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# Evaluating the Efficacy of Cosmetic Product Safety Regulations in Malaysia: The Role of the National Pharmaceutical Regulatory Agency (NPRA) and Industry Compliance

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**Abstract:** Various legislative measures, such as the Sale of Drugs Act 1952, Control of Drugs and Cosmetics Regulations 1984, Poison Act 1952, Guidelines for Control of Cosmetic Products 2022, and other directives introduced by the NPRA in Malaysia, are intended to control the safety of cosmetic products. Despite these existing laws and directives, cosmetic products containing hazardous ingredients persist in the Malaysian market. NPRA reportedly received 1,041 complaints about cosmetic products in 2022, while its website also displays an annual increase in cases involving cosmetic products that contain hazardous ingredients. The persistent presence of harmful cosmetic products in the market highlights significant gaps in efforts to control hazardous cosmetic products. This study examined the efficacy of cosmetic product safety regulations in Malaysia, focusing on the role of the National Pharmaceutical Regulatory Agency (NPRA) and industry compliance. This qualitative study gathered data from library databases and conducted semi-structured interviews with NPRA officers, cosmetic manufacturers, and cosmetic industry experts. Findings suggest that despite the extensive nature of the regulatory framework, its implementation, which heavily relies on self-regulation and post-market surveillance, requires serious improvement. While some cosmetic producers adhere to Good Manufacturing Practice (GMP) standards, there are still persistent issues related to product notification, misuse of self-regulation, and inadequate penalties for non-compliance. Therefore, an intensive awareness campaign aimed at cosmetic manufacturers is necessary to ensure the production of safe cosmetic products. Consumers must play their role in helping the NPRA control the sale of hazardous cosmetic products by performing safety checks before purchasing them.

**Keywords:** *Cosmetic products; National Pharmaceutical Regulatory Agency (NPRA); cosmetic product safety, safety regulation, cosmetics directives*

## 1. Introduction

The word “cosmetics” comes from the ancient Greek word “*kosmos*" meaning “adornment” (Power, 2010). Cosmetics also includes body and beauty care, which focuses on preserving, restoring, and improving the human body's attractiveness (Rahse, 2019). The Control of Drugs and Cosmetics Regulations 1984 defines cosmetics as “any substance or preparation intended to be placed in contact with various external parts of the human body (including epidermis, hair system, nails, lips, and external genital organs) or the teeth or mucous membranes of the oral cavity with a view, exclusively or mainly, to clean, perfume, change the appearance or correct body odors, and protect or keep the areas in good condition”.

The Control of Drugs and Cosmetics Regulations 1984 (CDCR) conclusively defines cosmetics as items used for various external body functions. The definition of cosmetics limits the purpose and function of cosmetic products for use only on permitted parts of the human body (Zakaria et al., 2019). The word "in contact" means that the function of cosmetic products cannot go beyond the epidermis, and it must be applied only to the epidermis, hair system, nails, lips, external genital organs, or the teeth or mucous membranes in the oral cavity. The function of cosmetics must be within the definition of cosmetics stipulated in CDCR, including cleaning, scenting, altering body appearance, correcting body odors, and protecting or maintaining a healthy human body.

Cosmetic products must comply with the laws, regulations, and directives related to cosmetic product safety if they are to be marketed in Malaysia. Cosmetic products’ safety is regulated by the Sale of Drugs Act 1952 (SODA), Poison Act 1952, CDCR, Malaysian Guidelines for the Control of Cosmetic Products (GCCP) 2022, and

other forms of legislation relevant to the regulation of cosmetic products in Malaysia. Section 27 of the SODA provides an extension of all the provisions in the SODA that apply to soap, cosmetics, and toiletry preparations. In addition, Section 28 of the SODA grants the Ministry of Health (MOH) the power to introduce CDCR for governing the sale of drugs and cosmetics in Malaysia. MOH also appointed NPRA to control cosmetic products in Malaysia.

NPRA is under the purview of the Pharmaceutical Services Division (PSD) in MOH and was one of the initiatives introduced by the MOH. NPRA, initially known as the National Pharmaceutical Control Bureau (NPCB), was established in October 1978 as part of the Pharmacy and Supply Program's quality control operation to implement this regulatory responsibility (NPRA, 2015). The Director of the NPCB serves as one of the drug control authorities, and starting from 15 July 2016, the NPCB became known as the National Pharmaceutical Regulatory Agency (NPRA, 2015). NPRA introduced the GCCP in 2022 and it contains directives for further controlling the safety of cosmetic products. Regulation 18 of CDCR mandates that each cosmetic company should notify the NPRA of its cosmetic product(s) before manufacturing, selling, supplying, importing, possessing, or administering the said cosmetics in Malaysia.

Notification can be considered an initial control mechanism of cosmetic products before the products are marketed to consumers. This control mechanism has been in force since the first Guideline for Control of Cosmetic Products (GCCP) was introduced in Malaysia in 2008. The GCCP has undergone several amendments, the latest of which was published in 2022. Despite this, the production and sale of hazardous cosmetic products persists in the Malaysian market. In 2022, NPRA reported receiving 1,041 complaints about cosmetic products (NPRA, 2022), while its website displayed an annual increase in cases involving hazardous cosmetic products (NPRA, 2024).

The hazardous ingredients commonly found in cosmetic products include mercury, hydroquinone, tretinoin, and betamethasone 17-valerate (NPRA, 2024). Mercury can damage the kidneys and nervous system (Bernama, 2024). Hydroquinone can cause erythema, discomfort, changes in skin pigmentation, hypersensitivity, and increases the risk of skin cancer, while Tretinoin can lead to erythema, irritation, tenderness, desquamation, and increased photosensitivity (The Sun, 2024). Conversely, using betamethasone 17-valerate can cause skin atrophy, making it more likely to get irritated, develop acne, change its color, and get absorbed by the body, which could lead to adverse side effects (Bernama, 2024). The persistent presence of hazardous cosmetic products in the Malaysian market indicates an inadequate quality control mechanism (Othman et al., 2020) and a deficiency in cosmetic product safety regulations, thus, highlighting the need to revise current laws and regulations to ensure consumer safety. This study examined the efficacy of cosmetic product safety regulations in Malaysia, focusing on the role of the NPRA and industry compliance.

Studies on cosmetic safety control are lacking, as most studies focus on consumers' behavior toward cosmetic products. However, two studies are related to the control of cosmetic products. Zakaria (2015) examined the European Union model for cosmetics operations and used Malaysia as a case study. The study referred to the EU Cosmetics Directive (76/768/EEC) and the European Parliament's EU Cosmetics Regulations (Regulation (EC) No. 1223/2009). The study found that Malaysia has dramatically benefited from the EU's regulatory framework, particularly in improving consumer safety against harmful products. Although this study discussed the law on cosmetic products, the discussion primarily focused on the regulation of cosmetic products before and during 2015. Othman et al. (2020) conducted a subsequent study on safety protection, specifically focussing on the application of cosmetic products in Malaysia. It focused on consumer protection by highlighting the Consumer Protection Act 1999, which aims to ensure consumer safety and prohibit the supply of hazardous cosmetic products. It also briefly discussed the Control of Drugs and Cosmetic Regulations 1984 (CDCR) but did not delve into a detailed discussion on safety control measures for cosmetic products. The gap in the literature concerning NPRA's role in regulating cosmetic products and industry compliance inspired this study.

This current study is significant given Malaysia's regulatory structure, which primarily relies on self-regulation and post-market surveillance, where consumers are highly exposed to dangerous and low-quality cosmetic products produced by unscrupulous cosmetics manufacturers and sellers. In addition, it intended to identify regulatory and industrial practice features that require improvement by addressing challenges faced by local

enforcement and exploring how the industry complies with guidelines. It also highlights the importance of enhancing laws and public education in countries with limited consumer awareness of cosmetic safety, thus, enabling consumers to make safer choices. Enhancing Malaysia's regulatory framework will strengthen public health safeguards and help the domestic cosmetics sector adhere to international safety standards, thereby fostering consumer confidence and economic development.

## 2. Literature Review

### Regulatory frameworks governing cosmetic products

In Malaysia, cosmetic products are regulated by the Sale of Drugs Act 1952 (formerly the Sale of Food and Drugs Ordinance 1952) (SODA). Section 26 of SODA gives the Ministry of Health (MOH) the power to make regulations related to cosmetic products. As such, the MOH issued the CDCR to control the sale of drugs and cosmetics. The CDCR regulates the registration of products containing drugs and the notification of cosmetic products. Regulation 29 of the CDCR requires mandatory compliance with all the directives or guidelines issued by the Director of Pharmaceutical Services (DPS), in which any violation of CDCR shall be punishable according to the general penalty outlined in Section 12 of SODA.

Section 12 of SODA provides that “any person who commits an offense under this Act or any regulation made under this Act for which no penalty is expressly provided shall be liable on conviction to a fine not exceeding twenty-five thousand ringgit or imprisonment for a term not exceeding three years or both, and for a second or subsequent offense the person shall be liable on conviction to a fine not exceeding fifty thousand ringgit or imprisonment for a term not exceeding five years or both. A body corporate that commits an offense under this Act or any regulation made under this Act for which no penalty is expressly provided shall be liable on conviction to a fine not exceeding fifty thousand ringgits”.

Compliance with all regulations about cosmetic products should start before cosmetic companies notify the NPRA of their products. Cosmetic manufacturers must obtain the relevant licenses from local authorities (PBT) to conduct business and manufacturing activities. They must ensure that the factory layout, premises, and facilities adhere to the Guidelines for Cosmetic Good Manufacturing Practice (GCGMP).

### A. Requirements for Cosmetic Good Manufacturing Practice (CGMP)

Good manufacturing practice (GMP) is not only compulsory for food production but is also obligatory for the cosmetics industry. Cosmetic companies are required to adhere to GMP before conducting product notifications (Ahmad et al., 2013). Cosmetic manufacturers must plan and design their manufacturing facilities according to the CDCR and Annex 1 Part 11 of the Guidelines for Cosmetic Good Manufacturing Practice. The CDCR does not highlight the manufacturing facility but emphasizes that the premises must be in excellent condition and observe a high standard of hygiene. GCGMP aims to ensure that the end product manufactured meets quality standards appropriate for its intended use, safety, and consumer benefits. Moreover, being GCGMP compliant enables cosmetic manufacturers to proceed with subsequent processes, such as product notification, manufacturing, and distribution of products to consumers (GCGMP, 2022). GCGMP emphasizes minimizing the risk of contamination in the manufacturing premises by addressing issues about quality control aspects, personnel, manufacturing premises, equipment, sanitation and hygiene, production, storage, quality control documentation, internal audits, storage, complaints, and product recall.

According to GCCMP, the manufacturing premises must maintain high levels of cleanliness. The walls, ceiling, and flooring in the processing area should be smooth and easy to maintain and sanitize. However, the GCGMP does not mention how the manufacturers should ensure the smoothness of their factory floors and walls. Clause 3.6 of the GCGMP states that the floor and walls must be "smooth" and easy to clean and sanitize. The processing area should be segregated from the packaging and the labelling process areas. Moreover, there must be sufficient space to accommodate the equipment and machines used in the production process, such as mixing and filling, which involves dissolving, charging, cooling, and filtering.

GMP also includes equipment and machinery. Equipment requires simple cleaning and proper maintenance to ensure its longevity (Gudowska, 2017). There is no need to provide evidence of the cleaning process's efficacy as this would entail a comprehensive analysis of surface residues and measurement of residues in rinsing

solvents, which can be a significant scientific undertaking (Moore, 2009). The equipment's surfaces that meet process materials should not react with or absorb them (NPRA, 2022). Leaky valves, oil leaks, and unsuitable changes or adaptations should not negatively affect the product (NPRA, 2022).

**B. Notification Requirements for Cosmetic Products**

Regulation 18A of the CDCR 1984 specifically mandates a compulsory notification for each cosmetic product before being manufactured, sold, supplied, imported, possessed, or administered. The Director of Pharmaceutical Services (DPS) may exempt the notification if a locally registered company manufactures or imports cosmetics for market sampling, internal evaluation, export, transit, sales, or supply in a free trade zone. The notification process is essential because it enables the NPRA to gather enough information about cosmetic products sold in the local market (Zakaria, 2015). The NPRA's website will serve as the notification platform for cosmetic products through the Quest 3+system. Since its establishment, the Quest 3+system has undergone three upgrades. It was previously known as the Quest System, but it underwent an upgrade to Quest 3 and is now known as Quest 3+. Notifying cosmetic products to NPRA is within the purview of Cosmetic Notification Holders (CNH). CNH is a Malaysian-registered local company specializing in cosmetics and oversees the placement of a product in the market. However, the CNH may or may not be the product owner (GCCP, 2022). To notify the NPRA, CNH should declare basic information about the product according to Clause 3.1 of the GCCP.

Clause 3.1 of the GCGMP stipulates that CNH must provide information about the product's name, type, intended use, presentation label, manufacturer's name and address, CNH's name and address, complete ingredient list with the content and percentage of restricted ingredients, authorization and declaration documents, manufacturing contract documents, and the product label. The Quest3+system's declared information binds manufacturers into producing products that align with what has been declared in the system. Quest 3+ is an auto-screen database that accepts only cosmetic products with acceptable and restricted ingredients within the approved composition percentage (NPRA, 2022). The system will automatically scrutinize the product's formula, as well as identify and block any prohibited ingredient in the cosmetic product or any new ingredient yet to be registered (NPRA, 2022). Hence, if the NPRA discovers any cosmetic product that contains prohibited substances, substances beyond permitted limits and conditions, or use of the claimed product for purposes beyond the scope of cosmetics, it will reject the product notification and deny the CNH a notification note (NPRA,2022).

The notification process can be the first step in regulatory control aimed at preventing the marketing of cosmetic products that contain prohibited ingredients. However, this control will fail if the CNH does not accurately declare the ingredients and all the information required under Clause 3.1. The NPRA will conduct post-notification controls as a subsequent control measure to verify the notification of the cosmetic product. Post-notification controls consist of auditing the Product Information File (PIF) and post-market surveillance.

**Product Information File (PIF)**

The CNH must develop a PIF, which is one of the post-notification processes, to substantiate a cosmetic product's safety, quality, and purported benefits (Salleh, 2013). The CNH should provide a PIF for every product introduced to the market. This document should include critical information, such as product safety, adverse effects, and ingredients contained in the marketed product. It must be available at the label's specified address and maintained for three years following the product's marketing (NPRA, 2022). The information about adverse side effects, product claims, and product efficacy must be derived from the cosmetic products' composition, tests, and supporting data (Zakaria, 2015). Contents of the PIFF must be consistent with both the notification note and the final product. The NPRA will conduct a PIF audit to verify the CNH's declaration of compliance during the notification submission process (Salleh, 2013).

The NPRA conducts PIF audits for products that meet specific criteria, including high-risk products, skin-whitening products, manufacturers or companies with a history of product complaints, consumer recalls poor Good Manufacturing Practice (GMP) practices, and products that fail laboratory tests (Salleh, 2013). Products with deceptive names and claims that go beyond cosmetics or intended for treatment purposes, such as mesotherapy, massage oils with therapeutic indications, or slimming products, are among the other criteria that trigger a PIF audit (Mesa, 2015). There are two possible PIF findings, namely major and minor. Major

findings will lead to cancelling the notification note and withdrawing products from the market. Meanwhile, for minor findings, cosmetic companies or the CNH will receive a warning letter without a product recall and will be required to take corrective measures within a specified time frame (Salleh, 2013).

**Post-market surveillance (PMS)**

The NPRA conducts ongoing post-market surveillance activities to monitor cosmetic products in the marketplace after notification (Huzaifi, 2014). The PMS program actively and systematically compiles information on the safety and quality of cosmetic products (Hegde and Konakanchi, 2011). It may be considered a monitoring tool for ensuring compliance with rules and guidelines stipulated by the Ministry of Health and protecting public health from adulterated and unsafe cosmetic products (Roslan et al., 2023). PMS activities about cosmetics include a screening of product formulation and information, product name and its purported benefits, sample collection, and testing, monitoring of label compliance, auditing of premises to ensure compliance with Cosmetic GMP, addressing product complaints, monitoring advertisements, monitoring adverse reactions, and auditing PIF.

The NPRA conducts PMS either through routine inspections or random sampling. A routine PMS would rely on the case list and information from the enforcement department. Whereas, random sampling would depend on complaints or inquiries from the public or queries from the Quest3+ system while issuing notifications and inputs from the GMP audit (Huzaifi, 2014). NPRA collects product samples either by requesting CNH to submit a product sample to NPRA or by buying directly from the market (also known as "best buy") (NPRA, 2022). According to Section 4 of the GCCP, if the NPRA requests a sample, the CNH must ensure that the sample packaging is unopened and in its original container, the test sample is similar to the production batch, the cosmetic product sample includes at least four units or containers with a net weight of 100 grams, and the sample label is attached to the packaging. The sample's expiry date should not be less than one year, based on the sample delivery date to the NPRA.

Section 5 of the GCCP delegates power to the DPS to cancel the notification note for any cosmetic product if the DPS believes, with reason, that the product has failed to adhere to the prescribed rules and guidelines. In addition, the DPS can issue a written order to the authorized person or person responsible for placing the notified cosmetic in the market to recall, remove, or withdraw the notified cosmetic from any premises (GCCP, 2022). A CNH, manufacturer, importer, or wholesaler can undertake a product recall by removing or withdrawing adulterous or defective cosmetic products from the market. The severity of the quality defect and adverse reactions to cosmetics determines the level of product recall (NPRA, 2022). Hence, if the product remains in the market, pharmacy enforcement officers can then take legal action against CNH and cosmetic manufacturers under the guidelines and the Act (NPRA, 2022).

**Self-Regulation in Cosmetic Industry**

Self-regulation is an industry regulatory tool (Sinclair, 1997) in which a structured group is represented by an industry-level organization (Gunningham & Rees, 1997) that controls the behavior of its members (Gunningham & Sinclair, 2017). Self-regulation is also considered a normative order practiced by private governments (corporations, schools, and hospitals), professional communities, and business networks. It also entails an industry-level organization issuing guidelines to its members who conduct business in the industry (Gunningham & Sinclair, 2017). Self-regulation allows a company to establish internal controls and enforce standards to govern the conduct of its entire workforce to guarantee compliance with industry regulations.

In the context of manufacturing and selling cosmetic products, self-regulation places the responsibility solely on the company to produce safe and quality cosmetic products they sell (Ismail et al., 2019). At the same time, it encourages a company's freedom to choose its strategy to comply with existing laws based on its own experience and conduct an assessment of its situation (Calcott, 2010). The duty to produce a safe product lies on the shoulders of the CNH, product owner, and product manufacturer, who are incidentally parties who should ensure that the product’s formulation and manufacturing process comply with stipulated laws and regulations.

Self-regulation has been widely criticized for its inability to control the safety of cosmetic products, but it is still used to establish a voluntary standard (Zakaria, 2015). Voluntary self-regulation is the most feasible and

efficient way to ensure consumer safety through aligned incentives (Daum, 2006). There are two incentives for industry self-regulation. The first involves industrial image control, in which controlling the industry's image is crucial for upholding the consumer's positive perception of product safety levels and sustaining retail sales (Daum, 2006). The second is to protect industry independence by ensuring an adequate level of industrial safety to avoid the formulation of stricter laws and regulations in the industry (Daum, 2006). However, limiting stricter laws and regulations in the industry cannot serve as a basis for implementing self-regulation. Unsupervised self-regulation in the cosmetics industry will create a state of dependence among the public on cosmetic companies whose business interests are primarily profit-oriented (Tecson, 2021). Furthermore, the lack of short-term detection of a cosmetic's effects renders it exceedingly hazardous, thus, casting doubt on its safety.

Self-regulation allows the company to monitor its compliance with legal requirements and to be accountable for verifying the ingredients' safety before manufacturing the product (Ismail et al., 2019). Therefore, self-regulation cannot stand alone. Cosmetic manufacturers and product owners should integrate self-regulation with the oversight of governing bodies and respective laws to ensure the production of safe products for consumers.

## 3. Methodology

This qualitative study collected data through a desktop study and semi-structured interviews. The desktop study facilitated the investigation by locating materials from numerous library resources, including online databases, textbooks, journal articles, and government documents. Library materials helped the study to comprehend the cosmetic control system, formulate interview questions, and establish the conceptual framework for this study. Subsequently, semi-structured interviews were conducted involving NPRA officers, cosmetic manufacturers, and industry experts. This study received approval from the National Medical Research Register (NMRR) ( NMRR ID: 23-00744-N8L) to interview NPRA officers. It also interviewed five cosmetic manufacturers (CM), consisting of small, medium, and large companies, and finally reached data saturation. In addition, it also interviewed three experts from the cosmetic industry. It conducted an ethical protocol by obtaining a letter of consent from each of the participants before conducting the interviews. Information from the informants is summarised in Table 1.

**Table 1: List of informants**

| Informants | Coding | Department/ Agency/ |
|---|---|---|
| Officer from NPRA | N1 | NPRA |
| Officer from NPRA | N2 | NPRA |
| Officer from NPRA | N3 | NPRA |
| Cosmetic manufacturer | CM1 | Small sized company |
| Cosmetic Manufacturer | CM2 | Small sized company |
| Cosmetic Manufacturer | CM3 | Medium-sized company |
| Cosmetic Manufacturer | CM4 | Medium-sized company |
| Cosmetic Manufacturer | CM5 | Large sized company |
| Industry Expert | Expert 1 | Trainer and consultant |
| Industry Expert | Expert 2 | Trainer and consultant |
| Industry Expert | Expert 3 | Trainer and consultant |

## 4. Discussion

This study examined the efficacy of cosmetic product safety regulations in Malaysia. The laws and regulations monitoring the safety of cosmetic products have long been in place in Malaysia to prevent cosmetic products containing hazardous substances from entering the market. Malaysia had initially implemented a registration process that required manufacturers to register their products by providing details and other documentation for approval before the product could go into production, and only then did it introduce ASEAN collaborative efforts in the cosmetics industry (Zakaria et al., 2019). However, since the introduction of the ASEAN Cosmetic Directive (ACD), the registration system has been transposed into a notification system based on Regulation 18 of the CDCR and GCCP. Currently, cosmetic manufacturers only need to notify the NPRA of their compliance.

Cosmetic companies can sell their products once they receive a notification note from the NPRA. This notification requirement is simple, but the companies or cosmetic manufacturers must comply with all the pre-requisite conditions before receiving a notification. Cosmetic manufacturers must first obtain GMP from the NPRA.

The GMP regulatory controls are strict to ensure the quality of cosmetic products, but most cosmetic manufacturers obtain GMP for their factory premises. N1 reported that:

"*Most manufacturers meet GMP requirements. Out of 80 inspections, 7 or 8 cases are considered unacceptable. The factors that prevent them from receiving an acceptable GMP are the following: the product is not similar to that mentioned in the documentation, production outside the cleaning room, and damaged wall surfaces such as peeling paint and dirty factories. The factory is dirty and dusty. The cosmetic ingredient itself causes the factory to be dusty and dirty"* (N1, 2023).

This shows that although the requirement for obtaining an acceptable GMP status from the NPRA is quite strict, most cosmetic manufacturers strive to obtain it for manufacturing their cosmetics. Some cosmetic manufacturers hire a consultant to help them with GMP documentation and meet GMP requirements. Cosmetic manufacturers are aware that GMP emphasizes the cleanliness of the premises and requires the floor and walls to be "smooth" and easy to clean and sanitize. Thus, to meet the requirements, they paint the factory floor and ensure the premises floor is always clean. However, maintaining a smooth floor requires high maintenance costs and constant efforts (CM 4). It is crucial to prioritize consumer safety as a precaution for ensuring high-quality and safe products although it can be somewhat burdensome for cosmetic companies.

The CNH must complete the notification form in the Quest system for each cosmetic product or any variants, if any, upon receiving an acceptable GMP, and then proceed with the payment to the NPRA. (Roslan et al., 2023). The notification process involves information concerning a particular cosmetic product for the attention of the NPRA and consumers (N2, 2023). The system will screen the product information without human intervention upon receiving the notification (N2,2023). However, the system will query if the CNH mentions ingredients not listed in the system, and the CNH must respond to that query (N2, 2023). Cosmetic companies can receive a notification note shortly after uploading all pertinent documents into the system, provided there are no issues with the product notification. Cosmetic manufacturers stated that they have no significant issues with the Quest system. They expressed satisfaction with the Quest system and regarded it to be highly industry-friendly. Despite its age, the Quest 3+ system has not encountered too many technical issues, and it streamlines the notification process. The only problem is that this system is based on self-regulation, and the dependence on self-regulation has frequently led to non-compliance, resulting in the persistent availability of hazardous cosmetic products in the market. N2 informed that:

"*The issue we have is that some companies are abusing the system, which is being abused in a way by some companies because it is easy to do so. They were supposed to take responsibility, but they misuse it".* (N2, 2023)
Cosmetic manufacturers are responsible for ensuring that their products align with the notifications received by the Quest3+system. However, not all companies are trustworthy (N2, 2023) as some cosmetic companies prioritize their profits over the safety of their consumers. They will notify the NPRA about cosmetic products containing permitted ingredients, but they continue to produce products with different ingredients (Expert 2, 2023). Every year, the NPRA cancels notifications and bans numerous products from the market due to their hazardous or poisonous ingredients (NPRA, 2023). This unscrupulous action risks consumer safety as the product enters the market following notification. However, its safety remains unknown until consumers complain or the NPRA conducts post-market surveillance (Expert 2, 2023). This shows that consumers will first become unwell before realizing the product is unsafe and this underscores the need to refine the implementation of the notification law.

In addition, the product claim must be contextual to the purpose, as in the definition of a cosmetic product. Claims made by cosmetic products are related to various functions, such as cleaning, scenting, altering appearances, correcting body odors, and protecting, or maintaining conditions. However, the law permits cosmetic companies to assert a secondary claim that pertains to a minor function not included in the above scope, such as anti-dandruff, caries, cellulite, hair loss, bust contouring, acne or anti-bacterial (Annex I, Part 8,

GCCP). The cosmetic formulation and/or substantial evidence must justify each claim in the Product Information File (PIF). A PIF is a document that supports the safety, quality, and claimed benefits of the marketed cosmetic product(s). However, industry experts assert that not all cosmetic companies provide a PIF, and they only do so after the NPRA informs them about the PIF audit (Expert 1 and Expert 2, 2023). This indicates the gap between existing law and the practices of cosmetic companies, as the regulations require every cosmetic company to have a PIF ready and accessible for the NPRA at the address indicated on the label (GCCP, 2022). This would also compromise the safety of cosmetic products, as the PIF must contain substantial evidence to support the product's claims. Failure to provide this PIF indicates the ineffectiveness of self-regulation among cosmetic industry players.

NPRA will conduct PMS based on public complaints or inquiries, notifications that trigger PMS, or input from the GMP division (NPRA, 2022). NPRA will also conduct PMS by consulting the list of notified products and utilizing the PMS marketing alert system (N3, 2023). This system allows ASEAN countries to share information about the marketing of Malaysian products that have been reported to have adverse effects in countries like Brunei, Thailand, and Indonesia (N3, 2022). The most common adverse effects are itching, erythema, scaling, burning of the skin, allergic reactions, redness, or swelling (ASEAN Secretariat, 2013). The NPRA also monitors cosmetics and magazine advertisements along roads. For example, if a product advertises a 7-day brightening effect, the NPRA will proceed with PMS screening (N3, 2023). This implies that the NPRA is very active in controlling the safety of cosmetic products, and all industry experts agree that the NPRA is doing an excellent job. Although the NPRA conducts proactive supervision, many cases involving products with harmful ingredients still exist.

Expert opinion claims that there are still many cases of cosmetic products that contain dangerous ingredients because the punishment for irresponsible cosmetic manufacturers is less severe (Experts 1 and 2, 2023). Section 12 of the Sale of Drugs Act 1952 stipulates that an individual faces a fine not exceeding twenty-five-thousand-ringgit, imprisonment for a term not exceeding three years, or both. Whereas, for a body corporate, a fine not exceeding fifty thousand ringgit upon conviction is applicable. Any breaches of the cosmetic laws and regulations that are not subject to a specific penalty will be subject to this general punishment. The considerable passage of time since the establishment of SODA and its overly broad scope that includes all categories of offenses, warrants a revision of the penalty. In addition, science and technology have advanced to the point where they can now create cosmetic products with numerous chemicals and complex processes, making it challenging to promptly detect any adverse consequences to the human body. It is high time for the Ministry of Health (MOH) to consider revising the CDCR and introduce specific punishments for companies that manufacture and sell cosmetic products that contain substances harmful to consumers.

Aside from increasing specific punishments and the NPRA's efforts to govern the sale of cosmetic products, effective self-regulation necessitates supervision and awareness initiatives to ensure that producers and sellers consistently comply with pertinent safety regulations. Consumers should also actively engage in self-regulation by ensuring they only buy products they believe to be safe rather than opting for cheap but potentially hazardous and low-quality items.

## 5. Conclusion

This study emphasizes that despite Malaysia having developed extensive cosmetic product safety regulations, substantial deficiencies persist in achieving full compliance by manufacturers and consumer protection. Dependence on self-regulation and post-market surveillance has permitted certain non-compliant items to remain in the market, thus, presenting possible health hazards. To strengthen consumer safety, this study recommends enhancing enforcement mechanisms, revising penalties for non-compliance, and increasing public awareness initiatives. Ensuring manufacturers comply with Good Manufacturing Practices (GMP) and maintaining rigorous control of the notification procedure are also essential for promoting industry compliance and public trust in the safety of cosmetic products in Malaysia.

### Contribution to existing knowledge and policy implication

This study has contributed significantly to cosmetic product safety in Malaysia. It provides a comprehensive analysis of cosmetics legislation and regulations; emphasizing the role of self-regulation and post-market

surveillance in identifying and exterminating the existence of harmful cosmetic goods. This study identified problems such as abuse of self-regulation and incorrect or incomplete reporting of product ingredients by analyzing the industry's compliance issues. It addressed a significant gap in the literature by concentrating on the Malaysian context and highlighting the necessity for enhanced consumer protection through improved public education, thereby encouraging consumers to actively participate in ensuring the safety of their purchased products.

This study also has policy implications by suggesting that relevant authorities strengthen enforcement by revising the penalties under the Sale of Drugs Act 1952 to impose harsher punishment on manufacturers who violate safety regulations to prevent companies from prioritizing profits over consumer safety. This study recommends introducing a more rigorous pre-market evaluation process to prevent unsafe products from reaching consumers. Frequent and mandatory audits and inspections should support self-regulation to ensure compliance instead of relying solely on post-market surveillance or consumer complaints. Self-regulation cannot stand alone but must be accompanied by more public awareness campaigns to inform consumers about product safety verification through NPRA platforms, which enhances overall consumer protection. Finally, this study advocates that Malaysian cosmetics regulations should be more closely aligned with international standards, such as those of the European Union, to improve product safety and increase the competitiveness of Malaysia's domestic cosmetics industry on a global scale.

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