

Legal Control for the Safety of Cosmetic Products Application Use in Malaysia

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Abstract: This study discusses the legal control over the safety of local cosmetic products and the extent to which users are protected in Malaysia. Beauty is inseparable from women. Various efforts have been made to make the face look beautiful and perfect by using a variety of cosmetic products available in the market. As a result, manufacturers have to develop a wide range of promising products that show reaction within a short period by using illicit substances that threaten consumers in Malaysia. The purpose of this study is to examine the type of safety protection particularly on the cosmetic products application use in Malaysia. The results of the study found that there were still many products containing prohibited substances in the market which found that consumers experienced the harmful effects of the use of unsafe cosmetic products. Therefore, the law enforcement provided can control this matter through composition to operators who still produce products containing these prohibited substances.

Keywords: consumers law; cosmetics; cosmetics safety; ingredients in cosmetics

Received: 30th November 2019

Accepted: 13th March 2020

Published Online: 26th April 2020

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Citation: Othman NN, Zakaria Z, and Aziz A. Legal Control for the Safety of Cosmetic Products Application Use in Malaysia. *J Halal Ind Serv* 2020; 3(Special Issue): a0000080. <https://doi.org/10.3687/jhis.a0000080>

Introduction

Beauty is a natural fit for women; especially, to stay beautiful, attractive and stylish. Therefore, beauty practices are also synonymous with women which have also been practised since ancient times to maintain beauty. To achieve that goal, women are willing to spend money on buying cosmetic products with the aim of looking good and beautiful. This is evidenced by a study conducted in the United States of America where 88% of women aged 18 years and above are trying to beautify themselves by using cosmetics, and they feel that cosmetics will make them look more beautiful and more confident (Seewan & Benjaronkij, 2014). Along with the development of current knowledge and technology, the need for beauty also goes hand in hand by producing a variety of cosmetic products, and it is growing from time to time. Not only does it look at the technology, education and health point, but the need for self-improvement is also a key priority in everyday life especially for women, and one of the ways used to maintain the beauty and change one's appearance is to use cosmetic products.

The use of cosmetics has been known to human beings since centuries ago, which began in the 19th century. At that time, cosmetic products were used not only for beauty but also for maintaining health. Over the past 40 years, the production of cosmetic products has increased. The medical or physiological field has expanded their knowledge in the skin leading them to collaborate with beauty scientists and beauty experts in producing cosmetic products by compiling various formulas based on the concept of dermatology or health (Tranggono, 2007).

The production of cosmetics is now not only for personal use but also for domestic and international businesses. In line with the development of technology, various innovations have been done in producing cosmetic products for the community, especially for women, by promoting skin beauty, skincare, whitening and so on to attract consumers. The entrepreneurs and manufacturers are working and racing in producing products to gain profit without thinking about the safety aspects of con-

sumers. The widely used active ingredients in cosmetics products such as mercury, hydroquinone, and steroid (Ho et al., 2017) are associated with various changes in reproductive hormones, such as estrogen (Zota & Shamasunder, 2017).

In Malaysia, there are a number of legal provisions to control the production of these harmful cosmetic products in the market to ensure the safety and protection of consumers are guaranteed from using cosmetic products that use prohibited materials. Among the provisions of the law protecting the safety of cosmetic products are the Control of Drugs and Cosmetics Regulations 1984 (Peraturan-Peraturan Kawalan Dadah dan Kosmetik 1984) and the Sale of Drugs Act 1952 (Akta Jualan Dadah 1952). The provisions of this law have been enacted to protect consumers from using risky and dangerous cosmetic products.

Although there are some clear provisions forbidding and controlling the production and sale of these harmful products, there are still some issues regarding the sale and production of products that are mixed with harmful chemicals and the sale of unregistered cosmetic products.

Issues On Cosmetic Products Safety

Human desires, especially among women, have always been wanting to look beautiful and perfect in all respects, and this has been fully exploited by a number of irresponsible cosmetic product operators by producing and selling cosmetic products that do not meet the requirements by the authority. Their main target is women that want to look beautiful, but with quick and maximum results. They tend to buy cosmetic products that are easily available at cheap prices which lead them to look for an alternative way of buying cosmetic products, even though they do not meet the requirements, and these cosmetics are still sold freely in the market. This condition is clearly seen based on a newspaper report stating that women users prefer to use artificial products because there is a famous "brand" attached to it even though that product may cause adverse effects on their facial skin

(Nor Amalina Alias, 2017).

The legal provisions relating to product safety have been enacted and enforced to ensure that the products which are manufactured and used by consumers are safe, of good quality and do not bring any harm to consumers. They also aim to provide protection to consumers and encourage them to be more careful and sensitive in selecting and purchasing cosmetic products that do not contain any prohibited substances. Despite that, further production is still going on in the market, and various issues have arisen as a result of the use of these dangerous cosmetic products.

Among the issues that arise is the mix of ingredients in cosmetic products with chemicals such as drugs, poisons and even heavy metals that are not allowed by the Ministry of Health. The National Pharmacy Regulatory Division (NPRD), Ministry of Health Malaysia (MOH) made a press release in 2018 of 27 cosmetic products that contain scheduled poisons and prohibited substances such as Hydroquinone and Tretinoin. The products listed have been revoked by the Senior Director of Pharmaceutical Services, MOH and thus the sale of these products is banned in the Malaysian market (Kementerian Kesihatan Malaysia, 2019). In fact, as of May 2019, NPRD has taken back the notification number for 20 cosmetic products as they contain banned substances, including scheduled non-permissible poisons in cosmetic products such as Hydroquinone, Tretinoin, Mercury, Diphenhydramine and other harmful chemicals such as Chlorpheniramine, Griseofulvin, Metronidazole, Sulfamethoxazole, Ketoconazole and Trimethoprim (Biro Farmaseutikal Kebangsaan Malaysia, 2019).

Hydroquinone is a type of chemical that was originally used to kill 'melanocytes', a type of cell that acts to produce melanin (Biro Farmaseutikal Kebangsaan Malaysia, 2019). Therefore, the skin will look brighter and whiter. According to Guidelines for Control of Cosmetic Products in Malaysia, ANNEX III-Part 1-List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down, the maximum authorised concentration in the ready for use preparation of hydroquinone is only 0.02% (after mixing for use). Moreover, the use of Hydroquinone is only allowed for artificial nail systems (Guidelines for Control of Cosmetic Products in Malaysia, 2018). Tretinoin is the second dangerous chemical that can be found in some of the cosmetic products. It is usually used by doctors to treat serious acne (Biro Farmaseutikal Kebangsaan Malaysia, 2019). Also known as Vitamin A, Tretinoin belongs to a class of medications called retinoids. It will affect the growth of skin cells by gradually destroying the skin layer bit by bit as much as Hydroquinone does. The skin will look peeled, dry, red, painful and itchy when it is used and it will also become more sensitive to sunlight (Biro Farmaseutikal Kebangsaan Malaysia, 2019).

Mercury exists in three forms: organic, inorganic and elemental. Mercury is a protoplasmic poison, which can be absorbed by the respiratory tract as vapour or through the skin and gastrointestinal tract as finely dispersed granules and excreted through the kidneys and the colon (Park & Zheng, 2012).

Diphenhydramine is usually used in cosmetics and personal care products as the formulation of tonics, dressings, and other hair grooming aids (Iwata & Shimada, 2013). According to a statement issued by the National Pharmaceutical Regulatory Agency (NPRD), the Malaysian Health Ministry (MOH), the use of diphenhydramine without the supervision of a health professional could cause the skin to become more sensitive to sunlight, resulting in severe allergies (Bernama, 2019).

The Experimental Results of Chemical Ingredients Used in Cosmetic Products

Various studies have been conducted to study the ef-

fectiveness of chemicals in cosmetic products. Among them was the study of the effectiveness of Hydroquinone on the liver and kidneys from the aspect of Histology. The study used 24 female rabbits (weighing 400-1500 gm) and was divided into four groups (control, use of cream in the right ear, left ear, and stomach). These animals were given 2% hydroquinone for a period of 6 weeks. Histological findings from this study suggested that chronic exposure to hydroquinone resulted in significant histological changes that can affect the liver and kidneys (DeCaprio, 1999).

Other scientific studies identifying genotoxicity and cytotoxicity of Hydroquinone in cosmetic products proved that besides Hydroquinone inhibiting the formation of tyrosine enzymes, it also uses depigmentation action by producing cytotoxic effects on melanosomes which means it can kill living cells in the human body. In fact, Hydroquinone can also cause an increase in DNA fragmentation in the human body. The results showed that safe hydrocarbon concentrations used in cosmetic products were 1.89 ug/ml and this concentration was believed to reduce the damage to DNA (Khan et al., 2017).

Next, was a study to identify the ability of Hydroquinone in forming caseins (mutagenic) in the bodies of laboratory mice. Laboratory rats were given Hydroquinone doses of 0, 25, 50, 100, or 200 mg/kg bw/day for 28 days. The study found that hydroquinone affects the formation of cell adenosine in the kidneys and the rats' weights also decreased in all the treatment groups. However, no significant difference was observed in terms of mutations in the liver, abdomen, lungs, or kidneys between rats treated with Hydroquinone and simultaneous negative controls, while significant mutation inductions were observed in the positive control groups. This result indicated that mutagenic mechanisms are not responsible for the carcinogenesis caused by Hydroquinone (Matsumoto et al., 2014).

A past study has proven that the amount of mercury excreted by the kidneys was proportional to the quantity applied on the skin (Hursh et al., 1985) and this may lead to Nephrotic syndrome (Silverberg et al., 1967; Bérody et al., 2019). Previous studies have shown that membranous glomerulonephritis and proliferative glomerulonephritis were found in patients who had used skin lightening creams which contained mercury.

Subsequent past studies with an electron microscope have demonstrated that mercury bleaches the skin by probably inactivating the sulfhydryl enzymes (Denton et al., 1952; Silverberg et al., 1967). These enzymes will inactivate the tyrosine molecules and interrupt melanin production. Chronic use of mercury can also lead to increased pigmentation due to the accumulation of mercury granules in the dermis. These granules are absorbed via the skin appendages such as the hair follicles and sebaceous glands in the dermis. The deposition of mercury in keratin also leads to the discolouration and brittleness of the nails (Cole et al., 1930).

Hydroquinone and Tretinoin are pharmaceutical products that need to be registered with the Drug Control Authority and they are controlled and can only be used with advice from health professionals. Cosmetics that have been mixed with chemicals such as Hydroquinone, Tretinoin and also mercury can cause redness, swollen skin, discomfort, skin changes, and even make the skin become sensitive (Rabbayani, 2014).

The effect of using these materials can prevent the process of pigmentation (depigmentation) that can reduce the skin's protection from harmful UV rays and may increase the risk of skin cancer (Callender et al., 2011). It is clear that the prohibited substances are extremely risky and endanger the health and it is clear that the prohibition contained in Regulation 7 (A) of the 1984 Drugs and Cosmetics Regulations prohibits any products that are mixed with prohibited substances (Peraturan-Peraturan Kawalan Dadah dan Kosmetik, 1984). In the era of technological

and telecommunications advancement, it is undeniable that it is more convenient for people to shop online. As a result, online business activity has expanded and this has allowed traders to sell and become entrepreneurs independently without any restraints and by using only mobile phones, laptops and internet networks. In this regard, the sale of online cosmetic products has been done independently, without any restrictions, and thus causing cosmetic products containing these harmful substances being sold in the market despite getting no approval and notification from the Ministry of Health.

The issue of the use of prohibited substances in local cosmetic products has been increasing in recent years. Local cosmetic operators seem to challenge the authority of product safety and consumer protection laws that have been outlined by the government. This can be seen clearly through local newspaper reports and news that often illustrate the issue of prohibited substances in these local cosmetic products in their main report. The rapid development of this issue has sparked public concern over the safety of their cosmetic products. Director-General of Health Malaysia, Datuk Dr. Noor Hisham Abdullah, has directed that sellers and distributors of the involved cosmetics be warned to stop selling and distributing their products immediately (Noor Aiman Haziq, 2019). The toxic substances contained in the cosmetic products are clearly prohibited by the MOH and have been scheduled. Unfortunately, most of the local cosmetic entrepreneurs only think of profits instead of protecting consumers from danger. This clearly demonstrates the low quality of the inspection process for the cosmetics industry in this country. Consequently, the issue of the use of prohibited substances in these local cosmetic products should be taken seriously so that this issue can be handled appropriately.

Legal Control Methods for Cosmetic Products in Malaysia

Consumer Protection and Product Safety Regulation in Malaysia

As users, we should be provided with protection to control issues related to user's rights. Accordingly, the provisions of the law on consumer rights are enforced to protect consumers' rights to avoid harmful risks of low-quality products that contain prohibited substances.

Consumer protection is gradually becoming a characteristic of modern law that has begun to be recognised. This demonstrates the right to consumer protection rather than something that is considered to be a simple and trivial thing, but it has already begun to be taken seriously by the society and the authorities who are now more aware of the protection needs of consumers in the cosmetic products market (Yusoff, 2002).

Users have also the right to be protected from the marketing of goods or services that can harm their health and life. The government has created several alternatives to solve this problem by approving several laws for the purpose of protecting consumer rights from practices and things that could be harmful to consumers such as the use of various chemicals in the marketing of products and goods in the market. In addition, to ensure that all medicines and products are marketed in safe and effective markets, each drug and product sold in Malaysia should be registered with the Ministry of Health (MOH). For cosmetics and beauty products, they should be notified to the MOH and then only can they be advertised with the ministry's permission (Hamid, 2011).

The product security aspect should be emphasised to ensure safety and avoid hazardous risks in the use of each product by consumers. This has been explained by Rahmah Ismail (2000)

on the right to secure security —it is the right to be protected from products, production processes and services that endanger health and life. The safety of a product is an important aspect that should be taken into account in maintaining the user's welfare. Therefore, each user has the right to view and inspect the goods or the products that they wish to purchase to ensure that they are safe and free from any defects (Rahmah, 2000).

As there are many consumer products that flood the market, the safety of a product in the market must be emphasised and it is very important to protect consumers. Although product manufacturers have the sole power in producing and marketing their products, they must be responsible for ensuring that they use only safe materials that have been approved by MOH for consumer use to provide better safety standards for the users (Zakaria, 2014).

The issue of dumping goods that are of poor quality and that do not meet the prescribed standards is due to the uncontrolled trade and sales activity in Malaysia. Trading activities in Malaysia's sales of goods cannot be resolved due to the lack of resources and qualified staff as well as weak technical facilities that cause some problems in controlling the production of these cosmetic products that contain the prohibited substances by companies here as compared to other developed countries, such as the companies in the European and American Countries (Zakaria, 2012).

Consequently, consumer protection laws and product safety laws have been discussed to identify the level of consumer safety. Furthermore, through the legal concept, it will be linked to cosmetic products in Malaysia by looking at consumer protection and prescribed security controls to control the production of cosmetic products that contain prohibited substances.

Related Laws On Consumer Protection and Safety Of Cosmetic Products In Malaysia

Consumer Protection Act (CPP)

Product safety is an important part of every party to take care of and safeguard the harmful things that occur to consumers. Furthermore, how a country cares for the welfare of its people can be seen through its policy and regulatory safeguards on product safety that have been enacted and enforced in a country (Rahmah, 2000).

In this regard, Malaysia is also protecting its consumers in maintaining product safety. In order to now safeguard consumers, Malaysia has come up with the Consumer Protection Act (CPP) 1999 by enforcing laws pertaining to consumer rights. In this act, it details the consumer protection and product safety. The existence of this act is also intended to fill the gaps contained in product safety laws, and it is also the basis of government monitoring of product safety in Malaysia (Jalil, 2017).

As understood briefly in CPP 1999, it is a role not only to protect consumer rights against the safety of a product in the marketplace but also to avoid the production of products with no quality and that bring harm to consumers. In the provision of CPP 1999, there is a touch on product and consumer safety in some sections of Part III, where a Minister is authorised to prescribe the safety standard of an article through the regulations stipulated in it (Seksyen 19, Akta Perlindungan Pengguna 1999). Accordingly, producers and suppliers should comply with the rules set out in Section 19 as they are mandatory and enforceable. Furthermore, compliance with safety standards (Seksyen 20, Akta Perlindungan Pengguna 1999), the prohibition of any supplier, offering or advertising goods that do not comply with the safety standards set is deemed to be an offence. Therefore, suppliers and manufacturers of goods or products must follow the prescribed safety standard instructions. The collision of compliance with this safety standard is an offence subject to Section

25 (1) of this Act. The general requirement of safety for goods and services (Seksyen 21 dan 21A, Akta Perlindungan Pengguna 1999), in Section 25 (1) of the CPP Act clarifies the safety of goods and services for consumers.

Suppliers who supply and advertise unreasonable items will get a penalty. This clearly demonstrates that it aims to prohibit all the marketing and product release services that will endanger users (Seksyen 23, Akta Perlindungan Pengguna 1999. Seksyen 23(1), Akta Perlindungan Pengguna 1999). According to the order from the authorities, suppliers producing goods and services that are harmful shall bear the cost of loss or whatever the prescribed instructions are to prevent the marketing of hazardous products which are in the market such as, by recalling the prohibited goods that are located in the market (Seksyen 23 (2) (a), Akta Perlindungan Pengguna 1999), stop the supply or stop the offers to supply the prohibited goods or services (Seksyen 23 (2)(b), Akta Perlindungan Pengguna 1999) as well as stop the advertising of the prohibited goods or services (Seksyen 23 (2)(c), Akta Perlindungan Pengguna 1999).

Furthermore, any party supplying the prohibited products shall disclose to the public of any information relating to the character of the prohibited goods or services that make them unsafe (Seksyen 23 (2)(d)(i), Akta Perlindungan Pengguna 1999); that disclose shall include the use of such prohibition is insecure (Seksyen 23 (2)(d)(ii), Akta Perlindungan Pengguna 1999), repairs or replaces the prohibited goods or services of the prohibition (Seksyen 23 (2)(e), Akta Perlindungan Pengguna 1999), repay or indemnify any user who has used the prohibited product (Seksyen 23 (2)(f), Akta Perlindungan Pengguna 1999).

The Control of Drugs and Cosmetics Regulations 1984 (CDCR)

The government has taken several steps in protecting consumers and product safety by establishing specific activities relating to consumer rights. Cosmetic products are controlled under the Drug Sale Act 1952 and the Control of Drugs and Cosmetics Regulations 1984 (CDCR) (Portal MyHEALTH Kementerian Kesihatan Malaysia, 2019). These regulations will take into account the safety, quality and cosmetic product claim to ensure that all cosmetic claims can be supported by adequate data, to protect and promote public health.

The provisions of the Control of Drugs and Cosmetics Regulations 1984 are enforced to protect consumers for quality and safe cosmetic products in the market. It also aims to control the production of unregistered cosmetic products that contain prohibited substances.

Every cosmetic product must be first registered before it is marketed to ensure the safety of the cosmetic product before it is used by consumers. Registration for cosmetic products involves requesting a notification number from the National Pharmacy Regulatory Division (NPR) and Ministry of Health Malaysia (MOH) before they are manufactured, imported, distributed or sold in the Malaysian market. Product notification is a process whereby companies or parties responsible for marketing cosmetics produce declarations regarding their product information to NPR before they market the products in the Malaysian market. Companies that want to market cosmetic products in Malaysia must comply with the requirements of the prescribed Cosmetic Products Control Guidelines (Kementerian Kesihatan Malaysia, 2019).

Part 3 of the Control of Drugs and Cosmetics Regulations has clarified on the notices of cosmetic products which is to clarify that no party is authorised to produce, sell, import, own or administer any cosmetic product unless notified, or if such party is the person responsible for providing notice in the market or authorities by notification notes issued by the Director of Phar-

maceutical Services (Peraturan 18A (1) (b), Peraturan Kawalan Dadah dan Kosmetik 1984). Therefore, each manufacturer must be notified beforehand with a valid NPR before making any cosmetic product withdrawal. It aims to safeguard the safety of cosmetic products in the market by ensuring that only safe products can be marketed.

The ingredients found in cosmetic products must be safe for consumers to use. The cosmetic products that have been identified to contain any poisonous substances must be registered in the Poison Act 1952 (Peraturan 18A (1) (c), Peraturan Kawalan Dadah dan Kosmetik 1984). Therefore, cosmetic products that use poisonous substances found in the scheduled poison list under the Poisons Act 1952 will be subjected to actions taken against them (Akta Racun 1952 (Akta 366). Furthermore, the ingredients found in cosmetic products have been identified as the registered product (Peraturan 18A (1) (d), Peraturan Kawalan Dadah dan Kosmetik 1984). The content of the ingredients found in cosmetic products is particularly of concern to the authorities because if it is a prohibited substance then it will be harmful to the users.

Furthermore, another thing mentioned in the Control of Drugs and Cosmetics Regulations 1984 is the payment of fees during the notification process will not be returned (Peraturan 18A (6), Peraturan Kawalan Dadah dan Kosmetik 1984). The Director of Pharmacy Services has the power to decline the notification application (Peraturan 18A (7A), Peraturan Kawalan Dadah dan Kosmetik 1984) and to cancel the designated product (Peraturan 18A (8), Peraturan Kawalan Dadah dan Kosmetik 1984) at any time without providing a reason. The manufacturers of cosmetic products must also comply with any instructions or guidelines issued and any conditions that have been imposed by the Director of Pharmaceutical Services (Peraturan 18A (10), Peraturan Kawalan Dadah dan Kosmetik 1984) and maintain good records (Peraturan 18A (11), Peraturan Kawalan Dadah dan Kosmetik 1984). Therefore, for any party who violates any of the provisions of these Regulations, the Director of the Pharmaceutical Services, may release written instructions to the person responsible for withdrawing and issuing products already in the market (Peraturan 18A (12), Peraturan Kawalan Dadah dan Kosmetik 1984).

Authorities have strived to ensure that cosmetic products that are sold in the market are safe by making certain specific provisions regarding cosmetic products. Consumers should also take precautionary measures in purchasing cosmetic products by checking the notification and the listed materials before opting for cosmetics to avoid the use of health-damaging cosmetic products.

Conclusion

This research has proved that the consumer protection safeguards in Malaysia are not only emphasised before a product being notified but also after the sale of the product and the effect that will be received by the consumer upon using the product. Moreover, it is also to control the producers of dangerous products from supplying their unsafe cosmetic products to consumers in the market to ensure the safety of consumers is guaranteed and not violated. The sale and supply of unmarked products are an offence under the Control of Drugs and Cosmetics Regulations 1984 and if convicted, an individual under these Regulations shall be liable to a fine not exceeding RM25,000 (Malaysian Ringgit Twenty-Five Thousand Only) or imprisonment not exceeding three years or both. For the first offence, the fine shall not exceed RM50,000 (Malaysian Ringgit Fifty Thousand Only) or imprisonment not exceeding five years, or both for subsequent offences and a fine not exceeding RM 100,000 (Malaysian Ringgit One Hundred Thousand Only) for further offences. The cosmetic

product will certainly be evolving at some point due to the rapid development of technology. Therefore, related authorities particularly the Ministry of Health Malaysia always need to be alert and aware of the movements of the era for the law to be valid and applicable under any circumstances in the future.

Conflict of Interest

The authors declare that there is no conflict of interest.

Acknowledgments

This research was supported by Ministry of Education Malaysia research grant (grant vote MOO02-2018 awarded to Malaysian Higher Education Consortium of Halal Institutions) and University of Malaya Research Grant Challenge: Grant vote 002B-17HNE.

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