

UNIVERSITI TEKNOLOGI MARA

**A LEGAL STUDY ON THE
EFFECTIVENESS OF SALE OF DRUGS
ACT 1952 AND ITS REGULATIONS IN
CONTROLLING THE SALE OF
COSMETIC PRODUCTS IN
MALAYSIA**

NORHIDAYAH BINTI MOHAMAD

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


Faculty of Law

January 2018

AUTHOR’S DECLARATION

I declare that the work in this dissertation 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	:	Norhidayah binti Mohamad
Student I.D. No.	:	2016205452
Programme	:	Master of Enforcement Law- LW707
Faculty	:	Law
Dissertation Title	:	A Legal Study on the Effectiveness of Sale of Drugs Act 1952 And Its Regulations in Controlling the Sale of Cosmetic Products in Malaysia
Signature of Student	:	
Date	:	January 2018

ABSTRACT

In Malaysia, the control of the sale of cosmetic products is governed by Sale of Drugs Act 1952 and Control of Drugs and Cosmetics Regulations 1984. According to this Act and its regulations, cosmetic products in Malaysia need to be notified before it can be placed in the local market without any requirement for the quality test during the notification process. This provides a huge potential risk to the consumer due to they might be exposed to the cosmetic products containing harmful ingredients. Therefore, the objectives of the study are to examine the adequacy of the current provisions in the Sale of Drugs Act 1952 and its regulations in controlling the sale of cosmetic products in Malaysia; to identify and analyze other country laws such as China in controlling the sale of cosmetic products; and to propose recommendations to improve the current legislation in order to minimize the problems. The methodology used in this study is a doctrinal study which is library-based. All the relevant information collected based on the Sale of Drugs Act 1952 and its regulations; and also from reports, journals, newspaper, articles and websites. The other method used is empirical research whereby interview schedule and interview questions were used as research instruments. All data were transcribed and analyzed accordingly. This study found that there is an inadequacy in the current legislation. Notification process only involved submission of certain documents and does not require any test done by the authority to ensure the safety and quality of the cosmetic products. Although post-marketing surveillance carried out by the National Pharmaceutical Regulatory Agency after the cosmetic products have been marketed, it is not compulsory for all cosmetic products and priority given to whitening cosmetic products. In addition, there is no compulsory to attach the notification number to the label of cosmetic products. As compared to China, all imported cosmetic products need to undergo quality and safety test performed by an institution or organization appointed by their authority as one of the requirements for registration before it can be sold in the local market. The cosmetic product owner also needs to attach registration number on the product label, so that the consumers can distinguish whether the cosmetic products are registered or not. Therefore, this mechanism can guaranty the quality and the safety of the cosmetic products to end user and the risk of harmful cosmetic products can be reduced. Hence, there is a need to improve the law to curb the problems. The study result may benefit the Pharmaceutical Services Division, Ministry of Health as the policy makers and also may help the consumer to use safe cosmetic products.

TABLE OF CONTENTS

	Page
AUTHOR’S DECLARATION	ii
ABSTRACT	iii
ACKNOWLEDGEMENT	iv
TABLE OF CONTENTS	v
LIST OF TABLES	ix
LIST OF FIGURES	x
LIST OF ABBREVIATIONS	xi
LIST OF SYMBOLS	xii
CHAPTER ONE: INTRODUCTION TO THE RESEARCH	1
1.1 Introduction	1
1.2 Research Background	1
1.3 Problem Statement	4
1.4 Research Questions	4
1.5 Research Objectives	5
1.6 Research Methodology	5
1.7 Scope and Limitation of the Research	6
1.8 Significance of the Research	7
1.9 Outline of the Research Structure	7
1.10 Conclusion	8
CHAPTER TWO: LITERATURE REVIEW	9
2.1 Introduction	9
2.2 Definition of Cosmetic Products and Notified Cosmetic Products	9
2.2.1 Definition of Cosmetic Products	9
2.2.2 Definition of Notified Cosmetic Products	11

2.3	Claims of Cosmetic Products	12
2.4	Regulations in Controlling the Sale of Cosmetic Products in Malaysia	13
2.4.1	Sale of Drugs Act 1952	13
2.4.2	Control of Drugs and Cosmetics Regulations 1984	14
2.4.3	Guidelines for Control of Cosmetic Products in Malaysia	15
2.5	Theories Related to the Consumer	16
2.5.1	Concept of Consumer Protection	16
2.5.2	Theory of Asymmetric Information	18
2.5.3	Theory of Consumer Behaviour	19
2.5.4	Theory of “Due Care”	20
2.6	Impact of Harmful Ingredients in the Cosmetic Products to the Consumer	21
2.7	Pharmacy Enforcement Division	27
2.8	Conclusion	29
	CHAPTER THREE: LAWS GOVERNING THE SALE OF	30
	COSMETIC PRODUCTS IN MALAYSIA	
3.1	Introduction	30
3.2	Legal Framework for the Sale of Cosmetic Products in Malaysia	30
3.2.1	Sale of Drugs Act 1952	30
3.2.2	Control of Drugs and Cosmetics Regulations 1984	32
3.2.3	ASEAN Cosmetic Directives	33
3.2.4	Guidelines for Control of Cosmetic Products in Malaysia	35
3.2.4.1	<i>Cosmetic Notification Holder</i>	35
3.2.4.2	<i>Notification Process</i>	37
3.2.4.3	<i>Cosmetic Claims</i>	39
3.2.4.4	<i>Good Manufacturing Practice</i>	41
3.2.4.5	<i>Product Recall</i>	41
3.2.4.6	<i>Cosmetic Ingredients</i>	42
3.2.4.7	<i>Post Marketing Surveillance</i>	44
3.2.4.8	<i>Product Sampling Requirements</i>	44
3.3	The Sale of Cosmetic Products: A Comparison with China	45