

UNIVERSITI TEKNOLOGI MARA

**A CRITICAL STUDY ON THE EXTENT OF THE
ISSUES AND CHALLENGES FACING THE
PHARMACY ENFORCEMENT OFFICERS IN THE
ENFORCEMENT OF COUNTERFEIT MEDICINES IN
MALAYSIA, WITH SPECIAL REFERENCE TO THE
POSITION IN ENGLAND AND WALES**

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Abstract

Counterfeit medicine is a threat due to its impact on health and life. The enforcement of counterfeit medicines by the Pharmacy Enforcement Officers is surrounded by numerous issues and challenges. The aims of this study is to determine the issues and challenges facing the Pharmacy Enforcement Officers in the enforcement of counterfeit medicines and also to provide some recommendations which could improve the standard and quality of their enforcement exercise. The research is carried out using qualitative research method, library research on the primary sources of the laws and statutes in Malaysia, England and Wales as well as the fieldwork involving semi-structured interviews in Malaysia. The legal chapters (chapter 3 and 4) provide the legal framework in the enforcement of the counterfeit medicines in Malaysia, England and Wales. The findings chapter (chapter 5), reports on the fieldwork findings of the two respondents regarding their perceptions on the issues and challenges facing the Pharmacy Enforcement Officers in the enforcement on counterfeit medicines in Malaysia.

Issues identified are divided into law-related, socio-economic and operational-related. Challenges identified are divided into the detection of the counterfeit medicines, the challenges in the investigation process, the challenges in the prosecution process and the socio-economic challenges. It is learned in this study that the Pharmaceutical Services Division should adopt a holistic approaches to enhance the standard and quality of the Pharmacy Enforcement Officers. This includes enhancing the co-operation with the stakeholders, taking steps to review the laws and provides training. The Pharmacy Enforcement Division should upgrade the facilities and technology as well as paradigm shift and approaches in the enforcement of the law by the Pharmacy Enforcement Officers. The Pharmacy Enforcement Officers should be more pro active and creative in considering the use of other relevant provisions and the laws. All these may be a catalyst in improving the standard and quality of the Pharmacy Enforcement Officers in carrying out their enforcement tasks.

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Table of Contents

Abstract	ii
Acknowledgements	iii
Table of Contents	iv
List of Cases	xii
List of Abbreviations	xiii
CHAPTER ONE: INTRODUCTION TO THE RESEARCH	1
1.0 Introduction	1
1.1 Background of the Research	1
1.2 Research Question	2
1.3 Research Objectives	3
1.4 Research Methodology	3
1.5 Research Scope	4
1.6 Research Limitation	4
1.7 Significance of the Research	4
1.8 Research Plan	5
1.9 Conclusion	5
CHAPTER TWO: LITERATURE REVIEW	6
2.0 Introduction	6
2.1 Criminal Justice System	6
2.2 Pharmacy Enforcement Division	8
2.3 The Medicines and Healthcare products Regulatory Agency	8
2.4 The Concept of Law Enforcement	10
2.5 The Concept of Counterfeit Medicines	11

CHAPTER ONE

INTRODUCTION TO THE RESEARCH

1.0 Introduction

This chapter basically discussed the components of this research. The components that will be discussed include the background of the research, the research question, the research objectives and the research methodology. It will also cover the research scope, the research limitation and the significance of the research.

1.1 Background of the Research

There is no recent figure regarding the prevalence of the counterfeit medicines in Malaysia. Two studies were carried out by the Ministry of Health, Malaysia (MOH) in 1997 and 1998 to gauge the magnitude of counterfeit medicines in the local pharmaceutical market. The study involves western pharmaceutical in 1997 and traditional medicine in 1998.¹ For western pharmaceuticals, 5.3% (64 out of 1212 samples) were found to be counterfeited and 0.35% (2 out of 570 samples) of the traditional medicines was also found to be counterfeited.²

Drug regulation in Malaysia was initiated in 1985 with the intention of ensuring quality, efficacious and safeties of the products marketed in this country.³ However, despite having an efficacious and effective regulatory and enforcement system in place, the government is cognizance of the fact that counterfeited and unregistered products continued to make their way into the domestic pharmaceutical market.⁴

¹ Ministry of Health Malaysia, Annual Report 1998, p. 219.

² Ibid.

³ Speech by YB Datuk Seri Chua Soi Lek, Minister of Health Malaysia, at the Seminar on Counterfeit Pharmaceuticals: A Global Perspective, Bandar Sunway, Selangor, Malaysia, 5 December 2006.

⁴ Ibid.