Government or approved by the Director General of Health;
(d) a person holding a valid and subsisting permit to purchase and use psychotropic substance issued under regulation 15; or
(e) subject to regulation 4, a purchaser outside Malaysia.

(2) Any person who sells or supplies psychotropic substance--

(a) as commercial sample shall be required to have a valid clinical trial import licence issued under the Control of Drugs and Cosmetics Regulation 1984 [P.U.(A) 223/84], for such psychotropic substance;
(b) to a person in Malaysia, in such quantity and at such frequency that appears to be not reasonably required by such person acting in the ordinary course of his profession, function or employment shall be required to obtain -
(i) such person's signature in the supply register or a signed written order; and
(ii) a written attestation from such person relating to his requirement for such psychotropic substance in such quantity and at such frequency, as the case may be,before any sale or supply is made.

Regulation 13. Exemption from regulation 12(1).

The provisions of subregulation (1) of regulation 12 shall not apply -

(a) to the sale or supply of psychotropic substances by a licensed pharmacist or a registered
pharmacist in the public service, or, in the absence of such person, a registered medical practitioner, who is employed in any hospital, and who sells or supplies within the same hospital such psychotropic substance to the person, and for the purposes, specified in paragraph (f) of subregulation (2) regulation 3; or

(b) to a case where the psychotropic substance is to be returned to the original supplier within Malaysia who supplied the psychotropic substance in the first instance; provided that such a transaction is noted in the relevant register for psychotropic substance and an official acknowledgement of receipt from such supplier is kept.

Regulation 14. Issue of permit to purchase and use psychotropic substance.

For the purposes of these Regulations, a permit to purchase and use psychotropic substance shall only be issued to -

(a) a professional person or tradesman for the purpose of such person's or tradesman's profession or trade only; or
(b) a game warden or a person assigned to act as a game warden by the relevant authority for such game warden's or person's use on animals only.

Regulation 15. Application for a permit to purchase and use psychotropic substance.

(1) An application for a permit to purchase and use psychotropic substance shall be made in Form D in the Third Schedule to the Licensing Officer who may in his discretion issue such a permit or reject the application.

(2) A permit to purchase and use pcyshotropic substance shall be in Form E in the Third Schedule and shall be valid for a specified period not exceeding twelve months.

(3) The Licensing Officer may in issuing a permit under this regulation impose such terms and conditions as he thinks fit, and may from time to time vary the terms and conditions so imposed.

(4) The fee for a permit to purchase and use psychotropic substance shall be one hundred ringgit.

(5) The Licensing Officer may cancel any permit issued under this regulation, if he is satisfied that -

(a) the holder of the permit has contravened any provisions of these Regulations or any terms and conditions imposed by the Licensing Officer; or
(b) the holder of the permit has furnished false, misleading or inaccurate information, or has concealed or failed to disclose material facts, in his application for such permit.

(6) The Licensing Officer shall, before cancelling any permit under subregulation (5), cause to be given to the holder of such permit a notice in writing of his intention to do so and calling the person concerned to show cause why his permit should not be cancelled.

(7) Any person aggrieved by the refusal of the Licensing Officer to issue a permit under subregulation (1), or by the cancellation of any permit under subregulation (5), may appeal in writing to the Minister against such refusal or cancellation within a period of thirty days after the date of such refusal or cancellation.

(8) The Minister may, after hearing the appeal, make such order as he deems fit and that order shall be final.

Regulation 16. Control of administration of psychotropic substance.

No person shall administer any psychotropic substance unless he is -

(a) a registered medical practitioner;
(b) a registered dentist Division I;
(c) a veterinary surgeon; or
(d) a person acting in accordance with the direction of a registered medical practitioner, registered dentist Division I or a veterinary surgeon, and the psychotropic substance is administered for the purpose of medical or dental treatment of a particular patient or animal treatment of a particular animal.

Regulation 17. Control of dispensing, etc. of psychotropic substance.

No person shall dispense, compound or mix any psychotropic substance with any other substance, whether a psychotropic substance or not, for the purpose of it being used for medical, dental or animal treatment unless he is -

(a) a licensed pharmacist; or
(b) a pharmacist in the public service.

Regulation 18. Control of manufacture of psychotropic substance.

No person shall manufacture any psychotropic substance unless he is a licensed pharmacist or a pharmacist in the public service or a person working under the immediate personal supervision of a licensed pharmacist or a pharmacist in the public service :

Provided that where in the process of manufacture, any weighing or measuring of any psychotropic substance or any mixing of any psychotropic substance with any other substances is required to be done under the immediate personal supervision of such person, it shall not be deemed to have been done unless such person has himself checked and endorsed in writing such weighing, measuring or mixing

Regulation 19. Records for purposes of medical, dental or animal treatment.

Any person who sells or supplies or administers any psychotropic substance for the purposes of medical or dental treatment of a particular patient or animal treatment of a particular animal shall keep and maintain a register to be called the "Prescription Register For Psychotropic Substance", and shall, on the day such psychotropic substance is sold or supplied or administered, enter or cause to be entered therein true particulars with respect to --

(a) the date on which the psychotropic substance was sold or supplied or administered and the serial number of the entry in such register;
(b) the name and strength of the psychotropic substance and the quantity sold or supplied or administered;
(c) the name and address of the patient, or where the prescriber is a veterinary surgeon or the prescription relates to animal treatment, the name and address of the recipient:

Provided that where such sale or supply is made upon a prescription which is repeated it shall be sufficient to enter in the prescription register for psychotropic substance the quantity of the psychotropic substance sold or supplied, the date and the serial number of the sale or supply originally entered.

Regulation 20. Records for purposes other than medical, dental or animal treatment.

Any person who sells or suplies any psychotropic substance for purposes other than medical or dental treatment of a particular patient or animal treatment of a particular animal shall keep and maintain a register to be called the "Supply Register for Psychotropic Substance", and shall not deliver such psychotropic substance until -

(a) he has entered or cause to be entered in such register true particulars with respect to the full name and address of the prospective purchaser or recipient, the date of the sale or supply, the name, strength and quantity of the psychotropic substance sold or supplied and the purposes for which it is stated to be required; and
(b) the prospective purchaser or recipient has affixed his signature to the entry or has forwarded to the seller or supplier a written order in respect of such sale or supply signed by such person and containing the particulars required to be entered under paragraph (a). Every such written order shall be retained by the seller or supplier and a reference to the file in which such order is retained shall be entered in the supply register for psychotropic substance in place of the prospective purchaser's or recipient's signature.

Regulation 21. Records of manufacture of psychotropic substance.

Any person who manufactures any psychotropic substance shall keep and maintain a register to be called the "Production Register For Psychotropic Substance", and shall enter therein true particulars with respect to -

(a) the date of which the psychotropic substance was used for manufacture and the amount used;
(b) the pharmaceutical dosage form of the psychotropic substance manufactured and the quantity of psychotropic substance found in each unit of the pharmaceutical dosage form;
(c) the theoretical yield of the psychotropic substance in pharmaceutical dosage form manufactured and the batch number assigned to it;
(d) the actual yield of the psychotropic substance in pharmaceutical dosage form manufactured;
(e) the total units of the psychotropic substance in pharmaceutical dosage form sampled for the purpose of quality control; and
(f) the total units of the psychotropic substance in pharmaceutical dosage form transferred for the purpose of sale or supply.

Regulation 22. Keeping and maintenance of register.

Every person who is required to keep and maintain any register under these Regulation -

(a) shall use a separate register or a separate part of the register with respect to each type of psychotropic substance;
(b) shall enter in the register every quantity of psychotropic substance received by him whether for the purpose of sale, supply, manufacture, administration or any other purpose, the total stock of such psychotropic substance in his possession, the name and address of the supplier of such psychotropic substance, and the date on which such psychotropic substance was received by him;
(c) shall not make any cancellation, obliteration or alteration of an entry in any register, and any correction of an entry must be made by way of a marginal note or a footnote which must specify the date on which the correction is made;
(d) shall make the required entry in chronological order with respect to the previous entries in the register;
(e) shall keep the register on the premises to which the register relates to the sale, supply or manufacture or administration of any psychotropic substance in such premises.

Regulation 23. Form of register.

Every register required under these Regulations shall -

(a) be in the form of a bound book or in the form which has the written approval of the Licensing Officer; and
(b) be preserved for a period of two years from the date of the last entry in such register.

Regulation 24. Control of storage of psychotropic substance.

(1) Any person who possesses any psychotropic substance for the purposes of manufacturing,
dispensing, compounding, mixing, sale, supply , education, research or chemical analysis, shall store such psychotropic substance in a room, cabinet, safe or receptacle which shall remain locked except in so far as may necessary to have such room, cabinet, safe or receptacle opened in order to--

(a) carry out the purposes described above in connection with the psychotropic substance stored therein;
(b) keep other psychotropic substance in such room, cabinet, safe or receptacle; or
(c) conduct a stock check of the psychotropic substance stored therein.

(2) Any room, cabinet, safe or receptacle used to store any psychotropic substance shall only be locked and unlocked by the person authorised to possess such psychotropic substance and the keys to such room, cabinet, safe or receptacle shall be kept by him only.

(3) For the purposes of this regulation, any room, cabinet, safe or receptacle used for storing any psychotropic substance shall be so constructed and with reasonably sufficient security measures in order to prevent theft or diversion of the psychotropic substance stored therein.

Regulation 25. Control on disposal of psychotropic substance.

(1) No person who is required to keep and maintain a register under regulation 19, 20 or 21 shall dispose of the psychotropic substance in his possession except in the presence and in accordance with the instructions of a Drug Enforcement Officer.
(2) True particulars of the date of disposal and the quantity of the psychotropic substance which is disposed of shall be entered in the register to which it relates and shall be acknowledged by the Drug Enforcement Officer.
(3) The Drug Enforcement Officer may, for the purpose of analysis, demand, take or obtain a sample of any psychotropic substance which is to be disposed of.
(4) For the purposes of this regulation, "dispose of" and its grammatical variations, in relation to psychotropic substance, mean to bury, burn or otherwise render in a manner with no or negligible risk of recovery.

Regulation 26. Control on labelling of psychotropic substance.

(1) Except as otherwise provided in these Regulations, no person shall keep, have in his possession or under his control, any psychotropic substance otherwise than in a container labelled, in a conspicuous position thereon and in a clear and distinct manner, with--

(a) the name of the psychotropic substance; and
(b) the word "Poison" in Bahasa Malaysia, English, Chinese and Tamil printed in red or in a red background :

Provided that the requirement of paragraph (b) of this regulation shall not apply to a container
which is enclosed in an unbroken case or package as received from the manufacturer of the
psychotropic substance outside Malaysia.

(2) Where any container of any psychotropic substance is enclosed in a box or covering, such box or covering shall be labelled in the same manner as the container :

Provided that nothing in this subregulation shall make it necessary to label any transparent cover or wrapper, or any hamper, packing case, crate or other covering used solely for the purpose of transportation or delivery.

(3) The requirement of paragraph (b) of subregulation (1) shall not apply to any psychotropic substance contained in an ampoule, cacher or similar article, if every box or other covering in which the ampoule, cachet or article is enclosed is duly labelled.

(4) Nothing in this regulation shall apply to any psychotropic substance kept or possessed by, or under the control of, a person in the case where such psychotropic substance was sold or suplied to him by or upon a prescription prescribed by a registered medical practitioner, registered dentist Division I or veterinary surgoen for medical, dental or animal treatment.

Regulation 27. Labelling requirements for purposes other than medical, dental or animal treatment.

No person shall sell or supply any psychotropic substance for purposes other than medical or dental treatment of a particular patient or animal treatment of a particular animal unless the container of such psychotropic substance is labelled conspicously and distinctly -

(a) in the manner specified in subregulation (1) of regulation 26;
(b) in the case of a medicine which contains psychotropic substance as one of the ingredientsthereof -
    (i) with the particulars of the proportion in which the psychotropic substance contained in such medicine bears to the total ingredients;
    (ii) with the warning "Caution: This preparation may be habit forming on prolonged use"; and
(c) with the name of the seller or supplier and the address of the premises on which it was sold or supplied:

Provided that this requirement does not apply in the case of a container which had been labelled with the name of the seller or supplier and the address of the premises on which it was previously sold or supplied.

Regulation 28. Labelling requirement for purposes of medical, dental or animal treatment.

Where any psychotropic substance is sold or supplied for the purpose of medical or dental treatment of a particular patient or animal treatment of a particular animal, the container of such psychotropic substance shall be labelled in a conspicuous and distinct manner with -

(a) the full name and address of the seller or supplier;
(b) the full name of the patient or purchaser;
(c) adequate directions for the use of such psychotropic substance;
(d) the date when such psychotropic substance was sold or supplied; and
(e) the name and strength of the psychotropic substance.

Regulation 29. Order prohibiting possession, sale, supply, etc. of psychotropic substances.

(1) Where -

(a) a person who is a registered pharmacist, registered medical practitioner, registered dentist Division I or veterinary surgeon has been convicted of an offence relating to psychotropic substances under the Ordinance or these Regulations; or

(b) the Minister has reasonable ground to believe that a person who is a registered medical practitioner, registered dentist Division I or a veterinary surgeon is prescribing, administering or supplying or directing the administration of psychotropic substances in an irresponsible manner,the Minister may, subject to and in accordance with regulation 30, make an order under subregulation (2) in respect of that person.

(2) An order under this subregulation in respect of any person shall be an order -

(a) if that person is a registered pharmacist, prohibiting him from having in his possession, selling, supplying, manufacturing, compounding, mixing, dispensing and supervising the manufacture of such psychotropic substances as may be specified in the order;

(b) if that person is a registered medical practitioner, prohibiting him from having in his possession, selling, supplying, prescribing, dispensing, mixing, administering and from directing the administration of such psychotropic substances as may be specified in the order;

(c) if that person is a registered dentist Division I or a veterinary surgeon, prohibiting him from having in his possession, selling, supplying, prescribing, administering and from directing the administration of such psychotropic substances as may be specified in the order.

Regulation 30. Procedure before making an order under regulation 29(2).

(1) Before making an order under subregulation (2) of regulation 29, the Minister shall serve or cause to be served on the person against whom the order is proposed to be made a written notice informing him of -

(a) the terms of the proposed order;
(b) the ground on which the proposed order is to be made; and
(c) his right to make a written representation to the Minister within the period of thirty days beginning with the date of the service of the notice.

(2) If any such representations are received by the Minister within the period aforesaid, he shall refer the case to the relevant advisory committee constituted in accordance with the following provisions of these Regulations; and it shall be the duty of the advisory committee to consider the case and to advise the Minister as to the exercise of his power under subregulation (3).
(3) After the expiration of the period of thirty days and, in the case of a reference to an advisory committee under subregulation (2), after considering the advice of that committee, the Minister may –

(a) make in respect of such person the relevant order under subregulation (2) of regulation 29; or
(b) order that no further proceedings under this regulation shall be taken in the case.

Regulation 31. Provisions supplementary to regulations 29 and 30.

(1) The provisions of the Fourth Schedule shall have effect with respect to the constitution and procedure of any advisory committee appointed for the purpose of regulation 30.

(2) The Minister shall cause a copy of any order made by him under subregulation (2) of regulation 29 to be served on the person to whom it applies and notice of it to be published in the Gazette.

(3) The Minister may by order cancel or suspend any order made by him under subregulation (2) of regulation 29 or cancel any order of his under this subregulation by which the order so made is suspended.

(4) Any order made under subregulation (3), or under subregulation (2) of regulation 29, shall take effect when a copy of it is served on the person to whom it applies or a notice of it is published in the Gazette, whichever is the earlier.

(5) Any person who contravenes any order made under subregulation (2) of section 29 shall be guilty of an offence.

Regulation 32. Exemption for pharmacy assistant and medical assistant.

Notwithstanding the provisions of regulations 3, 11(1) and 17, a pharmacy assistant or, in his absence, a medical assistant, employed in any hospital, clinic or institution wholly maintained by the Government at which human ailments are treated, may -

(a) possess, compound or mix; and
(b) upon a prescription prescribed by a registered medical practitioner or a registered dentist Division I, supply or dispense, any psychotropic substance for the purposes of medical treatmet of a patient:

Provided that such possession, supply, dispensing, compounding or mixing is made or conducted in accordance with the provisions of these Regulations relating thereto.

Regulation 33. Exemption for master of a ship.

(1) The master of any ship is deemed to be authorised to purchase and possess, and a licensed
pharmacist is deemed to be authorised to sell or supply, such limited quantities of any psychotropic substances certified by a Port Health Officer of the port of call of the ship as may be necessary for the equipment of the ship for the purpose of first-aid or emergency cases.
(2) Every such sale or supply made under subregulation (1) shall be made in the manner prescribed under regulation 20, and that the certificate issued by the Port Health Officer shall be taken to mean a signed written order.

Regulation 34. Exemption of fees for government officers.

Any officer of the Government who imports, exports or requires a permit to purchase and use
psychotropic substance in the course of carrying out his duty on account of the Government shall be exempted from any fees specified in these Regulations.

Regulation 35. Duty to give information, etc.

Any person who sells, supplies, manufactures, uses or otherwise has in his possession, any psychotropic substance shall -

(a) answer truthfully any questions and inquires put to him by a Licensing Officer, Drug Enforcement Officer, police officer not below the rank of Inspector or senior officer of Customs with respect to his obtaining, selling, supplying, manufacturing or using psychotropic substances; and
(b) in the case of a person who sells, supplies or manufactures psychotropic substance, disclose or produce to any such officer on demand the stock of psychotropic substance in his possession, and the register, book or other document relating to dealing in any such psychotropic substance.

Regulation 36. Offences for giving of false particulars, etc.

No person shall -

(a) furnish to any Licensing Officer, Drug Enforcement Officer, police officer or senior officer of Customs as true, information which he knows or has reason to believe to be false;
(b) enter in any register required to be kept under these Regulations any particulars which he knows to be false or does not believe to be true;
(c) make a false document for the purpose of obtaining any psychotropic substance;
(d) use as genuine any false document knowing it to be false for the purpose of obtaining the supply of psychotropic substance;
(e) for the purpose of obtaining any psychotropic substance, make a declaration or statement which was false in any particular.

FIRST SCHEDULE

FORM A

(Regulations 5(1), 6(1))

FORM A

APPLICATION FOR AUTHORISATION TO IMPORT / EXPORT* PSYCHOTROPIC SUBSTANCES

The Licensing Officer,
Ministry of Health, Malaysia,
Kuala Lumpur,

I, ... (name of applicant)
a ..... (state profession) practising
at ..... (business address)
hereby apply for an authorisation to import / export * the psychotropic substance(s) specified hereunder.

2. The consignment of psychotropic substance(s) (hereinafter referred to as "the consignment") referred to in this application is to be imported from / exported to * ..... with premises address at ..... and will pass through the Malaysian Custom check point at .....

3. The consignment consists of -
(a) the following psychotropic substance(s) in pharmaceutical dosage form;

Proprietary name	*International Proprietary name (INN) (if any)*	*Dosage form (tablet, ampoule, etc.)*	*Total units of dosage form*	*Account of psychotropic substance in each unit and total equivalent amount as base*

(b) the following psychotropic substance(s) in non-pharmaceutical dosage form:

International Proprietary name (INN), (lacking which the chemical name)	Form (solution, powder, etc.)	Total quantity of form	Total amount of psychotropic substance and equivalent amount as base

4. Enclosed herewith is Money Order / Postal Order / Draft * No ..... for the sum of Ringgit ..... being fee for the import / export authorisation in the event that my application is approved.

I, the undersigned, hereby declare that all the above-mentioned particulars are true and correct in
any respect to the best of my knowledge and belief.

Date : .....

.....
Signature of applicant

* Delete where not applicableFIRST SCHEDULE

FIRST SCHEDULE

FORM B

(Regulation 5(2))

FORM B

CONVENTION OF PSYCHOTROPIC SUBSTANCES 1971
IMPORT AUTHORISATION

Import Authorisation No : .....

In pursuance of regulation 5(2) of the Poisons (Psychotropic Substances) Regulations 1989, I, the Licensing Officer, hereby authorise .....
(here insert name and full postal address of importer)

(hereinafter referred to as "the importer") to import from ..... (here insert name and full address of exporter)

the following psychotropic substance(s) in the specified quantity :
.....
.....
.....
.....
.....

This authorisation is subject to the folowing conditions :

(a) the psychotropic substance(s) shall be imported through the Malaysian Customs check point at ..... ; and

(b) at the time of importation, the psychotropic substance(s) and this authorisation shall be
produced before the Drug Enforcement Officer or any proper officer of Customs, whose endorsement shall be obtained in the space provided in this authorisation.

This authorisation is valid from ..... to .....

Date : .....

.....
Licensing Officer

ENDORSEMENT BY CUSTOMS / DRUG ENFORCEMENT OFFICER

I hereby certify that the psychotropic substances specified in this authorisation have been
duly imported on .....
(Specify amount if it varies from that specified in the authorisation)

Signature : .....

Official Stamp

Name : .....

(Enter particulars below if importation is conducted by agent of importer)

Name of agent : .....

NRIC No. : .....

Signature of agent : .....

FIRST SCHEDULE

FORM C

(Regulation 6(2))

FORM C

CONVENTION ON PSYCHOTROPIC SUBSTANCES 1971
EXPORT AUTHORISATION

Export Authorisation No : .....

In pursuance of regulation 6(2) of the Poison (Psychotropic Substances) Regulations 1989, I, the Licensing Officer, hereby authorise ..... (here insert name and full postal address of exporter)

(hereinafter referred to as "the exporter") to export to ..... (here insert name and address of importer)

the following psychotropic substance(s) in the specified quantity :

.....
.....
.....
.....
.....

This authorisation is subject to the following conditions :

(a) the psychotropic substance(s) shall be exported through the Malaysian Customs check point at .....; and
(b) at the time of exportation, the psychotropic substance(s) and this authorisation shall be produced before the Drug Enforcement Officer or any proper officer of Customs, whose endorsement shall be obtained in the space provided in this authorisation.

This authorisation is valid from ..... to .....

Date : .....

.....
Licensing Officer

ENDORSEMENT BY MALAYSIAN CUSTOM / DRUG ENFORCEMENT OFFICER	ENDORSEMENT BY MALAYSIAN CUSTOM / DRUG ENFORCEMENT OFFICER
I hereby certify that the psychotropic substances specified in this authorization have been duly exported on ..... Signature : ..... Name : ..... Official stamp	I hereby certify that the psychotropic substances specified in this authorization have been duly imported. (Specify amount imported if it varies form that stated in the authorization). Signature : ..... Designation : ..... Date : ..... Official stamp (Please return copy to : The Licensing Officer, Ministry of Health, Malaysia)

SECOND SCHEDULE

(Regulation 9)

LIST OF PSYCHOTROPIC SUBSTANCES TO BE ACCOMPANIED WITH EXPORT AUTHORISATION ON IMPORT OR WHILE IN TRANSIT

1. Amfetamine ((?)-2-amino-1-phenylpropane)

Dexamfetamine ((+)-2-amino-1-phenylpropane)

Fenetylline (dl-3, 7-dihydro-1, 3-dimethyl-7-(2-[(1-methyl-2-phenylethyl) amino] ethyl)-1H-purine-2, 6-dione)

Levamfetamine (l--methylphenethylamine)

Levomethamphetamine (l-N, -dimethylphenethylamine 3-(o-chlorophenyl)-2-methyl-4 (3H)-quinazolinone)

Mecloqualone (3-(o-chlorophenyl)-2-methyl-4 (3H)-quinazolinone)

Methamfetamine ((+)-2-Methylamino-1-phenylpropane)

Methamphetamine racemate ((?)-N, -dimethylphenethylamine)

Methaqualone (2-methyl-3-o-tolyl-4 (3H)-quinazolinone)

Methylphenidate (2-phenyl-2-(2-piperidyl) acetic acid, methylester)

Phencyclidine (1-(1-phenylcyclohexyl) piperidine)

Phenmetrazine (3-methyl-2-phenylmorpholine)

Secobarbital (5-allyl-5-(1-methylbutyl) barbituric acid)

2. The salts of the substances specified in paragraph 1 of this Schedule wherever the existence of such salt is possible.

3. Any preparation, solution, compound, mixture or product containing one or more of the substances specified in paragraphs 1 and 2 of this Schedule.

THIRD SCHEDULE

FORM D

(Regulation 15(1))

FORM D

APPLICATION FOR A PERMIT TO PURCHASE AND USE PSYCHOTROPIC SUBSTANCES

To : The Licensing Officer

Through : .....
.....
.....
.....

I, ..., being engaged in the business of whose business address is
.....
hereby apply for a permit to purchase and use the following .....psychotropic substance(s) :

International proprietary Name (INN) and form	*Strength*	*Quantity*	**Official use**

for the purpose of .....

2. Enclosed herewith is Money Order / Postal Order / Draft * No for the sum of Ringgit ..... being .....
fee for the above-mentioned permit.

Date : .....

.....
Signature of applicant

THIRD SCHEDULE

FORM E

(Regulation 15(2))

FORM E

PERMIT TO PURCHASE AND USE PSYCHOTROPIC SUBSTANCE

Permit No. .....

In pursuance of regulation 15(1) of the Poisons (Psychotropic Substances) Regulations 1989,
I, the Licensing Officer, hereby Grant this permit to ..... to purchase thefollowing psychotropic substance(s) not exceeding the amount specified:

to be used only for the purpose of ..... and subject to the conditions overleaf.

This permit is valid from ..... to .....

Date : .....

.....
Licensing Officer

CONDITIONS OF PERMIT

1. The permit holder shall maintain a bound record book or a separate part of such record book for each of the psychotropic substance specified in this permit, and shall enter therein the name and form of the psychotropic substance, name and address of supplier, date and amount received, date and amount used and stock in balance.

2. The permit holder shall inform the Licensing Officer by registered post of each purchase of psychotropic substance made, not later than fourteen days after the receipt of the psychotropic substance stating the name and form of psychotropic substance received, amount and date received, and the name and address of supplier.

FOURTH SCHEDULE

(Regulation 31)

1. The advisory committee shall consist of -

(a) in the case of a registered pharmacist, the Director General of Health, the Director of Pharmaceutical Services, and two registered pharmacists not in the public service appointed by the Minister;

(b) in the case of a registered medical practitioner, the Director General of Health, The Director of
Medical Services, and two registered medical practitioners not in the public service appointed by the Minister;

(c) in the case of a registered dentist Division I, the Director General of Health, the Director of Dental Services, and two registered dentists Division I not in the public service appointed by the Minister; and

(d) in the case of a veterinary surgeon, the Director General of Health, the Director of Veterinary Services, and two veterinary surgeons not in the public service appointed by the Minister.

2. (1) The person against whom the order is to be made shall be entitled to appear before and be heard by the advisory committee in person.

(2) An advisory committee may regulate its own procedure.

Made the 14th November 1988.

LAWS OF MALAYSIA

Act 366

POISON ACT 1952

An Act to regulate the importation, possession, manufacture, compounding, storage, transport, sale and use of poisons.

[West Malaysia – 1st September 1952;
East Malaysia – 1 st June 1978]

Short title and application

1. (1) This Act may be cited as the Poisons Act 1952.

(2) This Act shall apply throughout Malaysia.

Interpretation

2. (1) In this Act unless the context otherwise requires –

"Acetylating substance" includes acetic anhydride, acetyl chloride and acetyl bromide;

"animal treatment" means the treatment of animal ailments;

"British Pharmacopoeia" and "British Pharmaceutical Codex" respectively include supplements thereto;

"compounding", and its grammatical variations, mean the preparation, weighing, measuring and mixing if necessary of drugs and chemical for the treatment of ailments;

"contravention" of a provision includes a failure to comply with such provision;

"conveyance" includes ship, train, vehicle, aircraft or any other means of transport by which persons or goods can be carried;

"dental treatment" means the treatment of human ailments of the teeth or jaws or accessory structures or the performance of operations or the giving of treatment commonly undertaken or given by those practising dentistry;

"Director General of Health" means the Director General of Health, Malaysia;

"dispensed medicine" means medicine supplied by a registered medical practitioner, registered dentist or veterinary surgeon under and in accordance with section 19 or supplied, for the purpose of the medical, dental or animal treatment, of a particular individual by a licensed pharmacist on the premises specified in his licence;

"Drug Enforcement Officer" means any registered pharmacist in the public service duly authorized in writing by the Licensing Officer under section 31 (1);

"estate" means any agricultural land exceeding twenty-five acres in extent upon which agricultural operations of any kind are carried on or upon which the produce of any plants or trees is collected or treated or any mine to which the provisions of Part IX of the Labour Code of the Federated Malay States [F.M.S. cap 154] or any of such provisions or any provisions, corresponding to such provisions, in force in any State have been lawfully applied;

"estate hospital" means a horpsital or dispensary maintained by an employer on or in the neighbourhood of an estate for the treatment of labourers thereon and includes a group hospital within the meaning of the Labour Code of the Federated Malay States [F.M.S. cap 154] or of any written law in any State corresponding thereto;

"Exempted preparation" means a preparation containing a poison of the kind or having the strength or otherwise coming within the description specified in the last column of the Poisons List entitled "Exempted Preparations";

"generally accepted name" means the name by which a substance is generally known in the trade;

"a Group A Poison" "a Group B Poison" "a Group C Poison" "a Group D Poison" "a Group E Poison" and "a Group F Poison" respectively means a poison having the strength or otherwise coming within the description specified in the column of the Poisons List entitle Group A, Group B, Group C, Group D, Group E or Group F respectively opposite to the name of such poison appearing in the first column of the Poisons List;

"Licesing Officer" means a person appointed to be a Licensing Officer under section 26 and includes the Director General of Health;

"licensed pharmacist" means a registered pharmacist who is the holder of a Type A Licence issued to him under section 26;

"licensed retailer" means a person holding a licence issued to him under section 26 to sell poisons by retail and includes a listed seller;

"licensed wholesaler" means a person holding a licence issued to him under section 26 to sell poisons by wholesale;

"listed seller" means a person holding a Type C Licence issued to him under section 26;

"manufacture" and its grammatical variations, mean the preparation, compounding, mixing and making of a pharmaceutical preparation in bulk but does not include the dispensing of a pharmaceutical preparation for a particular individual;

"medical treatment" means the treatment of human ailments"

"Minister" means the Minister charged with the responsibility for medical and health services;

"Part I Poison" means a Group A, Group B, Group C, Group D, Group E or Group F poison specified in the column of the Poisons List entitled "Part I' of the First Schedule;

"Part II Poison" means a poison specified in the column of the Poisons List entitled "Part II" of the First Schedule;

"poison" means any substance specified by name in the first column of the Poisons List and includes any preparation, solution, compound, mixture or natural substance

containing such substance, other than an exempted preparation or an article or preparation included for the time being in the Second Schedule;

"Poisons List" means the Poisons List set out in the First Schedule as amended from time to time in accordance with section 6;

"possess for sale" and its grammatical variations include having in possession knowing that the article possessed is likely to be sold or exposed for sale;

"premises" includes any house, shop, store, room, cubicle, shed, conveyance, structure or any place whether open or enclosed;

"retail sale" means any sale other than a wholesale sale;

"registered dentist" means a dental practitioner registered in Division I or Division II of the Register kept under section 11 (1) of the Dental Act 1971 [Act 51]; and "registered dentist Division I" and "registered dentist Division II" means a dental practitioner whose name has been registered in the first or second division respectively of the said Register;

"registered medical practitioner" means a medical practitioner registered under the Medical Act 1971;

"registered pharmacist" means a pharmacist registered under any written law relating to the registration of pharmacists, and inclues, in Sabah or Sarawak, a person holding a qualification recognized by the Director of Medical Services in Sabah or Sarawak, as the case may be, as a sufficient guarantee of the possession of the requisite knowledge and skill for the efficient practice of the profession of a pharmacist;

"sell" or "sale" includes barter and also includes offering or attempting to sell;

"supply" includes the supply of commercial samples and dispensed medicines, but does not include the direct adminisration by or under the immediate personal supervision of a registered medical practitioner or registered entist of a poison or medicine to his patient in the course of treatment where such administration is authorized under section 19;

"veterinary officer" has the meaning assigned thereto in the Veterinary Surgeons Act 1974 [Act 147] ;

"West Malaysia" has the meaning assigned thereto in section 3 of the Interpretation Act 1967 [Act 23/67], and includes the Federal Territory of Kuala Lumpur and Labuan;

"wholesale" means a sale to any person who intends to sell again and any sale by a licensed wholesaler authorized by paragraphs (d) to (j) inclusive of section 15 (2);

"written law" has the meaning assigned thereto in the Interpretation Act 1967.

(2) In this Act where anything is required to be done under the immediate personal supervision of any person it shall be deemed to have been so done if such person was at the time it was done upon the premises where it was done and available for immediate consultation by the person doing such thing:

Provided that where any dispensing compounding or mixing of any poison with any other substance is required to be done under the immediate personal supervision of any person, it shall not be deemed to have been so done unless such person has himself checked such dispensing, compounding or mixing.

Establishment of Poisons Board

3. (1) For the purpose of this Act and to advise the Minister generally thereon, there shall be established an advisory board, called the Poisons Board, consistingt of the members following –

(a) the Director General of Health who shall be an ex-officio member;

(b) one pharmacist holding office in the service of the Government to be appointed by the Minister.

(c) One officer of the Department of Chemistry to be appointed by the Minister;

(d) One officer of the Department of Agriculture to be appointed by the Minister;

(e) One officer of the Veterinary Department holding office in the service of the Government to be appointed by the Minister; and

(f) eight persons ordinarily resident in Malaysia and not in the service of any Government in the Federation to be appointed by the Minister who shall be nominated as follows –

(i) one by the Malaysian Medical Association;

(ii) one by the Malaysian Medical Council established under the Medical Act 1971;

(iii) one by the Malaysian International Chamber of Commerce and Industry;

(iv) one by the Associated Chinese Chambers of Commerce and Industry of Malaysia;

(v) one by the Malaysia Chambers of Commerce

(vi) one by the Associated Indian Chambers of Commerce, Malaysia

(vii) one by the Malaysian Pharmaceutical Association; and

(viii) one by the Malaysian Rubber Producer's Council.

(2) Every member, other than the ex-officio members, shall, unless he shall sooner resign, hold office for a period of three years or such shorter period as the Minister may in any particular case determine from the date of his appointment.

(3) Any person ceasing to be member of the Board shall be eligible for re-appointment.

(4) The Minister may appointment a person similarly qualified to be a temporary member of the Board during the incapacity through illness or during the absence from Malaysia of any member, other than an ex-officio member, of the Board:

Provided that no person shall be appointed in the place of a member nominated under subsection (1) (g) except upon the nomination by the body by which such member was nominated.

(5) Every such temporary member shall be deemed to be a member of the Board.

Proceedings of Board

4. (1) The Director General of Health shall be the Chairman of the Poisons Board and shall preside at all meetings which he attends.

(2) In the absence of the Chairman from any meeting the members present shall elect one of their memgbers to preside.

(3) The Chairman or member presiding at any meeting shall have an original vote and also, if upon any question the votes are equally divided, a casting vote.

(4) The Board shall meet at such places and times as the Chairman may appoint and at any meeting four members including the Chairman or memgber presiding shall form a quorum.

(5) The Board may invite any one or more persons to attend any meeting of the Board but a person so attending shall not have the right to vote at the meeting.

(6) There may be paid to members of the Board such allowances and other expenses as may be determined by the Board with the approval of the Minister and such allowances and expenses shall be payable out of the general revenues of the Federation.

(7) The Minister may, after consultation with the Board, appoint a Secretary to the Board who shall not be a member of the Board or have any right to vote at its meetings.

Powers of Board to regulate proceedings

5. (1) Subject to this Act the Poisons Board shall have power to regulate its own procedure.

(2) No action or proceeding of the Board shall be questioned on the ground –

(a) of the existence of any vacancy in the membership or any defect in the constitution of the Board; or

(b) of any ommission, defect or irregularity in procedure not affecting the merits of the case.

Power of Minister to amend Poisons List

6. The Minister may, from time to time, after consultation with the Poisons Board by order notified in the Gazette, add to, remove from or reinstate in the Poisons List any substance as he may deem fit or proper, or remove from transfer to or include in any column of the Poisons List any poison, or exempted preparation or amend any definition of any poison or exempted preparation contained in such list or in any column thereof.

Application of the Act

7. (1) Nothing in this Act shall apply –

(a) to any exempted preparation; or

(b) to any article or preparation specified in the Second Schedule.

(2) The Minister may, from time to time, after consultation with the Poisons Board by order notified in the Gazette, add to or remove from the Second Schedule any article or preparation.

(3) Save in so far as is expressly provided by any regulation made under this Act, this Act shall not apply to the sale or supply of any poison or of any medicine containing poison by any officer or person, who

(a) is employed in any hospital, infirmary, dispensary or veterinary hospital wholly maintained by the Government of Malaysia or any State Government or by any local authority or out of public funds or by a charity approved by an order, whether general or special, of the Director General of Health, and who sells or supplies in the course of his duty such poison or medicine to any out-patient of such hospital, infirmary or dispensary for the medical or dental treatment of such patient or, in the case of an officer or person employed in a veterinary hospital, to any person for the animal treatment of any animal tended by him; or

(b) is employed in any hospital, infirmary, dispensary, clinic, nursing home or other institution at which human ailments are treated, and who sells or supplies in the course of his duty such poison or medicine for the use in the wards, operating theatres or other sections thereof:

Provided that such sale or supply is made and conducted in accordance with any regulations expressly applicable thereto made under this Act..

Control of imports of poisons

8. (1) No person other than a person licensed under this Act in that behalf shall import any poison from any place outside Malaysia.

(2) This section shall not apply to –

(a) any person arriving in Malaysia from a place outside Malaysia who imports, as part of his personal luggage and solely for his personal use or for the use of his family, a prepared or packaged medicine containing any poison, not exceeding such quantities as may be reasonably required for one month's use by one person; and

(b) any person importing a prepared or packaged medicine containing any poison for his own personal use or for that of his family by letter or parcel post, in such quantities and subject to such conditions as may be prescribed by regulations made under this Act; and

(c) any officer of the Government importing in the course of his duty any poison on account of the Government; and

(d) any other person whom the Minsiter may absolutely or conditionally exempt from the provisions of this section.

(3) Any person who imports any poison in contravention of this section or who contravenes any term or condition of any licence granted to him or the provisions of any regulation made or any condition of any exemption granted to him under this section shall be guilty of an offence against this Act.

Packaging, labelling and storing of poisons

9. (1) No person, whether licensed under this Act or not, shall knowingly sell, supply, keep or have in his possession or under his control or store any poison otherwise than in accordance with the regulations made under this Act and in force relating to the possession, containers, packaging, labelling or storing of such poison.

(2) In any proceedings under this section if any person is proved to have sold, kept or had in his possession or under his control or stored any poison he shall be deemed to have done so knowingly, unless the contrary is proved by him.

(3) Any person who contravenes subsection (1) shall be guilty of an offence against this Act.

Transport of poisons

10. No person shall transport or consign for transport any poison otherwise than in accordance with the regulations made under this Act.

Control of manufacture of preparations containing poisons

11. No preparation containing any poison shall be manufactured otherwise than in accordance with the regulations made under this Act.

Control of compounding of poisons for use in medical treatment

12. (1) No person shall dispense, compound or mix any poison with any other substance, whether a poison or not, for the purpose of its being used for medical treatment unless he is –

(a) a registered pharmacist or a person working under the immediate personal supervision of a registered pharmacist;

(b) a person acting in the course of his duties who is employed in a hospital or dispensary maintained by the Government of Malaysia or any State Government or out of public funds or by a charity approved by an order whether general or special of the Director General of Health or in an estate hospital and who is authorized in writing by the registered medical practitioner for the time being in charge of such hospital or dispensary to dispense, compound and mix poison; or

(c) a registered medical practitioner or a person working under the immediate personal supervision of such a practitioner who dispenses, compounds or mixes poisons for the use of such practitioner or of his patients.

(2) No poison shall be dispensed, compounded or mixed with any other substance whether a poison or not otherwise than ini accordance with any regulations made under this Act.

Possession for sale of poison and sale of poison in contravention of this Act an offence

13. Any person who –

(a) possesses for sale any poison, unless he is licensed under this Act to sell or supply such poison or authorized under section 18 to sell or supply such poison; or

(b) sells or supplies any poison in contravention of, or otherwise than in accordance with, this Act, or of any regulations made thereunder or of the terms and conditions of any licence issued to him under this Act, relating to the sale or supply of poison, or relating to the sale or supply of poison included in that Part or Group ofr the Poisons List in which the poison so sold or supplied is included.

Shall be guilty of an offence against this Act.

Control of acetylating substances

14. (1) Any person who has in his possession an acetylating substance shall be guilty of an offence against this Act unless he proves –

(a) that he is licensed under this Act;

(b) that he is authorized under this Act; or

(c) that the acetylating substance is in his possession for a lawful purpose.

(2) In any procution for an offence under this section, any person who is found to have in his custody or under his control any acetylating substance shall be deemed to have been in possession of the substance and to have known the nature of the substance, until he proves to the contrary.

(3) Any person convicted of an offence against this section shall be liable to imprisonment for a term not exceeding fourteen years and not less than three years, and he shall also be punished with whipping of not less than six strokes.

(4) Notwithstanding any other provision in any other written law to the contrary, a person charged under this section shall not be granted bail.

Sale of poisons by wholesale

15. (1) No poison shall be sold by wholesale except by a licensed wholesaler in accordance with the term and conditions of his licence.

(2) No poison shall be sold by a licensed wholesaler except to –

(a) a person licensed to retail such poison;

(b) a purchaser outside Malaysia to whom such poison is to be imeediately exported on sale;

(c) another licensed wholesaler;

(d) the owner of the manager acting on behalf of the owner of any estate for the purpose of the business of such estate or for enabling such owner, or his manager acting on his behalf, to comply with any requirements made by or under any written law with respect to the medical treatment of persons employed on such estate; or

(e) a professional person or tradesman for the purpose of such person's of trademan's profession or trade oand not for resale;

(f) a registered medical practitioner or registered dentist for the treatment of his patients or a veterinary surgeon for the treatment of any animal which such surgeon is employed to treat;

(g) a licensed pharmacist;

(h) a Government Department, local authority or public body;

(i) a hospital, infirmary, dispensary or veterinary hospital maintained by the Government of Malaysia or any State Government or by any local authority or out of public funds or by a charity approved by an order, whether general or special, of the Director General of Health;

(j) a person or institution concerned with scientific education or research or chemical analysis for the purpose of such education, research or analysis.

(3) The seller by wholesale of any poison shall not deliver it until –

(a) he has made or caused to be made an entry in a book to kept for such purpose, in the prescribed form, stating the name and address of the purchaser, the date of the sale, the name and quantity of the poison sold and the purposes for which it is stated by the purchaser to be required; and

(b) the purchaser has affixed his signature to the entry or has forwarded to the seller a written order in respect of such sale signed by the purchaser and containing the particulars required to be entered under this subsection. Every such written order shall be retained by the seller and a reference to the file in which such order is retained shall be entered in the book in place of the purchaser's signature.

(4) Notwithstanding the provisions of subsection (3), if it shall appear to the seller that any poison is required urgently and that it is imposible or unreasonable to obtain the signature of the purchaser or his signed written order before delivery thereof, it shall be lawful for the seller, after making an entry in the book stating the reasonable for his action and the date of delivery, to deliver such poison to the purchaser without such signature or order;

Provided that, in every such case, the seller shall take all necessary steps to obtain, and the purchaser shall forward, a written order signed by the purchaser in respect of such sale, within seven days of the date of such delivery.

(5) Any purchaser who fails or neglects to forward to the seller a written order duly signed by him within the time prescribed by the proviso to subsection (4) in respect of any poison delivered to him under the provisions of such subsection shall be quilty of an offence against this Act.

(6) Nothing in this section shall be held to authorize the sale by wholesale of any particular kind of poison otherwise than in accordance with this Act or of any regulatons made thereunder relating to such kind a poison.

(7) Any person who sells or delivers any poison by wholesale in contravention of this section shall be guilty of an offence against this Act.

Sale of poisons by retail

16. (1) Subject to section 18 no poison shall be sold by retail except by a person licensed to sell such poison by retail and in accordance with the terms and conditions of such licence.

(2) Every such sale shall be effected on the premises specified in such licence.

(3) Every such sale shall be effected by or under the immediate personal supervision of the person named in such licence.

(4) Every such sale shall be effected in accordance with this Act and of any regulations made thereunder relating to such poison.

(5) Any person who sells any poison by retail in contravention of this section shall be guilty of an offence under this Act.

Prohibition of sale to persons under 18

17. (1) No poison shall be sold or supplied to any person under eighteen years of age, otherwise than for purpose of the medical treatment of such person.

(2) Any person contravening this section shall be guilty of an offence against this Act.

(3) It shall be a sufficient defence to any charge under this section that the person charged had reasonable cause to believe that the person to whom such sale was made was above the age of eighteen years.

Restriction on the sale of Part I poisons generally

18. (1) Part I Poison shall not be sold or supplied to any person except –

(a) by wholesale in accordance with section 15; or

(b) by retail sale effected by or under the immediate personal supervision of a licensed pharmacists;

Provided that a group F Poison may be sold or under the immediate personal supervision of a listed seller as well as by a licensed pharmacist; or

(c) as an ingredient of a dispensed medicine, by a registered medical practitioner, registered dentist or veterinary surgeon in accordance with section 19; or

(d) to be exported to purchasers outside Malaysia; or

(e) to a person or institution concerned with scientific education or research or chemical analysis and for the purpose of such education research or analysis.

(2) Nothing in this section shall be deemed to authorize the sale of any kind of poison otherwise than in accordance with this Act or of any regulations made thereunder relating to such kind of poison or otherwise than in accordance with the terms and conditions of the licence in that behalf held by the seller.

Supply of poisons for the purpose of treatment by professional men

19. (1) Any poison other than a Group A Poison may be sold, supplied or administered by the following persons for the following purposes –

(a) a registered medical practitioner may sell, supply or administer such poison to his patient for the purposes of the medical treatment of such patient only;

(b) a registered dentist Division I may sell, supply or administer such poison to his patient for the purposes of the dental treatment of such patient only; and

(c) a veterinary officer may sell or supply such poison to his client for the purposes of animal treatment only.

(2) A registered dentist Division II may sell, supply or administer to his patient for the purposes of the dental treatment of such patient only any poison other than a Group A of a Group B Poison.

(3) Every medicine containing any poison sold or supply supplied under subsection (1) or (2) shall be prepared by or under the immediate personal supervision of such practitioner, dentist of veterinary officer, as the case may be:

Provided that any medicine, received by such practitioner, dentist of veterinary officer in a prepared state from a manufracturer or wholesaler, shall be deemed, for the purposes of this section, to have been prepared by such practitioner, dentist or veterinary officer respectively, if the receptacle containing such medicine is labelled by or under the immediate personal supervision of such practitioner, dentist or veterinary officer in such manner as may be prescribed by regulations made under this Act, relating to the labelling of dispensed medicines.

(4) Any medical practitioner, dentist or veterinary officer who sells or supplies any poison or medicine containing a poison not prepared by him or under his immediate personal supervision shall be guilty of an offence against this Act.

Group A Poisons

20. Group A Poison shall not be sold or supplied by wholesale or retail except;

(a) by a licensed wholesaler to a licensed pharmacist or to another licensed wholesaler; or

(b) by a licensed wholesaler to be immediately exported to a purchase outside Malaysia.

Group B Poisons

21. (1) Group B Poison shall not be sold or supplied by retail to any person except:

(a) where the sale or supply of such poison, if it had been a Group A Poison, would have been authorized under section 20;

(b) by registered medical practitioner, registered dentist Division I or veterinary officer selling or supplying the same in accordance with section 19; or

(c) by a licensed pharmacist, as a dispensed medicine on and in accordance with a prescription prescribed by a registered medical practitioner, registered dentist or veterinary officer in the form required by subsection (2) and when

supplied in accordance with this Act and of any regulations made thereunder relating to such sale or supply on a prescription.

Form of Prescription for Group B Poison

(2) Every prescription for any Group B Poison prescribed by a registered medical practitioner, registered dentist, or registered veterinary officer shall:

(a) be in writing signed and dated by the prescriber thereof;

(b) state the address of the prescriber;

(c) state the name and address of the patient or, in the case of a prescription by a veterinary officer, the name and address of the person to whom such medicine is to be delivered.

(d) Indicate the total amount of medicine to be supplied and the dose; and

(e) specify the number of times (not exceeding three) the medicine may be dispensed and, if dispensed more than once, at what intervals.

(3) No person shall sell or supply by retail any Group B Poison on a prescription which does not comply with all the requirements of subsection (1) or whtich contravenes subsection (5) or shall sell or supply such poison otherwise than in accordance with the terms of such prescription.

(4) Every person selling or supplying any Group B Poison on a prescription shall, at the time of selling or supplying the same, endorse upon the face of the prescription, above the signature of the prescriber, his name and address and the date on which such poison or medicine was sold or supplied.

(5) No rescription for any Group B Poison shal be written wholly or partly in code or in such manner that it is not readily decipherable and capable of being dispensed by any pharmacist.

(6) Notwithstanding the provisions of the foregoing subsection of this section, if it shall appear to the seller or supplier that any medicine is required urgently and that it is imposible without unreasonable delay to obtain a prescription complying with the requirements of subsection (1)' it shall be lawful for the seller or supplier' after making an entry to that effect in his prescription book, upon the verbal or telephoned instructions of a medical practitioner, personally known to him, to sell or supply such poison without such prescription:

Provided that in every such case the seller or supplier shall take all necessary steps to obtain, and the prescriber shall deliver, a prescription in accordance with subsection (1) within one day of the date of such sale of supply.

(7) Any person, selling or supplying any Group B Poison in contravention of this section, of failing or neglecting to endorse such prescription as required by subsection (4), or writing any prescription in code or otherwise in contravention of subsection (5), or failing to take any necessary step to obtain, or failing to deliver, the prescription as required by subsection (6), shall be guilty of an offence against this Act.

Group C Poisons

21. Group C Poison shall not be sold or supplied by retail to any person except:

(a) where the sale or supply of such poison, if it had been a Group B Poison, would have been authorized under or by virtue of, and is effecdted in accordance with section 21; or

(b) as a dispensed medicine or an ingredient in a dispensed medicine.

Group D Poisons

23. (1) Group D Poison shall not be sold or supplied by retail to any person except:

(a) where the sale or supply of such poison, if it had been a Group C Poison, would have been wuthorized under or by virtue of section 22; or

(b) by a licensed pharmacist to a person known personally to such pharmacist or introduced to the pharmacist personally by a person known personally to the pharmacist and when such poison is sold or supplied in accordance with this section and of any regulations made under this Act relating to such sale of supply.

Poisons Book

(2) Where any Group D Poison is sold to any person by a retailer otherwise than as a dispensed medicine or an ingredient in a dispense medicine, the retailer shall not deliver it until –

(a) he has made or caused to be made an entry in a book to be kept for such purpose in the prescribed form (in this Act referred to as the "Poison Book") stating the name and address of the purchaser and the name and address of the person (if any) introducing such purchaser, the date of the sale, the name and quantity of the poison sold and the purposes for which it is stated by the purchaser to be required; and

(b) the purchaser has affixed his signature to the entry or has forwarded to the retailer a written order in respect of such sale signed by the purchaser containing the particulars required to be entered in the Poisons Book under this section. Every such written order shall be retained by the seller and a reference to the file in which such order is retained shall be entered in the book in the place of the purchaser's signature.

(3) Notwithstanding subsection (2) if it shall appear to the retailer that any such poison is required urgently and that it is impossible or unreasonable to obtain the signature of the purchaser or his signed written order before delivery thereof it shall be lawful for the retailer after making an entry in the Poisons Book stating the reasons for his action and the date of delivery to deliver such poison to the purchaser without such order or signature.

Provided that in every such case the retailer shall take all necessary steps to obtain, and the purchaser shall forward, a written order signed by the purchaser in respect of such sale within seven days of the date of such delivery.

(4) Any purchaser who fails or neglects to forward to the seller a written order, duly signed by him, within the time prescribed by subsection (3), in respect of any poison delivered to him under the provisions of such subsection, shall be guilty of an offence against this Act.

(5) Subsection (3), any retailer who delivers to any person any Group D Poison in contravention of subsection (2) shall be guilty of an offence against this Act.

Prescription book

24. (1) Where any poison is sold or supplied as a dispensed medicine or as an ingredient in a dispensed medicine, the seller or supplier shall, on the day on which such poison or medicine is sold or supplied, enter or cause to be entered in a book, kept for such purpose (in this Act referred to as the "Prescription Book") –

(a) the date on which the medicine was sold or supplied and the serial number of the entry in such book of the prescription (if any);

(b) the name of the popison and the ingredients of the medicine or, in the case of a proprietary medicine, the name of the medicine and the quantity supplied;

(c) in the case of a sale or supply by a retailer on a prescription, the name of the patient, or, when the prescriber is a veterinary officer, or the prescription relates to animal treatment, the name of the recipient; and

(d) in the case of a sale or supply as a dispensed medicine otherwise than on a prescription, the name and address of the person to whom it was sold or supplied;

Provided that when a prescription is repeated it shall be sufficient to enter in the prescription book the date, the serial number of the sale, supply and prescription (if any) originally entered and the name of the patient or recipient.

(2) In this section "prescription" means any written or oral instruction to the seller or supplier to supply any poison, or medicine containing any poison, for the purpose of the medical, dental or animal treatment of any person or animal, given by any person; and "prescriber" means the person giving such instructions or causing such intructions to be given to the seller or supplier.

(3) If any prescription is given orally, such prescription shall be confirmed by a written prescription within one day.

Sale of Part II Poisons

25. (1) No person shall sell or supply any Part II Poison otherwise than in accordance with this Act and of any regulations made thereunder.

(2) No person, licensed to sell Part II Poison only, shall sell any arsenical or mercurial poison to any person, unless such person is engaged in agriculture, horticulture or the trade or business of curing skins or hides or the preservation of buildings or other structures, liable to be destroyed by insects, and requires such poison for the purpose of such agriculture, horticulture, trade or business.

(3) Any person selling or supplying any Part II Poison in contravention of subsection (1) or (2) shall be guilty of an offence against this Act.

Licences

26. (1) The Director General of Health, or the Director of Pharmaceutical Services or the Director of Medical and Health Services of any State duly appointed in writing by the Director General of Health to be a licensing Officer of any State or the Federal Territory may, subject to this Act, issue licences for purposes of this Act.

(2) Such licences may be –

(a) a Type A licence issued to a pharmacist to import, store and deal generally by wholesale and retail or by wholesale only or by retail only, subject to this Act, in all poisons;

(b) Type B licence issued to any person whorm the Licensing Officer may consider to be a fit and proper person to hold such licence, or issued to a responsible officer of a company incorporated under the Companies Act 1965 to import, store and sell by wholesale such poisons (not being a Group A Poison) as may be specified in such licence;

\Provided that no such licence shall be issued to any person or officer who is engaged or concerned in any business of selling goods by retail or shall continue valid at any time after such person or officer becomes so engaged or concerned;

(c) a Type C licence issued to any person (in this Act referred to as "a listed seller"), whom the Licensing Officer may consider to be a fit and proper person to hold such licence, to store and sell by retail Group F Poisons only:

Provided that no such licence shall be issued within a local authoruty area unless there is no pharmacist, licensed to sell by retail, carrying on business within such area;

(d) a Type D licence issued to any person, whom the Licensing Officer may consider to be a fit and proper person to hold such licence, to store and sell by retail such Part II Poisonss as may be specified therein;

(e) A Type E licence issued to any person who in the course of his business uses Sodium Hydroxide in such substantial quantity that the Licensing Officer deems it appropriate to issue to him a licence to import, store ande use Sodium Hydroxide.

(3) Every such licence shall be substantially in the form prescribed applicable to the type of such licence and shall state the name of the person to whom it is issued, and the premises on which any sale or use may be effected, and the period for which such licence is valid.

(4) Every such licence shall be subject to such terms and conditions, not inconsistent with this Act or of any regulations made thereunder, as the Licensing Officer may in his discretion impose, subject however in all cases to appeal to the Minister.

(5) The Licensing Officer may, in his discretion, refuse to issue any such licence or may cancel any such licence previously issued:

Provided that any person aggrieved by the refusal of the Licensing Officer to issue a licence or by the cancellation of a licence may appeal to the Minister whose decision shall be final.

(6) Every such licence shall be personal to the licensee named therein and shall not in any case, be transferable to another person and no licence shall authorise the sale of any poison by any person other than the person named therein or otherwise than under his personal supervision, provided that the Licensing Officer, if he sees fit, may amend on a licence the address of the premises at which the person licensed carries on the business or profession in respect of which he is licensed.

Register of licences

27. (1) Every licence, issued under this Act by a Licensing Officer for any State in such State, shall be numbered consecutively in respect of each type and of the year in which it was issued, commencing each year with the number one.

(2) The Licensing Officer for each State shall keep a register of licences issued by showing all the particulars of each licence so issued, and the entries in such register shall be numbered to correspond with the serial numbers of the licences and there shall be noted in the register, in the event of the cancellation of any licence, the date of such cancellation.

(3) Any extract from or copy of an entry in a register kept under this section shall be prima facie evidence of the facts stated therein, if such extract or copy is certified under the hand of the Licencing Officer to be a true extract of copy.

Annual list to be published

28. (1) The Director General of Health shall, in or about the month of February in each year, cauce to be printed and published, in the Gazette, list of all persons, named in aphabetical order, licensed under this Act together with particulars of the nature of the licence or licences issued to each such person, and specifying the profession or business and the premises in respect of which such licences have been issued.

(2) Every list so published shall be prima facie evidence that, at the date to which such list relates, the persons therin named are or were licensed under this Act in the manner stated in such list, and that any person not named therein is or was not licensed under this Act.

Control of the import manufacture and sale of lead tetra ethyl

29. (1) In this section –

"lead tetra ethyl" includes other similar lead containing compounds used as ingredients of motor fuel;

"ethyl petrol" means motor spirit containing lead tetra ethyl

"concentrated ethyl fluid" means any fluid containing lead tetra ethyl in a proportion exceeding one part to nine hundred and fifty parts in volume.

(2) Notwithstanding any other provisions, including section 7 of this Act, or of any licence issued under any other provisions of this Act, no person shall manufacture lead tetra ethyl or sell, import, possess or use any ethyl petrol or concentrated ethyl fluid

otherwise than in accordance with any regulations applicable thereto made under this Act.

**Control of import, export, manufacture, sale, etc.
Of psychotropic substances**

30. (1) In this section, "psychotropic substance" means any of the substances specified in the Third Schedule.

(2) The Minister may, from time to time, after consultation with the Poisons Board, by order publisehd in the Gazette amend the Third Schedule.

(3) Notwithstanding any other provisions in this Act, no person shall import, export, manufacture, compound, mix, dispense, sell, supply, administer, possess or use any psychotropic substance otherwise than in accordance with any regulations applicable thereto made under this Act.

(4) In any prosecution for an offence under this section, any person who is found to have in his custody or under his control any psychotropic substance shall be deemed to have been in possession of the substance and to have known the nature of the substance, until he proves the contrary.

(5) Any person who contravenes subsection (3) or any regulations made under this Act relating to psychotropic substances shall be guilty of an offence and shall, on conviction, be liable to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding four years or both.

**Powers of investigation, examination and
entry into premises**

31. (1) The Licencing Officer may authorize in writing any registered pharmacist in the public service to exercise the powers of a Drug Enforcement Officer under this Act.

(2) A Drug Enforcement Officer may investigate the commission of an offence under this Act.

(3) A Drug Enforcement Officer making an investigation under subsection (2) may examine orally any person supposed to be acquinted with the facts and circumstances of the case.

(4) The person referred to in subsection (3) shall be bound to answer all questions relating to the case put to him by the Drug Enforcement Officer except that he may refuse to answer any question if the officer fails or refuses on demand to produce to him the authorization in writing given by the Licensing Officer to the officer under subsection (1) and that such person may refuse to answer any question the answer to which would have a tendency to expose him to a criminal charge or penalty or forfeiture.

(5) A person making a statement under this section shall be legally bound to state the truth whether or not such statement is made wholly of partly in answer to questions.

(6) A Drug Enforcement Officer examining a person under subsection (3) shall first inform that person of the provisions of subsections (4) and (5).

(7) A statement made by any person under this section shall, whenever possible, be reduced into writing and, after it has been read to the person in the language in which he

made it and he has been given an opportunity to make any corrections he may wish, shall be signed by him or affixed with his thumbprint.

(8) When any Drug Enforcement Officer, any police officer not below the rank of Inspector or any Senior Customs Officer has reasonable cause to believe that an offence under this Act or any regulation made thereunder has been or is being committed in any premises or in connection with any business carried on in any premises, he may at all reasonable times by himself or by some other person accompanying him and acting under his instructions and in his presence enter, search and examine such premises and may 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 thereunder and may, in case of obstruction or resistance, break open any outer or inner door of such premises and any cupboard, chest, trunk, package or other receptacle and by force if necessary, enter upon any part of such premises and remove any obstruction to such entry, search and seizure and detain any person found in such premises until the search has been completed.

(9) Any police officer not below the rank of Inspector or any Senior Customs Officer may, in the exercise of his powers under subsection (8), arrest any person, being in such premises, in whose possession such article may be found or who is reasonably suspected by such officer to have cancealed or deposited such article therein.

(10) Any person who obstructs or impedes a Drug Enforcement Officer in the performance of his duties under this Act or any regulation made thereunder shall be guilty of an offence and shall be liable to a fine not exceeding three thousand ringgit or to imprisonment for a term not exceeding one year or to both.

Penalties

32. (1) Any person who wilfully fails to keep any book required to be kept under this Act or under any regulation made thereunder or who wilfully fails to make in such book any entry required to be made by any of this Act or of any regulation made thereunder or who knowingly or recklessly makes any false entry in such book which he knew to be false or which he did not believe to be true shall be guilty of an offence and punishable by a fine not exceeding five thousand ringgit or by imprisonment for a term not exceeding two years or both.

(2) Any person guilty of an offence against this Act, for which no other penalty is specifically provided by this Act or by any regulations made thereunder, shall be punishable by a fine not exceeding two years or both.

Provided that if the act or omission with which such person is charge is in the opinion of the court of such a nature as to amount to wilful default or culpable negligence, which endangered or was likely to endanger human life, such person shall be liable, on conviction, to a fine not exceeding five thousand ringgit or to imprisonment for a term not exceeding two years to both.

(3) Where a person charged with an offence against this Act or of any regulation made thereunder is a body corporate every person who, at the time of the commission of such offence, is a director or officer of such body corporate may be charged jointly in the same proceedings with such body corporate and where the body corporate is convicted of the offence charge, every such director or officer shall be deemed to be guilty of such offence unless he proves that the offence was committed without his knowledge or that he took reasonable precautions to prevent its commission.

(4) Any person who would have been liable under this Act or of any regulation made thereunder to any penalty for anything dome or ommited if such thing had been done or omitted by him personally, shall be liable to the same penalty is such thing has been done or omitted by his partner, agent, or servant, unless he proves that he took reasonable precaution to prevent the doing or omission of such thing.

(5) Any person in respect of which an offence against this Act has been committed shall be forfeited and delivered to the Director-General of Health for disposal.

(6) Every penalty or forfeiture imposed under this Act shall be in addition to, and not in substitution for, any other penalty to which the accused may be liable under any other law, and no conviction under this Act shall be pleaded in any civil proceedings in mitigation of damages claimed against the person convicted.

Sessions or Magistrate's Court, to have full jurisdiction Over offences against this Act

33. A Session Court or a Court of a First Class Magistrate in West Malaysia or a Session Court in the State of Sabah or Sarawak shall have jurisdiction to hear and determine all prosecutions under this Act and, notwithstanding anything to the contrary contained in any other written law, a Session Court shall have powers to impose the full penalty or punishment provided by this Act.

Sanstion to prosecute and conduct of prosecutions

34. (1) No prosecution shall be instituted under this Act or any regulation made thereunder without the sanction in writing of the Public Prosecutor.

(2) Prosecutions in respect of offences under this Act or any regulation made thereunder may be conducted by any registered pharmacist in the public service authorized in writing by the Public Prosecutor.

Regulations

35. (1) The Minister may make regulations to carry out the purposes of this Act and, in particular, but without prejudice to the generality of the foregoing powers , may make regulations with respect to any of the following matters or for any of the following purposes:

(a) the importation of poisons;

(b) the manufacture of preparations containing poisons;

(c) the sale, whether by wholesale or retail, or the supply of poisons, by or to any person or class of persons including –

i) regulating or retricting the sale or supply of poisons by persons licensed under this Act and prohibiting the sale of any specified poison or class of poisons by any class of such persons; and

ii) dispensing with, or relaxing with respect to any specified poison, any of the provisions contained in this Act, or in any regulation made thereunder relating to the sale of poisons;

(d) the storage, transport and labelling of poisons;

(e) the containers in which poisons may be sold or supplied'

(f) the addition to poisons of specified ingredients for the purpose of rendering them readily distinguishable as poisons;

(g) the compounding and dispensing of poisons;

(h) the period for which any books required to be kept for the purposes of this Act are to be preserved;

(i) requiring persons in control of the manufacture of pharmaceutical preparations containing poisons to be registered pharmacists or persons possessing the prescribed qualifications in chemistry;

(j) prescribing the covering, stoppers and fastenings of and the marks to be placed or made on or on the coverings of or on the labels affixed to any vessels, bottle, case, package, box or other receptacle or container whatsoever in which any poison is kept, sotred, sold or in any way dealt with;

(k) providing exemption from the operation of this Act or of any regulation made thereunder of such persons or classes of persons as may seem expedient;

(l) prescribing the form of licences, registers and returns;

(m) fixing fees and exempting any person or body of persons from the payment of such fees;

(n) prescribing anything which may be prescribed under this Act;

(o) the import, manufacture, possession, sale or use of lead tetra ethyl, ethyl petrol or concentrated ethyl fluid;

(p) prescribing penalties not exceeding the penalties prescribed in section 32 (2) for contravention of any regulation made under this section;

(q) the sale, whether by wholesale or retail, or the supply of psychotropic substances by or to any person or class of persons;

(r) the storage, transport and labelling of psychotropic substances;

(s) the compounding, dispensing and mixing of psychotropic substances;

(t) the import, export, manufacture, possession, purchase or use of psychotropic substances;

(u) requiring persons in possession of psychotropic substances to keep and maintain a register and prescribing the manner in which the register should be maintained;

(v) prescribing the mode or the manner of disposal and sampling of psychotropic substances.

THIRD SCHEDULE
(Section 30)

1. Amfepramone
   Aminorex
   Barbituric acid and other substances structurally derivated thereform; their compounds
   Benzphetamine
   Buprenorphine
   Brotizolam
   Cathine
   Clobazam
   Clotiazepam
   Diazepam and other substances structurally derivated from 1,4-benzodiazepine except flumazenil, flunitrazepam, nimetazepam and pirenzepine
   Ethchlorvynol
   Ethilamphetamine
   Fencamfamin
   Fenetylline
   Fenproporex
   Glutethimide
   Lefetamine
   Mazindol
   Mecloqualone
   Mefenorex
   Meprobamate
   Mesocarb
   Methaqualone
   Methylphenidate
   Methylprylone
   Mitragynine
   Pemoline
   Pentazocine
   Phencyclidine
   Phendimetrazine
   Phenmetrazine
   Phentermine
   Pipradrol
   Propylhexedrine
   Pyrovalerone
   Zipeprol
   Zolazepam
   Zolpidem
   Zopiclone

2. Any product which is registered under the Control of Drugs and Cosmetics Regulations 1984 and contains any of the following substances:

   Alfentanil
   Dihydrocodeine
   Fentanyl
   Ketamine
   Methadone
   Morphine
   Oxycodone
   Pethidine
   Sufentanil

3. The following shall apply to all substances mentioned in this Schedule:
   - the analogues, homologues, compounds, intermediates, derivatives, isomers, esters, ethers and salts of the substances mentioned in this Schedule and other substances structurally derived.

Interview A

Date of interview	:	14 October 2010 (Thursday)
Time	:	9.00 am
Name of Interviewee	:	Interviewee 1
Post	:	Deputy Director, Pharmaceutical Enforcement Department, Pharmaceutical Services Division, Ministry of Health Malaysia

1. What is the system or strategy used in control the psychotropic substances especially in curtail the substances been abused and diversion?
2. What is the chain of distribution of psychotropic substances in Malaysia?
3. Are there any issues on supply of psychotropic substances?
4. Why data of importation of psychotropic substances in 2009 decrease than 2008?
5. Based on statistic, why midazolam and diazepam is benzodiazepine group highest used in Malaysia? Are these substances contributed to the drug abuse in Malaysia?
6. Do you think our supply and distribution of the psychotropic substances is legally defined and sufficient control by enforcement?
7. In Methadone Dispensing Program, are there any issues in enforcement on handling and supply of psychotropic substances?
8. In view of enforcement and based on the statistic, who is the mastermind and key player in the abuse and diversion of the psychotropic substances in Malaysia?
9. Are there any issues on the medical practitioners practicing of the supply and handling of psychotropic substances in Malaysia?
10. Any suggestion and recommendation to improve the enforcement of psychotropic substances in Malaysia?

Interview B

Date of interview	:	27 October 2010 (Wednesday)
Time	:	11.00 am
Name of Interviewee	:	Interviewee 2
Post	:	Senior Principle Assistant Director, Prosecution Unit, Pharmaceutical Enforcement Department, Pharmaceutical Services Division, Ministry of Health Malaysia

1. Is there any issue & challenges in "illegal supply of Psychotropic by Medical Practitioner" from prosecution perspective & perhaps investigation perspective also?
2. Any 3 or 5 cases in illegal supply of psychotropic substances by Medical Practitioner could be example to be analyzed?
3. Are there any weaknesses in the system or laws which contribute an opportunity to medical practitioner to not comply with the laws or involve in the supply of alternative drugs to be abuse most likely as drug traffickers?
4. Any recommendation and strategy to improve the entire loophole and weaknesses.

Interview C

Date of interview	:	5 October 2010 (Tuesday)
Time	:	9.00 am
Name of Interviewee	:	Interviewee 3
Post	:	Senior Principle Assistant Director, Diversion Control Unit, Pharmaceutical Enforcement Department, Pharmaceutical Services Division, Ministry of Health Malaysia

1. Statistic data 2007 until 2010?
2. Who is importer of psychotropic substances? And how many of authorized importer in Malaysia?
3. Problems and issues in quota system?
4. Why data of importation of psychotropic substances in 2009 decrease than 2008?
5. Any suggestion and recommendation to improve the control system on psychotropic substances supply and distribution? (for make sure the patient is not under treatment of pain)
6. What is the system @ strategy used in control the psychotropic substances especially in curtail the substances been abused and diversion?
7. Are there any issues on supply of psychotropic substances?
8. Based on statistic, why midazolam and diazepam is benzodiazepine group highest used in Malaysia? Are these substances contributed to the drug abuse in Malaysia?
9. Do you think our supply and distribution of the psychotropic substances is legally defined and sufficient control by enforcement?
10. In Methadone Dispensing Program, are there any issues in enforcement on handling and supply of psychotropic substances?
11. Section 30(5) poisons act 1952 is the most prosecution cases held. Why? What are the offence details under section 30(5) poisons act 1952?
12. In view of enforcement and based on the statistic, who is the mastermind and key player in the abuse and diversion of the psychotropic substances in Malaysia?

13. Are there any issues on the medical practitioners practicing of the supply and handling of psychotropic substances in Malaysia?
14. Any suggestion and recommendation to improve the enforcement of psychotropic substances in Malaysia?

Interview D

Date of interview	:	2 November 2010 (Tuesday)
Time	:	2.00 pm
Name of Interviewee	:	Interviewee 4
Post	:	Senior Principle Assistant Director, Prosecution Unit, Pharmacy Division, Jabatan Kesihatan Wilayah Persekutuan Kuala Lumpur and Putrajaya

1. Is there any issue & challenges in "illegal supply of Psychotropic by Medical Practitioner" from prosecution and investigation perspective in Kuala Lumpur cases?
2. Any 3 or 5 cases in illegal supply of psychotropic substances by Medical Practitioner could be example to be analyzed?
3. Are there any weaknesses in the system or laws which contribute an opportunity to medical practitioner to not comply with the laws or involve in the supply of alternative drugs to be abuse most likely as drug traffickers?
4. Any recommendation and strategy to improve the entire loophole and weaknesses.