

A STUDY ON ADEQUACY OF MALAYSIAN LAW GOVERNING
DRUG ADULTERATION : SILDENAFIL

By

Shufira bt Muslim (2010255068)
Hasni Muniati bt Hassan (2010235198)

Submitted in Partial Fulfilment of the Requirements for the Master of Enforcement
Law

Universiti Teknologi MARA
Faculty of Law

January 2012

The students/authors confirm that the work submitted is their own and that appropriate credit has been given where reference has been made to the work of others.

ABSTRACT

As the adulteration of poison in Malaysia is still rampant, it causes a big impact on the government, enforcement agencies and users. It is a library-based research, however, semi-structured interviews were also carried out which lead to a few findings of this study. The main Act that govern the manufacturing of poison is the Poisons Act 1952 (Act 366). Besides Act 366, the manufacturing of poison are also governed under the Sales of Drugs Act 1952 (Act 368) and the Control of Drugs and Cosmetics Regulation 1984. Subsequently, there is a role of the Good Manufacturing Practices that needs to be complied with. Apart from that, the regulatory being controlled by the Drug Control Authority, the Pharmacy Enforcement Division and the National Pharmaceutical Control Bureau including their roles in Pre and Post Marketing Surveillance, the use of Adulterated Database and also the new safety feature using distinct Hologram for registered products in Malaysia are clearly identified. Certain provisions in the Poison Act 1952, the Sales of Drugs Act 1952 and the Control of Drugs and Cosmetics Regulation 1984, need to be reviewed to accommodate with the current situation. The study examines and compares the existing laws in other country, namely the United State of America. It is recommended that stiffer penalty be imposed and to have a single specific Act that governs poison, for legal and administration improvement.

TABLE OF CONTENTS

Acknowledgement	ii
Abstract	iii
Contents	iv
List of Cases	vii
List of Abbreviation	viii

CHAPTER ONE: THE STUDY

1.0	Introduction	1
1.0.1	What is sildenafil?	1
1.0.2	What is an analogue?	2
1.0.3	Adulterant	2
1.0.4	Adulteration	3
1.0.5	Types of Adulteration	4
1.0.6	Dangerous Effects of Adulteration	5
1.1	Problem Statement	8
1.2	Objective of the Study	8
1.3	Research Methodology	9
1.4	Scope and Limitation	12
1.5	Significance of the Study	12
1.6	Divisions of Chapters	13
1.7	Conclusion	13

CHAPTER TWO: ANALYSIS OF STUDY

2.0	Introduction	15
2.1	Laws that Govern Manufacturing of Drug	15
2.1.1	Poison Act 1952	15
2.1.2	Control of Drugs and Cosmetics Regulations 1984	17
2.2	The Good Manufacturing Practice and Its Role in Drug Manufacturing	19
2.3	Drug Regulatory Authority	22
2.3.1	Pre and Post Market Surveillance	23
2.3.2	Use of Adulterated Database	24
2.3.3	Use of New Safety Feature: Hologram	25
2.4	Offences and Penalties Related to the Adulteration of Drug Under the Related Acts	25
2.4.1	Poison Act 1952	25
2.4.2	Control of Drug and Cosmetic Regulations 1984	26
2.4.3	Sales of Drug Act 1952	27
2.5	Other Acts Related to Drug Adulteration	27
2.5.1	Food Act 1983	27
2.5.2	Trade Description Act 1972	29
2.5.3	Consumer Protection Act 1999	31
2.6	Sources of Illegal Drugs Contain Adulterated Sildenafil	33
2.6.1	Smuggling Activity	33

2.6.2	via Internet	34
2.7	Power of Pharmacy Enforcement Division	36
2.7.1	Powers under the Sale of Drugs Act 1952	36
	2.7.1.1 Appointment of Analysts, Officers and Inspectors	37
	2.7.1.2 Power of officers and inspectors to enter any place	37
	2.7.1.3 Power to demand, select and take samples	37
	2.7.1.4 Power to call for information	38
2.7.2	Powers under the Poison Act 1952	38
	2.7.2.1 Appointed as the Drug Enforcement Officer	38
	2.7.2.2 Powers of Investigation, Examination and Entry into Premises	39
	2.7.2.3 Power to prosecute	40
2.7.3	Powers under the Control of Drugs and Cosmetics Regulations 1984	40
	2.7.3.1 Appointed Officer	41
2.8	Weaknesses and Limitations of the Pharmacy Enforcement Division	41
2.8.1	Lack of Enforcement Power	42
	2.8.1.1 Power to Access to Computerized Data	42
	2.8.1.2 Power to Arrest	43
	2.8.1.3 Power to Intercept Phone Conversation	43
	2.8.1.4 Power to Acquire Evidence	43
2.8.2	Difficulty in Detecting the Activity of Drug Adulteration	44
2.9	Conclusion	44

CHAPTER THREE: COMPARISON OF THE LEGAL FRAMEWORK ON ADULTERATION OF SILDENAFIL IN THE UNITED STATES OF AMERICA (USA)

3.0	Introduction	45
3.1	Legal Control on Adulteration of Drug in the USA	45
	3.2.1 The legislation on adulteration of sildenafil in the USA	46
	3.2.2 Principle Provisions under the Food, Drug and Cosmetic Act 1938	48
3.3	Monitoring for Approval of Drugs and Foods	50
3.4	Enforcement by the Food and Drug Administration	51
3.5	Penalties under the Food, Drug and Cosmetic Act 1938	53
3.6	Conclusion	54

CHAPTER FOUR: CONCLUSIONS AND RECOMMENDATIONS

4.0	Introduction	55
4.1	Concluding Remarks	55
4.2	Recommendation 1: Revision of the Existing Law	56
4.3	Recommendation 2: The Penalty	56
4.4	Recommendation 3: Power of Pharmacy Enforcement Agency	57

CHAPTER ONE

THE STUDY

1.0 INTRODUCTION

1.0.1 What is sildenafil?

In Malaysia, sildenafil and its analogue (or its salt) are categorized as Group B poison in Part I Poisons List of First Schedule of Poisons Act 1952 (PA). This group of poison is further classified as vasodilators in the Appendix of Poisons List. Vasodilators are the agents that act as blood vessel dilators and open vessels by relaxing their muscular walls thus resulting in vasodilatation.¹ Vasodilatation refers to the widening of blood vessels resulting from relaxation of smooth muscle cells within the vessel walls, particularly in the large arteries, smaller arterioles and large veins.²

Sildenafil citrate is an active ingredient in *Viagra*, clinically it has been a major advancement in the treatment of male erectile dysfunction (impotence) and pulmonary arterial hypertension. The most frequent side effects of sildenafil are headache and facial flushing as the vasodilating action of sildenafil affects both the arteries and the veins. For that reason, patients prescribed with sildenafil must be closely monitored by physicians and could only be obtained at pharmacies with the prescription from doctors.

Since they are Group B Poison under PA, sildenafil and its analogue are controlled under several existing laws in Malaysia in the aspect of their importation, possession, manufacture, compounding, storage, transport, sale and use.³ The governance of all poisons is by enforcing the PA. However when a poison is used as an ingredient of medicine, few other Acts and regulation also be applied to regulate it namely, the Sales of Drugs Act 1952, the Control of Drugs and Cosmetics Regulation 1984, the Medicines (Advertisement and Sale) Act 1956 and the Registration of Pharmacists Act 1951. They are many terms used to indicate medicine

¹ A.S Hornby, *Webster's New World™ Medical Dictionary* (Wiley Publishing, Inc 3rd edn 2008)
² Ibid
³ Preamble of the Poisons Act 1952