

UNIVERSITI TEKNOLOGI MARA

**AN ANALYSIS ON THE LAW ENFORCEMENT
ISSUES IN COMBATING
COUNTERFEIT MEDICINES
IN MALAYSIA**

**MOHD SYAHIR BIN MOHD SAIBON
DELLIA FAIZA BINTI ABDUL RAZAK**

Dissertation submitted in partial fulfilment
of the requirements for the degree of
Master of Enforcement Law

Faculty of Law

July 2015

AUTHOR'S DECLARATION

I declare that the work in this thesis was carried out in accordance with the regulations of Universiti Teknologi MARA. It is original and is the results of my own work unless otherwise indicated or acknowledged as referenced work. This thesis has not been submitted to any other academic institution or non-academic institution for any degree or qualification.

I, hereby, acknowledge that I have been supplied with the Academic Rules and Regulations for Post Graduate, Universiti Teknologi MARA, regulating the conduct of my study and research.

Name of Student : Mohd Syahir Bin Mohd Saibon
Student I.D. No. : 2013133119
Name of Student : Dellia Faiza Binti Abdul Razak
Student I.D. No. : 2013694116
Programme : Master of Enforcement Law
Faculty : Law
Dissertation Title : A Study on the Law Enforcement Issues in Combating Counterfeit Medicines in Malaysia

Signature of Student : Signature of Student :

Date : Date :

ABSTRACT

This study aims to examine the law and enforcement issues in combating counterfeit medicines in Malaysia. The prevalence of counterfeit medicines in Malaysia has increased to as high as 3-6% of market value. In other developed countries such as the United States and the United Kingdom, the percentage of counterfeit medicines in the market is below 1% due to several reasons. The reasons are a wider scope of laws and stricter enforcement measures. In Malaysia, there are several laws that could be applied to address the problem of counterfeit medicines. The laws are the Sales of Drug Act 1952 and its Regulation, and the Trade Description Act 2011. In addition, several enforcement bodies, including the Pharmacy Enforcement Division of the Ministry of Health and the Enforcement Division of the Ministry of Domestic Trade, Cooperative and Consumerism have taken steps to curb this problem. However, despite the existence of the legal framework and the effort of such bodies, the problem of counterfeit medicines is still alarming which suggests the insufficiency of the law enforcement. Therefore, this study aims to investigate the law enforcement issues in curbing the matter. Adopting a qualitative approach of both doctrinal and empirical methods, the study found that there are several issues affecting the insufficiency of the enforcement of the legal framework in Malaysia. The issues are ranging from the legal, the investigation, the administrative, the technological and the operational issues. Therefore, this study demonstrates that the barriers in laws and enforcement measures have significantly contributed to the insufficient enforcement of the laws and the rising of the counterfeit medicines in Malaysia.

TABLE OF CONTENTS

Author's Declaration	ii
Abstract	iii
Acknowledgement	iv
Table of Contents	v
List of Abbreviations	x
List of Cases	xii
List of Statues	xiii

CHAPTER ONE: INTRODUCTION

1.0	Introduction	1
1.1	Background	1
1.2	Problem Statement	4
1.3	Research Question	4
1.4	Research Objectives	5
1.5	Research Methodology	5
1.6	Scope of Research	6
1.7	Limitations of Research	6
1.8	Significance of Research	6
1.9	Outline of Research	6
1.10	Conclusion	7

CHAPTER TWO: OVERVIEW OF COUNTERFEIT MEDICINES

2.0	Introduction	8
2.1	Terms and Definitions	8
2.2	Threats and Risks	11
2.3	Reasons for the Crime	14
2.4	Adverse Implications	15
2.5	Combating the Problems	18
2.5.1	Role of Laws	19
2.5.2	Role of Enforcement Bodies	19
2.5.3	Investigation Procedures	20

2.6	Other Enforcement Measures	21
2.6.1	Control of Pharmaceutical Supply Chain	21
2.6.2	Operational Control at the Entry Point	22
2.6.3	Role of Manufacturers	23
2.6.4	Role of Re-packagers	24
2.6.5	Role of Wholesalers	25
2.6.6	Authentication Technologies	25
2.7	Conclusion	27

CHAPTER THREE: APPLICABLE LAWS AND ENFORCEMENT MEASURES IN MALAYSIA

3.0	Introduction	28
3.1	Background of the Laws	28
3.1.1	The Sales of Drug Act 1952 and the Control of Drug and Cosmetic Regulations 1984	28
3.1.2	The Trade Description Act 2011	29
3.2	Legal Issues	29
3.2.1	Lack of Specific Provisions	30
3.2.2	Insufficient Penalty	30
3.2.3	Failure to Meet the International Standard	32
3.3	Enforcement Issues	32
3.3.1	Administrative Problem	32
3.3.1.1	Pharmacy Enforcement Division of the Ministry of Health	33
3.3.1.2	Enforcement Division of the Ministry of Domestic Trade, Co-operatives and Consumerism (MDTCC)	33
3.3.2	Non-Comprehensive Investigation	34
3.3.3	Challenges to Secure Pharmaceutical Distribution Chain	36
3.3.3.1	Lack of Operational Control at the Border	36
3.3.3.2	Complex Pharmaceutical Distribution Chain	37
3.3.4	Insufficiency of Meditag Hologram	38
3.4.	Conclusion	40