

UNIVERSITI TEKNOLOGI MARA

**A STUDY ON THE ADULTERATED
TRADITIONAL-HERBAL
MEDICINAL PRODUCTS IN
MALAYSIA**

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MSc

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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.


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ABSTRACT

The adulteration issues of Traditional-Herbal Medicinal (THM) products have been discussed quite lengthily in Malaysia due to its availability in the Malaysian market and the ease of purchase by the public. There has been an increased in announcements and in the news concerning the adulteration of THM products that have caused undesirable side effects for the consumer. As a consequence, the Malaysian authorities have established several relevant and important guidelines and have heightened strategic enforcement agendas in the attempt to curb adulteration issues. Several laboratory-based studies have been undertaken, to investigate the presence of adulterants or heavy metals in THM products. However, there are limited Malaysian data that have been published on the characteristics and adverse effects associated with adulterated THM. The aims of this study were to establish the current characteristics of adulterated THM in the Malaysian market while assessing the magnitude of adverse reactions associated with THM product in Malaysia. In order to evaluate the characteristics and trends of adulterated THM products in Malaysia, a total of 59,440 THM products that were seized in Malaysia by the Pharmacy Enforcement Division from the year 2008-2014 were analysed. Of these 6, 452 were included in the final analyses after taking into consideration inclusion and exclusion criteria for this study. More than 50% (N= 3, 549) were international THM products. The most common adulterants reported were steroid, phosphodiesterase inhibitors and monoamine reuptake inhibitor. In terms of the evaluation of the extent of adverse reactions associated with THM products in Malaysia, a total of 1, 102 reports of adverse reactions associated with THM were extracted from the spontaneous adverse reports database. In total, 900 adverse reaction reports were used in this study according to the inclusion and exclusion criteria. Hepatobiliary disorders (N=155, 17.22%) is the most common adverse reaction reported associated with the use of THM products in Malaysia. This was followed by blood & lymphatic disorders (N=149, 16.56%) and gastrointestinal disorders (N=68, 7.56%). Proportional Reporting Ratio and Reporting Odds Ratio medication safety signalling tools were used in this study to generate adverse reaction signals. Adverse reaction signals were generated for: 1) respiratory & thoracic disorders and THM products indicated for cough and cold, 2) cardiac disorders for THM products indicated for slimming and 3) reproductive and breast disorders for THM products indicated for women's health. In conclusion, this study highlights the trend of the adulterated THM products in Malaysia and the most common adverse reactions associated with the use of THM products in Malaysia. It is hope that the significance of results of this study could help the Malaysian authorities to strategise optimally based on the utmost priority.

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