



COSMETICS REGULATORY APPROACHES IN MALAYSIA

GAGANASHREE TV¹ AND BALAMURLIDHARA V^{*2}

- 1: M. Pharm – Research student, Department of Pharmaceutical Regulatory Affairs, JSS College of Pharmacy, Mysuru, JSS Academy of Higher Education Research, Mysuru-570015, Karnataka
- 2: Associate Professor Department of Pharmaceutical Regulatory Affairs, JSS College of Pharmacy, Mysuru, JSS Academy of Higher Education Research, Mysuru-570015, Karnataka

***Corresponding Author: Dr. Balamuralidhara V: E Mail: baligowda@gmail.com**

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ABSTRACT

Cosmetics are products that are used to beautify people by imparting or increasing their beauty. Men and women both use cosmetics to greatly influence their perceptions of attractiveness and morality. Malaysia's pharmaceutical industry has been seeing rapid growth throughout the years. Pharmaceutical sales and advertising need pharmaceutical obligations to disseminate product information and materials through a specific regulatory process of increasing product sales. Malaysia's pharmaceutical manufacturing cluster is overseen by the Malaysian Ministry of Health (MoH). It examines the challenges facing Malaysia's cosmetic sector and consumers. Halal dimensions of cosmetics and personal care product businesses encompass ingredients and complete manufacturing techniques, all the way up to customer marketing, product protection, and efficacy tests everyone desires for lighter, fairer skin. However, certain cosmetics can be harmful to one's health, as well as the economy and scientific development. Because of increased local knowledge of personal care products, the government enacted legislation requiring the cosmetic dealers to identify all items prior distributing them in the existing economy, guaranteeing that clients utilise quality products. Other techniques to overcome barriers and making progress in the cosmetic industry have been employed by varied industries.

Keywords: Cosmetics, (MoH), Malaysia, Halal, Regulatory, Industry

1. INTRODUCTION

Cosmetics often are regarded as a "should indeed" item in people's everyday life. Under the Control of Drugs and Cosmetics Regulations, the National Pharmaceutical Regulatory Agency (NPRA) controls cosmetic products in Malaysia (1984). The cosmetology business is regarded as among the most important, not only in terms of its contribution towards global GDP, but also in terms of its economic impact. But also for its capacity to influence all personal and community life [1].

A cosmetic product is defined as "any 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 oral mucous membranes for the sole or primary purpose of cleaning, perfuming, changing their appearance, correcting body odours, protecting, or keeping them in excellent condition."

According to current trends, a few experts suggest that consumers are seeking for products which include psychoactive chemical and give considerable therapeutic results. The FDA performed a research on 1687 participants aged 14 and up in 1994, and it was observed that customers anticipated a product's effects after usage

should be the same as what was advertised on the box. This demonstrates that today's buyers possess preferences and are much more concerned with the effectiveness of the product they intend to purchase.

Despite the rising demand for cosmetics, it is also the primary responsibility of cosmetic industries and firms to assure product safety. However, some cosmetic manufacturers do not follow cosmetic product safety regulations because they continue to utilise banned drugs and chemicals as components in the products due to its low cost and efficacy, while being aware of the potential detrimental reactions. These dishonest manufacturers also hide their counterfeit cosmetic people with similar brands and designs to the actual goods and acquire them at low costs to exploit low-income consumers. Cosmetics' negative impacts have recently been recognised as one of the most important elements of cosmetics. Consumers were the intended participants in many of these studies, therefore the responses was frequently also used reference.

Products are managed under Malaysia by the Control of Drugs and Cosmetic Regulations (CDCR) 1984 that were enacted in response to the Sale of Drugs Act 1952. Skincare goods through Malaysia were

managed by a notification system that commenced on January 1st, 2008, in compliance with the ASEAN Cosmetics Directive (ACD). The Version must meet all of the requirements outlined inside this guideline and provide a statement to the Director of Pharmaceutical Services (DPS) through the National Pharmaceutical Regulatory Agency. False claims and/or products found to be in violation of the established standards and norms will result in regulatory action [2].

According to Regulation 18A of the CDCCR 1984, no one shall manufacture, sell, distribute, import, or possess any items only if the cosmetic is a registered cosmetic. Anyone who engages in such activity without first alerting the DPS commits a criminal.

Consumers who are competent and attentive normally keep up with publications, newspaper articles, and the Internet, and they frequently receive information as well as updates from the relevant authority regarding quality defects or terminations of cosmeceuticals that have been suggested to contain toxic products through data and independent analysis such as publications and the Web. Some clients, however, are not aware of the issues. Legislation cannot avoid or prevent cosmetic safety concerns and hazards. However, the danger to cosmetics

users may be reduced by examining their awareness and practice toward cosmetics safety, as well as their products behaviour and perspective.

Such information acquired could also be used as a reference purposes for the wider population, government bodies, including pharmaceutical manufacturers. The major goal of this research aimed to investigate Malaysian cosmetics consumers' cosmetic-related information, habits, attitudes, or beliefs, particularly in terms of security and negative consequences. To be more precise, a systematic cosmetovigilance system is required for the detection and awareness of hazardous components, therefore this foundation research was designed to act as either an environmental catalyst [3].

COSMETIC NOTIFICATION REGULATIONS

NPRA will require the corporation to meet the following requirements prior to the notification of any cosmetic products:

2.1 Requirement for safety

The amount of safety for a final product, in this instance any cosmetic product, must be determined based on at least three factors: components, chemical structure, and level of exposure. This is the NPRA's starting point, which is also in line with ASEAN Cosmetics Directive Article 8(d) [4].

The maker must satisfy the following conditions before NPRA would inform any cosmetic items:

- a. Careful choice of cosmetic ingredients, ensuring that they have been safe at a particular concentration in a provided final product;
- b. Cosmetic brands will not contain ingredients forbidden by the local authorities (Poison Act 1952 and the Guidelines);
- c. Verifying local tolerance of a final product;
- d. Choosing appropriate packaging to preserve the purity of cosmetic products while avoiding risks of overuse or accidents as much as feasible;
- e. Quality control, primarily microbiological and chemical, as well as stability tests of the cosmetic product's shelf life and packing;
- f. Appropriate processes in the event of negative effects from the advertised cosmetic product; and
- g. Implementing remedial action or follow-up if any evident product alteration or fake products is reported in the market [5].

2.2 Requirements for Labelling

According to the NPRA, proper labelling for cosmetic items must display in their product package or, if no outside packaging exists, on the cosmetic products' immediate packaging. The following details must be included: the product's name and its function;

- a. product usage instructions;
- b. entire component listing, which must be reported in decreasing order of weight at the moment of addition;
- c. country of manufacturing
- d. the name, address, and phone number of the firm in possession of the necessary licence or certificate;
- e. the production batch number and the product's manufacturing or expiry date; and
- f. Special care should be taken before using [6].

1. COSMETIC NOTIFICATION

All cosmetic product warnings must be issued online utilising the Quest system after successfully registering for CNH in the system. CNH must complete the Quest system notification form and pay to NPRA a processing fee of Ringgit Malaysia Fifty Only (RM50.00) for every item and variant

(if any). The cosmetic items will next be put to a compliance screening to see if they fulfil regulatory requirements. If it meets the requirements, a notification letter is sent, and the cosmetic items can be registered and marketed. The notification procedure might take depending on the extra paperwork and information required by NPRA, anything

from one (1) week to one (1) month. Additionally, cosmetic product notifications are valid for two (2) years and must be renewed no later than one (1) month before the notice expires. The renewal costs for cosmetic product notification are the same: Ringgit Malaysia Fifty Only (RM50.00) (for each product and version) (if any) [7].

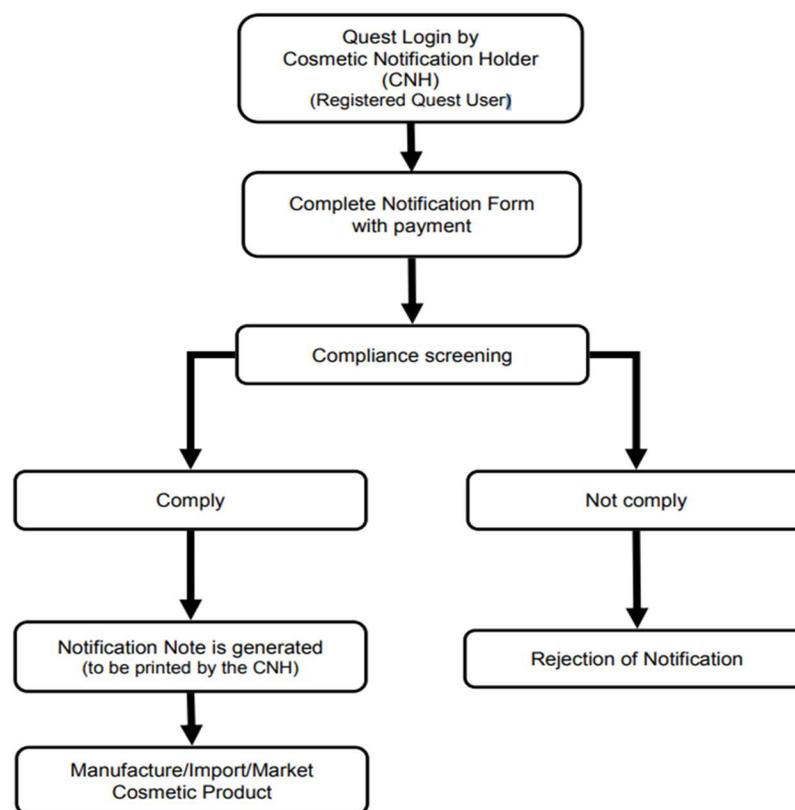


Figure 1: workflow of a notification process

Source: <https://www.npra.gov.my/index.php/en/component/content/article/147-guidelines-central/guidelines-cosmetic/1595-2-0-cosmetic-notification?Itemid=437>

3.1 Notice Submission Rejection

- The NPRA will review all aesthetic notice submissions. Cosmetic products found to include prohibited components or be utilised

outside of the authorised limits and circumstances, as well as those asserted and represented being used outside of the cosmetic scope, will be denied notice.

3.2 Notification Cancellation Note

If the DPS has reasonable reasons to believe that a cosmetic product does not conform with the prescribed standards and rules, he may cancel the notification note at any time. Any conditions related to the notification letter may also be changed by the DPS. When the DPS provides a written notice of cancellation, it becomes effective (known as a directive). The CNH must fulfil all of the DPS directive's instructions, including but not limited to the recall and disposal of the recalled items. By the date specified in the directive, a structured report must be drafted and delivered [8].

3.3 Sanctions/Penalties

Anyone who breaches any one of the standards or regulations commits an offence and is held responsible if convicted Section 30 (1) of the CDCR were enacted in 1984.

4. NOTIFICATION WITHDRAWAL

CNH must notify the NPRA of its decision should delete any cosmeceutical notice before its validity period expires, as well as their explanation. CNH is responsible for notifying the producer supplier.

Once withdrawn, a cosmetic product notice cannot be restored, and the notification remark for the removed product is regarded void. A fresh notification submission may be used to re-notify the product [9].

5. POST MARKET SURVEILLANCE PROGRAMME

The NPRA will monitor cosmetics and personal care products compliance through the Post Market Surveillance (PMS) programme.

- Product composition and information are screened to ensure that products do not include any prohibited, harmful substances, and that any restricted components are used within authorized limits and conditions of being used. The product's name and claimed benefits are also used as screening criteria.
- Obtaining and testing samples
- Monitoring label compliance
- Cosmetic GMP compliance audit of the premises
- Resolving customer concerns
- Advertisement monitoring
- Adverse reaction monitoring
- Review of the PIF
- Effective risk communication
- ASEAN Post Marketing Alert System information sharing (PMAS) [10]

6. CERTIFICATION OF FREE SCALE

A certificate of free sale (CFS) is a certificate that certifies that an item can be sold legally in Malaysia. The certificate is optional. As a

result, the NPRA will only provide it if the CNH specifically requests it and seeks to transport its registered cosmetic to a country that requires it.

CFS applications are only accepted online using the CNH's Quest system, and each certificate copy costs RM50.00. A product's CFS and its variant can be combined into a single certificate if the latter is designated as just a version of the primary brand.

7. COSMETIC INDUSTRIES: APPROACHES FORWARD AND CHALLENGING

7.1 The Ministry of Health Malaysia's government policy (MOH)

The government enacted the Control of Drugs and Cosmetic Regulations (CDCR) in 1984, which was classified underneath the Sale of Drugs Act 1952 and stated that all cosmetic products would be subject to it. As a result, before being marketed in Malaysia, any cosmetics or aesthetic products must be legally registered with the Ministry of Health Malaysia and the Drug Control Authority. Prior to January 1, 2008, the ASEAN Cosmetic Directive (ACD) had the capacity to regulate cosmetic goods in Malaysia through a notification system. The Cosmetic Notification Holder (CNH) was required to meet all of the Guideline's requirements and submit a declaration to the Director of

Pharmaceutical Services over the Internet via the National Pharmaceutical Regulatory Agency (NPRA) (known as DPS). Cosmetic suppliers would suffer legal penalties if the laws and procedures were not fulfilled [11].

According to the legislation, vendors shall not create, market, manufacture, either own cosmetic products unless they have been adequately educated. No merchant may engage in such operations without first contacting the DPS (NPRA, 2020). NPRA also regularly assesses all certified cosmetic goods through the Standard Monitoring System of Notified Cosmetic Goods to verify that every cosmetic product on the market complies with all applicable standards, regulations, quality, and safety requirements. Some of their responsibilities include screening product information, evaluating Product Information Files (PIF), sampling items for quality testing, monitoring label compliance, inspecting the product's facilities for APB adherence, and monitoring promoted product commercials. In addition, the NPRA keeps track of reports of negative effects and investigates complaints concerning cosmetics.

According to Malaysia's Cosmetic Control Guidelines, the following rules must be followed: -

1. Product information, such as the product name, kind, intended application, and presentation
2. The name and location of the manufacturer(s) and assembler, if relevant (s).
3. The CNH's name, address, and phone number (as well as e-mail address)
4. Contact information for the person representing CNH, including a legitimate phone number
5. The importer's name and address, if applicable.
6. Full product ingredient list (with the percentage of forbidden components specified)
7. Where appropriate, a letter of authorization/declaration/contract manufacturing letter
8. The product's label(s)

The product notification status of a company will be cancelled by NPRA if it fails to meet the legal and regulatory requirements of legislation. The company in question will be told to stop selling the goods. Those who break the Drugs and Cosmetics Control Regulations (DCCR) face a fine of up to RM 50,000 or a three- to five-year prison sentence. Organizations that commit the same offence more than once may face fined up to RM 100,000 [11].

7.2 Educating the wider public about the cosmetic product

Minority customers were ignorant of a health dangers linked with using chemical-laden cosmetics. Nonetheless, many of them were aware of the negative effects of these goods and sought certified organic skincare and cosmetics as a result. Despite the fact that the cosmetics company is exclusively responsible of ensure that products on the market are legal and of excellent quality, we, as customers, must be cautious about what we put on our bodies. When buying cosmetics, consumers must make informed decisions. Tejal did study in 2013 to see if clients are aware of the unique characteristics of cosmetics they had purchased. Customers often examine the expiration date, composition, and advantages and side effects of chemicals on their overall health before purchasing cosmetics. According to the research, both men and women indicated they read the safety notice before purchasing goods, indicating that shoppers are concerned about the potentially negative outcome. Furthermore, the majority of purchasers checked the manufacturing/expiration date before purchasing cosmetics. Customers should also be informed about the detrimental effects that cosmetics have on their physical wellbeing. Hydroquinone, retin, and betamethasone

valerates are all harmful medications that must be licenced by the Drug Control Authority and administered under medical supervision. Skin irritation, pigmentation, and organ damage are all possible adverse effects of using such ingredients in products without the supervision of a health specialist. On the NPRA website, the public may quickly check the status of notifications or the most recent lists of cosmetic goods containing forbidden components [12].

7.3 Overcoming Challenges and Developing the Cosmetics Industry

The cosmetics sector benefits from accelerating investment by small and medium-sized businesses (SMEs). The cosmetics and small company industries both benefit from increased coordination of advanced manufacturing investment with private and non-federal investors. Expanding the manufacturing sector, which strengthens worker capabilities by increasing the number of skilled employees, allows for the prompt production of more things.

It covers not just manufacturing sector, but also R&D, enabling for greater product development studies. Manufacturer and cosmetic creator education and training should be performed since this training enables for more efficient product production. Not only at the manufacturing level, but also as a supplier,

a workforce with effective product knowledge will be able to provide the exact demand to the consumer, especially in the sector of hands-on beauty items. The FDA-regulated industry's statistical method described the manufacturer's installation and maintenance for Corrective and Preventive Action (CAPA). It's necessary in order to produce a high-quality product. A procedure, job operations, concession, control quality reports, maintenance records, and complains about returned items must all be thoroughly documented for future development, according to the journals [12].

8. HALAL COSMETIC INDUSTRIES

The Malaysian halal cosmetic industry has existed since 1980, with a strong growth recently contributing 10 to 20 per cent of the total local cosmetics market. The industry is worth approximately USD800 million, with an annual growth rate of 24 per cent (Halal Industry Development Corporation, 2014). In the year 2013, the export of Malaysian halal cosmetic products was approximately at RM 464.45 million, with destinations such as the United States, the Middle East, China, ASEAN and Europe being the major markets.

In 2011, there were 114 local manufacturers in the industry certified as halal (Boo, 2013). Among the market leader in this sector include Unza, Clara international Beauty

Group Sdn. Bhd., SendayuTinggi Holdings SdnBhd and Simplysity Sdn Bhd. Hence, it is interesting to note that halal cosmetic industry has become one of the vital economic sectors of the Malaysian economy. Notwithstanding this, Malaysia has also attracted a huge number of leading foreign cosmetic manufacturers Procter & Gamble, Unilever, L'Oreal and Colgate-Palmolive to establish their manufacturing facilities in the country, driving foreign exchange earnings and employment opportunities. In Malaysia, the halal cosmetic products are governed by the Malaysian Standard MS 2200:2008 and Halal Certification Procedure Manual, which warrant strict manufacturing facilities inspection and audit by the Malaysian Department of Islamic Development (JAKIM) (Hashim and Mat Hashim 2013). Owing to the interesting development of Malaysian halal cosmetic industry, it is imperative to understand how the young Muslim consumers perceive the halal cosmetics and what factors affecting their adoption decision, as this could positively facilitate the manufacturers in producing and marketing products effectively.

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The global demand for halal cosmetics is increasing among the world's 2.4 billion Muslim clients. However, because the cosmetics market is dominated by non-halal cosmetic companies whose production procedures may not adhere to halal scientific

requirements, the need for halal cosmetics remains unmet. Halal cosmetics are still in the early phases of development, as is the evaluation of their product performance. The use of halal science in the manufacturing of most cosmetics is still insufficient. Furthermore, there is a global shortage of guiding documentation on the invention and assessment procedures utilised in entirely halal cosmetics manufacturing [13].

Malaysia's halal cosmetics business has existed since 1980, accounting for 10 to 20% of the country's total cosmetics market in recent years. The sector is worth about USD800 million and is increasing at a pace of 24 percent annually (Malaysian Industrial Development Corporation, 2014). (Halal Industry Development Corporation, 2014). In 2013, Malaysian halal cosmetics shipped RM 464.45 million, with significant buyers including the United States, the Middle East, China, ASEAN, and Europe. In 2011, there were 114 halal-certified establishments in the area. Unza, Clara International Beauty Group Sdn Bhd, Sendayu Tinggi Holdings Sdn Bhd, and Simplicity Sdn Bhd are among the industry leaders in this field [14].

As a result, the halal cosmetics industry in Malaysia has developed to be one of the country's most important economic sectors. Despite this, Malaysia has attracted a slew of

big global cosmetics businesses to develop production plants, including Procter & Gamble, Unilever, L'Oreal, and Colgate-Palmolive, resulting in increased foreign exchange profits and job possibilities. Malaysian Standard MS 2200:2008 and Halal Certification Procedure Manual regulate halal cosmetics, requiring the Malaysian Department of Islamic Development to oversee and inspect manufacturing facilities (JAKIM).

Because of the fascinating expansion of Malaysia's halal cosmetics business, it's essential to comprehend how young Muslim customers perceived halal cosmetics and also what variables influence their decision to adopt, as this will help producers create and promote products more efficiently. The Distribution of Innovation (DOI) Theory tries to explain how, why, and when new ideas spread across cultures. According to the theory, perceived innovation qualities, societal influence, and individual innovativeness all impact a person's acceptance of innovation. Innovation characteristics including perceived relative benefit, compatibility, and complexity account for 49 to 80% of the variation in innovation adoption rates.

The degree to which an invention is seen as being superior to the idea it replaces is referred to as relative advantage. Previous

studies have linked halal cosmetics to cleanliness, safety, and high quality; because these products must be manufactured under rigorous sanitary circumstances in Good Manufacturing Practice and Public Health Legislations are followed. Because they are not tested on animals and are made with natural ingredients that are gentle on hair and skin, halal cosmetics are suitable for both Muslims and non-Muslims. Compatibility, which relates to how well an innovation fits into various cultures, may encourage them to adopt the new product in addition to these criteria. Muslim customers may repurchase halal cosmetics if product features like as ingredients, texture, and performance factors meet their cultural norms and personal preferences [15].

Encouragement of excellence that is incompatible with Islamic values can lead to cultural conflicts and ethical dilemmas. Cosmetics and personal care goods for Muslim consumers must not only exceed regulatory safety requirements, but also be halal. While keratin (derived from hair), albumin (derived from human serum), and placenta (derived from the womb) are commonly used in conventional cosmetics, they are not authorised in the halal cosmetic manufacturing process since they include human components. The halal status of these

commodities is important because it affects Muslim worship and prayers. They may have religiously educated expectations of the items, which, if not met, would result in low consumer satisfaction. Similarly, potential adopters may assess the innovation based on its complexity, which relates to the degree of difficulty associated with implementing the invention, as well as the needed resources and cognitive activities. This implies that consumers' purchasing decisions will be influenced by the difficulty in obtaining halal cosmetics on the market. The absence of a halal emblem on a product, for example, may need a significant amount of time and cognitive effort on the part of the buyer to go through the components before making a purchase choice [16] .

9. CONCLUSION

The global cosmetics industry is rapidly increasing. This is a direct effect of the growing total employed women and men, as well as increased industrialization. Improved awareness as a result of education. Investigations on client purchases and usage of beautifiers are still necessary because consumer behaviour appears to be changing over time. As the brand's name plays a vital part in purchasing decisions, it also impacts customer behaviour, which can influence whether or not a purchase is made. Halal

cosmetics production entails rigorously selecting halal components, implementing halal procedures at every stage of the manufacturing process, and verifying product performance conforms to Islamic rites. Individuals who use cosmetic items are still unaware of the chemicals, which may have an impact on their health. In accordance with Malaysian government decisions on cosmetic regulations, unless a beauty or cosmetic product violates the rules and regulations, the NPRA will revoke its product notification status. The company in question will be told to stop producing them, and more legal action will be taken. The government has also set up an official website where customers may check the status of cosmetic item notifications and component lists. Otherwise, new ways for small and medium-sized businesses to improve and expand their customer base should be made available.

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Conflicts of interest

There are no conflicts of interest.

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