# Guidelines for Control of Cosmetic Products in Malaysia

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# 1. INTRODUCTION

This guideline was prepared by the Cosmetic Technical Working Group (CTWG), comprising of the National Pharmaceutical Control Bureau (NPCB) and representatives from the cosmetic industry. The Guidelines for Control of Cosmetic Products in Malaysia is prepared in accordance to the ASEAN Cosmetic Directive.

The primary goal of the CTWG is to implement an efficient regulatory control system without compromising consumer safety by incorporating the requirements of the ASEAN Cosmetics Directives. Ensuring safety, quality and claimed benefits of cosmetic products are the fundamental principles of cosmetics product control.

## 1.1 What is cosmetic product notification

This notification process will allow the NPCB to gather adequate information on the cosmetic products that are placed in the local market.

Under the Control of Drugs and Cosmetics (amendment) Regulations 2007, the company or person responsible for placing a cosmetic product in the local market must notify the Director of Pharmaceutical Services (DPS) through National Pharmaceutical Control Bureau (NPCB) prior to product manufacture or importation.

It is an offence for anyone to manufacture or import a cosmetic product without prior notification to the DPS.

# 2. THE REGULATION OF COSMETIC PRODUCTS

## 2.1 Introduction

The Government regulates the manufacture, sale and importation of cosmetic products in the following ways:

- By requiring that all cosmetic products be notified before manufacture, sale, supply by wholesale and import
- By requiring the company or person carrying out the notification be registered Please refer Annex 1, part 1 ï Membership Registration for Quest 2 system.

- By requiring the manufacture, importation and wholesale be authorized
- By conducting post-market surveillance

# 3. LEGAL ASPECTS OF COSMETIC CONTROL

## 3.1 Director of Pharmaceutical Services (DPS)

The authority responsible for the regulation of cosmetic products lies with the DPS. National Pharmaceutical Control Bureau (NPCB) is a secretariat to the DPS which is responsible for the cosmetic product notification process.

## 3.2 Definitions

The following definitions are based on the ASEAN Cosmetic Directives:

### 3.2.1 Cosmetic Product

A cosmetic product shall mean ñany substance or preparation intended to be placed in contact with various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good conditionò

Please refer to Annex 1, part 2 - Illustrative list of cosmetic product by categories

### 3.2.2 Manufacturer

A manufacturer is a company which is engaged in any process carried out in the course of making the cosmetic products. The manufacturing process includes all operations of purchase of starting materials, bulk intermediates and products, formulation and production (such as grinding, mixing, encapsulation and / or packaging), quality control, release, storage and distribution of cosmetic products and the related controls.

### 3.2.3 Primary Assembler

A primary assembler is a company which is engaged in a process of enclosing the product in a primary/intermediate container which is labeled or to be labeled before the product is sold or supplied in it.

### 3.2.4 Secondary Assembler

Secondary assembler is a company which is engaged only in a process of labeling the product container where the product is already enclosed in its primary container and / or packing the product which is already enclosed in its labeled primary container into a carton which is labeled or to be labeled, before the product is sold or supplied.

### 3.2.5 Product Variant

For the purpose of this guideline product variants shall mean, items in a range of cosmetic products, which are produced by the same manufacturer, similar in composition and are intended for the same use but are available in different colours, fragrances or flavours. In this context;

Colour shall mean, a substance used as an ingredient of cosmetic product solely to give tonality to the product;

Fragrance shall mean, a substance used as an ingredient of cosmetic product solely to impart odour to the product; and

Flavour shall mean, a substance used as an ingredient of cosmetic product solely to impart taste to the product.

## 3.3 Legislation covering the manufacturer

Under the Control of Drugs and Cosmetics Regulations 1984, manufacturers need to ensure compliance with the ASEAN Guidelines on Good Manufacturing Practice (GMP) for Cosmetic.

A company or person responsible to notify cosmetic products must ensure that the products are manufactured in facilities that comply with the ASEAN Guidelines on Good Manufacturing Practice (GMP) for Cosmetic and Malaysian Good Storage Practice (GSP) or its equivalent.

## 4. WHO SHOULD NOTIFY THE AUTHORITY

The company or person responsible for placing cosmetic products in the market is responsible for notifying the DPS prior to manufacture, import, supply by wholesale or sale of the products. A written authorization from the product owner is required if the company or person notifying does not own the product.

### 4.1 Criteria of company or person who notifies local authority

Applicant must be a company incorporated in Malaysia.

### 4.2 Responsibility of company or person who notifies local authority

The company or person placing the product in the market must be responsible for ensuring safety, quality, performance or efficacy of the cosmetic product placed in the local market and to ensure that the product complies with all existing regulations.

## 5. NOTIFICATION PROCEDURE

Notification must be made on-line through NPCB website **www.bpfk.gov.my/Quest2.**
All applicants must first register for a digital certificate for access to Quest2 online system. Please refer to Annex 1, part 3 for Template for Notification of Cosmetic Product.

### 5.1 Document which must accompany notification form

A Letter of Authorization from the product owner including the list of products (if the applicant is not the product owner) authorizing the applicant to notify the products.

Additional Note:
For skin whitening product, company is required to submit original Certificate of Analysis for finish good within 1 month after product has been notified to BPFK. Failure to do so may cause product cancellation.

### 5.2 Language

Any document and material submitted to NPCB must be in English or Bahasa Malaysia.
If an applicant wishes to submit materials not published in English or Bahasa Malaysia, they must supply an authorized English or Bahasa Malaysia translation.

### 5.3 Privacy markings

All information submitted to the NPCB will be treated as ócommercial-in-confidenceô, whether or not it is marked as such by the applicant.

### 5.4 Product Variant

Variant(s) may be submitted in one application and additional variant may be added to the notified product together with appropriate fee.

### 5.5 Multiple Manufacturer

More than one manufacturer may be submitted in one application provided the product name and formulation are identical.

### 5.6 Processing Fees

The processing fee is RM50.00 for each product and for each variant (if any). A fee of RM500.00 is applicable for authorization to wholesale which should be renewed annually.

### 5.7 Notification validity period

The notification of a cosmetic product shall be valid for 2 years. The renewal should be done no later than 1 month prior to expiry together with the processing fee.

### 5.8 Manufacture or importation of product

The company or person responsible may manufacture or import the cosmetic product upon receipt of authorization given in the Notification Note from the DPS. Notification number will be generated in a period of 1-3 days after payment being received to enable printing of Notification Note by the applicant themselves.

### 5.9 Changes in notification particulars

Any subsequent changes in particulars of the notified cosmetic product must be informed to the authority. In general, there are two types of changes; changes that require amendment to the current notification or changes that require new notification. Please refer to Annex 1, part 4 for Illustrative List for Types of Changes for Notified Product

# 6. POST MARKET SURVEILLANCE

The NPCB shall monitor compliance of cosmetic products through surveillance in the marketplace and at the premises of the company or person responsible for placing the product in the market. This involves among others, ensuring the Product Information File is in place and safety assessment of the product.

## 6.1 Product Information File (PIF)

The company or person placing the product in the market shall be responsible for providing all information, certificates and data requested by the NPCB. The PIF does not have to take the form of a õdossierò(i.e. an extensive collection of paper records stored in a specific location). The physical location of the information (potentially in electronic format) can be anywhere, as long as the information is readily accessible on request. For further details, please refer Annex 1, part 5 for Guidelines for Product Information File (PIF).

### 6.1.1. Language

The PIF must be in Bahasa Malaysia or English.

### 6.1.2. Updating

The PIF must be kept updated of all modifications such as new ingredients, new manufacturers, new raw material suppliers, new production process, new information etc.

## 6.2 Safety Assessment of Cosmetic Product

A cosmetic product placed on the market must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use. The company or person placing the product in the market shall ensure that safety assessment has been conducted. Please refer to Annex 1, part 6 for Guidelines for Safety Assessment of Cosmetic Product.

## 7. COSMETIC INGREDIENTS

The company or person responsible for placing the cosmetic product in the market shall comply with the following requirements:

**7.1** Marketing of cosmetic products containing the following ingredients is prohibited

- substances listed in Poisons List ( unless exempted ) ; Poison Act 1952.
- substances listed in Annex II
- substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down
- colouring agents other than those listed in Annex IV, Part 1 with the exception of cosmetic products containing colouring agents intended solely to colour hair
- colouring agents listed in Annex IV, Part 1 used outside the conditions laid down, with the exception of cosmetic products containing colouring agents intended solely to colour hair
- preservatives other than those listed in Annex VI, Part 1
- preservatives listed in Annex VI, Part 1 beyond the limits and outside the conditions laid down therein, unless other concentrations are used for specific purposes apparent from the presentation of the product
- UV filters other than those listed in Annex VII, Part 1
- UV filters listed in Annex VII, Part 1 beyond the limits and outside the conditions laid down therein

**7.2** The presence of traces of substances listed in Annex II shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms to Article 3 of the ASEAN Cosmetic Directive.

**7.3** Marketing of cosmetic products containing the following shall be allowed:

- the substances and other ingredients listed in Annex III, Part 2 within the limits and under the conditions laid down, up to the dates in column (g) of that Annex
- the colouring agents listed in Annex IV, Part 2, used within the limits and under the conditions laid down, until the admission dates given in that Annex

- the preservatives listed in Annex VI, Part 2, within the limits and under the conditions laid down, until the dates given in column (f) of that Annex. However, some of these substances may be used in other concentrations for specific purposes apparent from the presentation of the product
- the UV filters listed in Part 2 of Annex VII, within the limits and under the conditions laid down, until the dates given in column (f) of that Annex

## 8. LABELING REQUIREMENTS

Labeling means information written or printed or graphic matter on the immediate or outer packaging and any form of leaflets.

Name of the cosmetic product means the name given to a cosmetic product, which may be an invented name, together with a trademark or the name of the manufacturer;

Immediate packaging means the container or other form of packaging immediately in contact with the cosmetic product

Outer packaging means the packaging into which the immediate packaging is placed

The company or person responsible for placing the cosmetic product in the market shall ensure that the cosmetic products comply with the labeling requirement as defined in Annex 1, part 7 for Cosmetic Labeling Requirements.

The information on the label shall be in English and/or Bahasa Malaysia.

## 9. COSMETIC CLAIMS

As a general rule, claimed benefits of a cosmetic product shall be justified by substantial evidence and/or by the cosmetic formulation or preparation itself.

Cosmetic products should not make claims that are regarded as medicinal in nature. A guidance document on examples of non-permissible claim is provided in Appendix 7. Please refer to Annex 1, part 8 for the Cosmetic Claims Guidelines**.**

It is prudent for the company or person responsible for placing the cosmetic product in the market to seek legal or expert advice to ensure that the proposed claims are not in breach of existing Acts or Regulations.

## 10. GOOD MANUFACTURING PRACTICE (GMP)

All cosmetic products must be manufactured in accordance to Cosmetic GMP Guidelines. Please refer to Annex 1, part 9 for Guidelines for Cosmetic Good Manufacturing Practice (GMP) and Annex 1, part 10 for List of Equivalent Cosmetic GMP Guidelines Recognized by ASEAN.

## 11. AUTHORIZATION FOR MANUFACTURE, IMPORT OR WHOLESALE

This refers to the manufacture, import or wholesale authorization issued by the DPS.

### 11.1 Manufacturing authorization

Authorizes the manufacture and sale by wholesale or supply of notified cosmetic products in the premises specified in the manufacturing authorization which is defined in the notification note.

### 11.2 Import authorization

Authorizes the import and sale by wholesale or supply of notified cosmetic products from the address of the premise specified in the import authorization which is defined in the notification note.

### 11.3 Wholesale authorization

Authorizes the wholesale or supply of notified cosmetic products from the address of the premise specified in the wholesale authorization which is defined in the notification note. Separate authorization is required for a wholesaler who is not involved in the product notification and importation.

## 12. PRODUCTS FOR EXPORT ONLY OR IN-TRANSIT

Cosmetic products that are imported solely for direct re-export or locally manufactured solely for export-only are exempted from product notification requirement, as they will not impact the safety of local consumers. However, prior approval from the DPS must be obtained for such activities. The company should maintain proper records and documents. These records should be available for the inspection by the regulatory authorities at any time when required.

Country specific requirements for manufacturers or importers of cosmetic products meant solely for export or re-export must be complied with.

## 13. TEST MARKET SAMPLING OR AESTHETIC STUDIES AND IN-HOUSE EVALUATION

A company or person responsible for placing the cosmetic product in the market may manufacture or import un-notified products for the following purposes which are subjected to prior approval from the DPS:

### 13.1 Test Market Sampling or Aesthetic Studies

A selective, one-time entry of un-notified products to place in a study to ascertain whether the aesthetic properties of the product are well perceived by a potential group of consumers or manufacturers.

The cosmetic industry may be allowed to manufacture or import un-notified products for the sole purpose of a selective test market sampling or aesthetic studies before its notification.

### 13.2 In – House Evaluation

In-house evaluation (Internal evaluation) is a process where product samples either from R&D or production line, minimally or fully labeled are evaluated by the company or person responsible for placing the cosmetic product in the market for the purpose of product selection, in-house sampling or demonstration and not meant for consumer use or commercial sale.

In-house evaluation is conducted on imported as well as locally produced products. The products are typically R&D samples but can also be products that are readily available in the country of origin.

## 14. REPORTING OF ADVERSE EVENTS

The company or person responsible for placing the cosmetic product in the market shall report to NPCB of any serious adverse event or high incidences of adverse event occurred, regardless of the source of the report (consumer, healthcare professional, etc). Please refer to Annex 1, part 11 for Guide Manual for Adverse Event Reporting.

## 15. PRODUCT RECALL

Product recall is a process taken by the company or person responsible for placing the cosmetic product in the market to remove or withdraw a particular product from all channels of distribution. The removal or withdrawal may be due to critical quality defects discovered or serious adverse events reported which might cause health risks to users during and after distribution of the product.

The aim of product recall is to quickly and efficiently retrieve batch(es) of product, that does not comply with Guidelines For Control of Cosmetic Products in Malaysia, or that may have an undesirable effect on humans.

The decision for recall shall be made when there is or may be risk to the user of the cosmetic product. Recalls can be initiated:

- voluntarily by the company or person responsible for placing the cosmetic product in the market
- at the directive of the DPS

### 15.1 Degree And Level Of Recall

The DPS uses the following criteria to classify the degree and level of recall.

### 15.1.1 Degree of Recall

The degree of recall is classified according to the seriousness of quality defects and/or adverse events of the products.

- **Degree I**

  Products with major health risks that might present serious injuries or death.

  Should be under an embargo within 24 hours.

- **Degree II**

  Products with minor health risks or substandard. Should be under an embargo within 72 hours.

- **Degree III**

  Products with other reasons for recall. Should be under an embargo within 30 days or as specified.

### 15.1.2 Level Of Recall

The level of recall depends on the nature of the problem, the extent of the distribution of the product and the degree of hazard involved.

- **Level A**

  For all consumers (end-users).

- **Level B**

  For all points of sales.

- **Level C**

  To all sub-distributors (wholesalers).

- **Level D**

  For Importers/manufacturers.

## 15.2 Decision On The Degree And Level Of Recall

Unless the DPS has already specified the degree and level of particular product recall, the product recall committee will decide the degree and level based on the risks involved.

The products recall committee shall comprise of personnel who are responsible for the execution and coordination of recall.

In cases of product recall initiated by the company or person responsible for placing the cosmetic product in the market, the product recall committee must inform the DPS immediately of this decision.

### 15.3 Record Keeping

The company or person responsible for placing the cosmetic product in the market must keep records of the primary distribution of their products, for the purpose of product recall.

## 16. CANCELLATION OF NOTIFICATION AND AUTHORIZATION

The DPS may, at any time and without assigning any reason cancel any approval for the notification, manufacture, import and wholesale of any product.

## 17. WITHDRAWAL

The company or person responsible for placing the cosmetic product in the market shall inform the DPS of any decision to withdraw the notification of a product before the end of the validity of the notification.

## 18. PENALTY

Any person who contravenes any of the provisions of the guidelines and regulations commits and offence and shall be liable on conviction as stipulated under Section 30 (1) and (2) of the Control of Drugs and Cosmetics (amendment) Regulations 2007

## 19. COSMETIC ADVERTISING CODE

The objective of the code is to ensure that the marketing and advertising of cosmetics to the public is conducted in a manner that promotes the quality use of cosmetics, is socially responsible and does not mislead or deceive the consumer.

Advertisements should contain information that is reliable, accurate, truthful, informative, balanced, up to date, and capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce unjustifiable use or give rise to undue risks. Please refer to Annex 1, part 12 for Cosmetic Advertising Code.

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