**Topic of Research Proposal**

Review of Surveillance Projects on Cosmetic Products in Malaysia.

**Name of Candidate**

Noor Hidayah Mohd Nor

**Name of Supervisor**

Cik Zuraida Abdullah
Head of Surveillance & Complaints Section
Centre of Compliance & Quality Control
National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia

# 1. INTRODUCTION

## 1.1 Regulation of cosmetic products in Malaysia

In Malaysia, cosmetics is controlled via self-regulation or also known as notification procedure. The same control is practiced in all ASEAN countries where the requirements for regulation of cosmetic products is harmonised among the member states through the ASEAN Cosmetic Directive (ACD). The ACD is then transposed to local regulations of each member states. Unlike medicinal products which requires products registration, cosmetic products require only product notification. Notification for cosmetic product is a self-regulation system where the product can be sold in the local market without pre-approval from the authority.

The regulatory control of cosmetic product begun in 1992 under the third phase of implementation of the Control of Drugs and Cosmetics Regulations 1984 (P.U. (A) 223/1984) (hereinafter as "the CDCR") promulgated under the Sale of Drugs Act 1952 (Act 368 Rev. 1989) (hereinafter as "the SODA")[1]. National Pharmaceutical Regulatory Agency, Ministry of Health is responsible under the purview CDCR to control the cosmetic products in Malaysia including the safety and quality control of the products, inspection of the manufacturer for compliance to Good Manufacturing Practice and post-registration activities such as the post-market surveillance[2]. These are done to ensure the cosmetic products in the market are of good quality and safe for the consumer. Meanwhile, the enforcement division (i.e. the Pharmacy Enforcement Division, Pharmaceutical Services Division, Ministry of Health Malaysia) plays an important role in ensuring the provisions of existing legislations with regards to regulation of cosmetic products are complied with[3].

## 1.2 Surveillance activities and laboratory testing of cosmetic products

Surveillance activities are important to ensure the safety and quality of cosmetic products in the market. In Malaysia, the surveillance activities include product sampling from the market where the products are selected based on pre-determined monitoring plan such as product risks, product complaints and cosmetics' advertisements

compliance. The activities also involved laboratory testing on the products being sampled.

If a product is failed to comply with the stipulated guidelines or found to contain prohibited substance, regulatory actions will be taken in the form of notification cancellation or warning letters. If the product notification is cancelled, the product can no longer be allowed to be placed in the market for sales and the products may be asked to be recalled depending on the severity of the non-compliance.

The sales of cosmetics not notified with NPRA is an offence under the Control of Drug and Cosmetic Regulations 1984. Any individual who commits an offence under these Regulations can be fined up to RM 25,000 or imprisonment for a term not exceeding 3 years or both, and for second or subsequent offence the sellers shall be liable for conviction for a fine not exceeding RM 50,000 or imprisonment for a term not exceeding 5 years or both. A company found guilty can be fined up to RM 50,000 for the first offence and RM 100,000 for subsequent offence.

## 3. JUSTIFICATIONS AND AIMS OF THE STUDY

Cosmetics industries offer multi-billion-dollar business as there is huge demand for these products. Subsequently this creates more opportunities to the industries to produce more innovative products for consumer choices. Consumers, on the other hand, are swamped with choices and regulators have a huge responsibility to monitor the products in the market to ensure their quality and safety.

This study is aimed to analyse the trend of results of laboratory testing for cosmetic products being sampled under the Post Market Surveillance activities. The findings from this review can be used to improve and strengthen the surveillance’s monitoring plan for cosmetic products.

## 4. METHODS

All reports of the product testing issued by NPRA's laboratory for cosmetic products will be extracted from the National Surveillance Centre database. Only cosmetic products sampled through surveillance activities will be included in the study.

A standardised form will be designed based on product criteria outlined in the monitoring plan to extract relevant data from the database. Data will be analysed descriptively.

## 6.0 REFERENCES

1. *Drug Registration Guidance Document (DRGD) First Edition, Rev. July 2015*. Retrieved from http://portal.bpfk.gov.my/images/Drug-Registration-Guidance-Document/CompleteDRGD_with_appendices_update_July15.pdf (Date of access: 11th September 2015), p.33.

2. Selangor, Pharmaceutical Services Division, Ministry of Health Malaysia. *Pharmacy Enforcement Division*. Retrieved from http://www.pharmacy.gov.my/v2/en/content/pharmacy-enforcement-division.html (Date of access: 21th September 2015)

3. Selangor, Pharmaceutical Services Division, Ministry of Health Malaysia. *Pharmacy Enforcement Division*. Retrieved from http://www.pharmacy.gov.my/v2/en/content/pharmacy-enforcement-division.html (Date of access: 21th September 2015)