ENFORCEMENT OF THE SALE OF DRUGS ACT 1952 (ACT 368) ON REGISTERED PRODUCTS IN MALAYSIA

By

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The students 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

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ABSTRACT

In Malaysia, the Pharmaceutical Services Programme under the Ministry of Health Malaysia is the responsible authority to safeguard the sale and usage of medicinal products. The Sale of Drugs Act 1952 and its Regulations, the Control of Drugs and Cosmetics Regulations 1984 were promulgated to ensure product quality, efficacy and safety. The regulations provide for the establishment of the Drug Control Authority to regulate the pharmaceutical, traditional and cosmetic drugs industry, whereby the Pharmacy Enforcement Division, which is one of the main components of the Pharmaceutical Services Programme, is vested with the powers to enforce these Act and Regulations. It is crucial for the Pharmaceutical Services Programme to ensure that the enforcement of the Act and Regulations, and the enforcement activities under the Pharmacy Enforcement Division is carried out effectively and in accordance with the laws so provided in order to ensure public health and safety. Therefore, this study attempts to examine the Sale of Drugs Act 1952 and its Regulations, and the enforcement activities carried out under the Pharmacy Enforcement Division; and further to identify the weaknesses and problems of the two areas under study. The research adopts the qualitative approach which involved library based research and interviews. Accordingly, some recommendations for instance, constant revision of drug legislation, empowerment of drug regulatory authority, enhancement of monitoring and evaluation system and also enhancement of public education and protection programmes in order to overcome those weaknesses and problems are suggested.

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CHAPTER ONE: INTRODUCTION

1.0 Introduction

The use of medicines available without prescription has generally been accepted as an important part of healthcare. It is a natural consequence of a growing desire on the part of the members of the public to take more responsibility for their own health. Besides, when correctly practised, self-medication can also save expenses for the national healthcare system.[1] Unfortunately, however, the practice does expose consumers to unapproved, substandard and dangerous medicines categorized as unregistered, counterfeit and adulterated medicines which may instead have adverse effects on their health.

Problems related to the safety and quality of drugs exist in many places around the world today, in developing and developed countries alike, and some incidents have ended in tragedy, often with children as the victims. Therefore, the government of Malaysia is determined to ensure that the quality, efficacy and safety of the pharmaceutical products marketed for local consumption are properly verified and scrutinized in accordance with high standards.[2]

This chapter discusses the study topic as a whole. It consists of the background of the study, the problem statement, the objective of the study, the literature review, the significance and limitations of the study, as well as the methodology. The division of each chapter will be outlined at the end of this chapter to give an overall view of the study.

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1 www.aesgp.be/aboutSelfCare/english.asp, accessed on 12 September 2008.

2 Patrick Mirandah, "War against Counterfeit Medicine", available at www.mirandah.com, accessed on 29 April 2008.