

UNIVERSITI TEKNOLOGI MARA

**COMPARATIVE LEGAL STUDY
ON CONTROLLING COUNTERFEIT
MEDICINES IN MALAYSIA
AND UNITED STATES**

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Master of Enforcement Law

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AUTHOR'S DECLARATION

I declare that the work in this dissertation were 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.

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ABSTRACT

The counterfeit medicinal products are not clearly defined in current legislation, namely Poison Act 1952 and Regulations, the Sale of Drugs Act (SODA) 1952 and Control of Drugs and Cosmetic Regulation (CDCR) 1984. All cases pertaining to counterfeit medicinal products will be deal under provision of one of the acts or regulation stated. The main issues that contributes to this problem are the counterfeit medicines were not define and no specific provision for the offence regarding counterfeit medicine in the legislations, making difficulties for the drug enforcement officers in performing their duties. Absence or certain drug enforcement powers and low penalty imposed to the offence that related to the counterfeit offence does not reflect the seriousness of the offence towards society. Several flaws in the provision and low penalties imposed will lead to repeated offences related to counterfeit medicines. Current legislation seems to be inadequate in controlling the issue of counterfeit medicines in Malaysia. The United States' legislation is chosen as comparison since this country has an established legal framework in controlling the counterfeit medicines in their country. The aim of this study are to examine the adequacy of current legal framework in controlling counterfeit medicines in Malaysia, to investigate the laws in the United States and the established mechanism that prevents the counterfeit medicines from reaching their citizens and lastly, to propose suitable methods of improvement in preventing the counterfeits medicines in Malaysia. This research are carried out using a qualitative method, with combination of doctrinal research and semi-structured interview. This study may contribute towards more effective control of counterfeit medicines in Malaysia and helps to assist policy makers in implementing and improving current laws and regulations pertaining this issue and fill up the lacuna in the current law.

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