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Law Enforcement Against Cosmetic Businesses Operating Without a BPOM Distribution Permit

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Abstract: According to applicable law, cosmetics are pharmaceutical products that can only be distributed after obtaining a distribution permit. This permit serves as a consumer protection measure to ensure the safety of cosmetic products. To regulate the circulation of cosmetics without a valid distribution permit, the government has established regulations to oversee their distribution, ensuring consumer protection. This study aims to examine the legal framework governing cosmetic business licenses and the legal responsibilities of cosmetic business operators who lack a distribution permit. The research employs a normative juridical approach. Before being marketed, every cosmetic product must obtain a distribution permit through a notification process with the Food and Drug Supervisory Agency. Cosmetic distributors operating without this permit may face legal consequences, including both criminal and administrative sanctions.

Keyword: Audiobook Access, Blind Disabilities, Copyright, Legal Certainty, Marakess Treaty.

INTRODUCTION

In Indonesia, the increasing availability of beauty products has created a profitable opportunity for cosmetic entrepreneurs. In modern society, the strong desire among young female consumers to enhance their appearance has led some individuals to produce their own cosmetics using substandard ingredients and sell them to the public. Counterfeit cosmetics can be created in various ways. For instance, perpetrators may alter the original product packaging, replace the contents with hazardous substances, and then repackage and distribute the products both locally and through social media. These counterfeit cosmetics often contain harmful ingredients such as mercury, lead, and copper. Such toxic substances can cause skin irritation, allergic reactions, nervous system disorders, fetal complications, and even cancer.

According to Article 1 of the Decree of the Head of the Indonesian Food and Drug Supervisory Agency (BPOM) No. HK.00.05.4.1745 of 2003 on Cosmetics, cosmetics are defined as:

"Substances or preparations intended for use on the external parts of the human body (epidermis, hair, nails, lips, and external genital organs) or teeth and oral mucosa, primarily for cleansing, perfuming, altering appearance, correcting body odor, or protecting and maintaining the body in good condition."

Counterfeit cosmetic sellers often price their products lower than authentic ones to attract buyers by offering discounts. Additionally, some sellers distribute their products without registration codes or numbers under the pretense of importing them. However, unethical individuals may set similar prices to genuine products to avoid suspicion. This practice violates Article 8, Paragraph (1), Letter (E) of Law No. 8 of 1999 on Consumer Protection, which states that business operators are prohibited from manufacturing and/or trading goods and/or services that do not comply with the quality, grade, composition, processing methods, style, fashion, or usage as stated on the product label or description. Illegal cosmetic products are often packaged using labels identical to those of genuine cosmetics, deceiving consumers. As a result, the quality, composition, production process, and other details on the labels of illegal cosmetics do not match those of authentic products, highlighting the risks associated with their use.

On December 27, 2012, the Central Food and Drug Supervisory Agency (BPOM) issued a public warning, Number HM.03.03.1.43.14.12.8256, regarding cosmetics containing hazardous and prohibited substances. A total of 181 cosmetic items from various brands were found to contain banned or harmful ingredients, as identified by BPOM between September 2022 and October 2023. Some of the brands listed in BPOM's annex Number HM.01.1.2.12.23.50, dated December 8, 2023, include Aifubao Whitening Red Ginseng Whitening and Anti-Freckle Trial Pack (Night Cream), Airee Beautycare Night Cream, Alessia Whitening Night Cream, BL Ledehh Day Cream 1, BL Ledehh Night Cream, Caiyilin (Bird's Nest) Herb Whitening Night Cream, Collagen Plus Vit E - Day & Night Cream, among many others.

When hazardous cosmetic products with fake BPOM distribution permit numbers are sold to the public, consumers are the first to suffer the consequences. They are directly exposed to these dangerous products, making it crucial to prevent the spread of hazardous cosmetics with counterfeit BPOM distribution permits. The regulation of the distribution and/or marketing of officially registered cosmetics is outlined in Law No. 17 of 2023 on Health. Article 143, Paragraph (2) states:

"Any person who produces and/or distributes pharmaceutical preparations, medical devices, and household health supplies (PKRT) that have obtained business permits but are found not to meet safety, efficacy/benefit, and quality requirements shall be subject to administrative sanctions in accordance with the provisions of business licensing regulations."

Based on the background described above, the author is interested in conducting further research under the title:

"LAW ENFORCEMENT AGAINST COSMETIC BUSINESS OPERATORS WITHOUT BPOM DISTRIBUTION PERMITS."

METHOD

This research focuses on the application of normative legal research methods. In the normative juridical research method used in this study, the types of legal materials include primary legal materials, secondary legal materials, and tertiary legal materials. The statute approach is employed by examining all laws and regulations related to the legal issues being studied. The conceptual approach is based on legal theories, perspectives, and doctrines that have developed within the field of law.

RESULTS AND DISCUSSION

Legal Regulations on Cosmetic Business Licensing

Based on Presidential Decree Number 116 of 2000, the National Agency of Drug and Food Control (BPOM) is a non-ministerial government institution responsible for carrying out government affairs in the field of drug and food supervision. One example of this supervision is law enforcement against individuals who commit violations in the fields of cosmetics, drugs, and food. In addition to surplus monitoring, other demand-side supervision is also carried out through community empowerment to protect themselves from cosmetics, drugs, and food that do not meet requirements and pose health risks. Therefore, the Indonesian government established a non-ministerial agency to oversee drugs, food, cosmetics, and other complementary products to prevent undesirable events from occurring to consumers. The government's goal in establishing BPOM is to ensure quality, benefits, and safety for the public through the implementation of BPOM's duties, functions, and authorities.

The National Agency of Drug and Food Control has the main duties as stipulated in Article 2 of Presidential Regulation Number 80 of 2017 concerning the National Agency of Drug and Food Control, which are:

1. The National Agency of Drug and Food Control is tasked with carrying out government duties in the field of drug and food supervision in accordance with the provisions of laws and regulations.
2. Drugs and Food, as referred to in paragraph (1), include drugs, drug ingredients, narcotics, psychotropics, precursors, addictive substances, traditional medicines, health supplements, cosmetics, and processed food.

BPOM, in this case, has the authority to carry out drug and food supervision duties as stipulated in Article 4 of Presidential Regulation Number 80 of 2017 concerning the National Agency of Drug and Food Control, namely:

- a. Issuing product distribution permits and certificates in accordance with standards and requirements for safety, efficacy/benefits, and quality, as well as conducting drug and food testing in accordance with the provisions of laws and regulations;
- b. Conducting intelligence and investigations in the field of drug and food supervision in accordance with the provisions of laws and regulations;
- c. Imposing administrative sanctions in accordance with the provisions of laws and regulations.

Cosmetics are pharmaceutical preparations that must comply with quality, safety, and efficacy requirements before being distributed and used by consumers. Additionally, cosmetics must obtain a distribution permit issued by BPOM in the form of a notification. This requirement is regulated in Article 2 of the Minister of Health Regulation Number 1176/MENKES/PER/VIII/2010 concerning Cosmetic Notification, which states:

"Every cosmetic product in circulation must meet the standards and/or requirements for quality, safety, and efficacy in accordance with applicable laws and regulations." The criteria that must be met before cosmetics can be distributed in Indonesia, as stated in Article 2, paragraph (1) of the National Agency of Drug and Food Control (BPOM) Regulation Number 12 of 2020 concerning the Procedures for Submitting Cosmetic Notifications, are as follows:

- a. Safety, assessed based on the cosmetic ingredients used in accordance with laws and regulations, ensuring that the produced cosmetics do not pose a risk or harm to human health, whether used under normal conditions or foreseeable usage conditions;
- b. Efficacy, assessed based on compliance with the intended use and the claims made;
- c. Quality, assessed based on compliance with the requirements of Good Cosmetic Manufacturing Practices (CPKB) and the use of cosmetic ingredients in accordance with the Indonesian Cosmetic Codex, other recognized standards, and applicable laws and regulations;
- d. Labeling, which must contain complete, objective, and non-misleading information.

After meeting these criteria, cosmetic business operators must submit a cosmetic notification application as stipulated in Article 6, paragraph (2) of BPOM Regulation No. HK.03.1.123.12.10.11983 of 2010 concerning Criteria and Procedures for Submitting Cosmetic Notifications, which states:

- a. Cosmetic industries located in Indonesia in accordance with applicable laws and regulations;
- b. Individual businesses or business entities in the cosmetic sector that contract production with cosmetic industries located in Indonesia in accordance with applicable laws and regulations; or
- c. Importers engaged in the cosmetic sector in accordance with applicable laws and regulations.

BPOM will conduct testing on the submitted cosmetic ingredients before issuing a cosmetic notification. According to Article 3 of BPOM Regulation Number 23 of 2019 concerning Technical Requirements for Cosmetic Ingredients:

"Cosmetic ingredients must meet quality requirements as stipulated in the Indonesian Cosmetic Codex, other recognized standards, or in accordance with applicable laws and regulations."

Furthermore, Article 4 explains that the cosmetic ingredients referred to are those permitted for use in cosmetic manufacturing. The BPOM certification licensing process is now integrated with the OSS RBA (One Single Submission Risk-Based Approach) system. With the enactment of Law No. 11 of 2020 on Job Creation, all business licensing processes, including those related to the health sector, BPOM, and industry, are carried out through the OSS system. Therefore, the certification application process can now be conducted via OSS. The OSS system is regulated under Government Regulation No. 5 of 2021 on Risk-Based Business Licensing Implementation.

The process for submitting a cosmetic notification through OSS RBA is as follows:

- a. Visit the website oss.pom.go.id
- b. Select the PB-UMKU (Business Licensing to Support Business Activities) menu, then click New Application
- c. Choose the appropriate KBLI (Indonesian Standard Industrial Classification) for the cosmetic notification application
- d. Click UMKU Business Licensing Process
- e. Select Apply for UMKU Business Licensing
- f. Choose PB-UMKU Cosmetic Distribution License, select the cosmetic distribution license, enter "entire business activity description", click Continue, and then copy the submitted application ID
- g. Next, visit the website notifikos.pom.go.id

After completing the OSS system process, the applicant will proceed to BPOM's e-certification system via notifikos.pom.go.id. According to BPOM Regulation No. 21 on Procedures for Submitting Cosmetic Notifications, there are two stages:

1. Registration of the Notification Applicant
2. Registration of the Cosmetic Product Notification
3. Notification Applicant Registration Process

Both importers and individual businesses or business entities engaged in contract manufacturing must register as notification applicants to obtain a recommendation. The notification applicant must submit a facility inspection request to BPOM and meet the following requirements:

- a. Possess an NIB (Business Identification Number)
- b. The company leader or director applying as a notification applicant in the cosmetic sector must not be involved in any criminal offenses

- c. The technical responsible person must be designated by the notification applicant, with supporting documents such as a copy of diploma, ID card (KTP), and a cooperation agreement letter between the technical responsible person and the company leader
- d. The applicant must possess procurement and distribution documents for cosmetics
- e. The applicant must have proper facilities and storage areas that comply with sanitary requirements

A facility inspection will be conducted by BPOM's local technical unit (UPT BPOM) once the required documents have been verified as complete and accurate. If any corrections are needed, UPT BPOM will issue a letter requesting revisions. These corrections must be submitted within 20 days from the date the letter is issued. The notification application can be submitted electronically via BPOM's cosmetic notification service website: <https://notifikos.pom.go.id>.

The BPOM cosmetic product notification is valid for three years. After this period, the applicant must renew the cosmetic notification for an extension by following the notification renewal procedure, provided that there are no changes to the form or administrative documents. The notification renewal application for cosmetics must be submitted no later than 30 calendar days before the notification expiration date. This is outlined in BPOM Regulation No. 21 of 2022 on Procedures for Submitting Cosmetic Notifications.

Legal Liability for the Distribution of Cosmetics Without a BPOM Permit

Legal liability in the distribution of cosmetics without a BPOM permit is a crucial aspect that ensures consumer protection and business compliance with regulatory standards. According to Purbacaraka, legal responsibility arises from an individual's or entity's obligation to exercise their rights while fulfilling legal duties. This concept extends to all actions, whether performed adequately or inadequately, as every action carries consequences that require accountability.

Liability, in legal terms, refers to the obligation to bear the consequences of specific actions, resulting in legal implications. This responsibility is generally categorized into three main types: civil liability, criminal liability, and administrative liability. Each category serves to enforce justice and ensure that businesses operate within the legal framework, especially when dealing with consumer products like cosmetics.

One of the key aspects of legal responsibility in this context is product liability, which pertains to the responsibility of businesses to compensate for damages caused by their products. This liability is not limited to fully manufactured goods but also includes any cosmetic products that may pose risks to consumers.

Businesses involved in the distribution of cosmetics without a BPOM permit may be held accountable in several ways, including:

- Providing compensation for defective or harmful products
 - Refunding the purchase price of unauthorized cosmetics
 - Covering medical expenses for consumers who suffer adverse effects, such as skin damage, due to the use of unsafe cosmetics
- The existence or absence of harm to consumers plays a significant role in determining the legal liability of businesses.

The relationship between businesses and consumers is fundamentally tied to legal responsibility, particularly in cases where consumers face health risks from the use of unregistered cosmetic products. Therefore, ensuring that all cosmetics comply with BPOM regulations is essential to uphold consumer safety and prevent legal repercussions for businesses.

The distribution of cosmetics without a valid BPOM permit can be subject to legal accountability in the form of criminal liability and administrative liability, which will be explained as follows:

1. Criminal Liability

Criminal responsibility is a mechanism to determine whether a defendant or suspect is held accountable for a criminal act or not. To be punished, the criminal act must meet the elements specified by the law. Criminal responsibility implies that anyone who commits an unlawful act as defined by the law must be held accountable for their actions based on their fault. The imposition of criminal penalties is related to the criminal sentencing system, which is part of the penal law that outlines the types of punishments, the limits of imposing penalties, how and where they should be carried out, as well as provisions concerning the addition, reduction, or exceptions to the imposed penalties.

According to Article 10 of the Indonesian Penal Code (KUHP), criminal penalties are categorized into two groups: principal penalties and additional penalties, which consist of:

- a. Principal penalties can include the death penalty, imprisonment, detention, and fines.
- b. Additional penalties can include the revocation of certain rights, confiscation of specific items, and the publication of the court's decision.

The Indonesian criminal sentencing system, based on the Penal Code, classifies crimes into principal and additional penalties. The differences between principal penalties and additional penalties are as follows:

- a. The imposition of a principal penalty is mandatory (imperative), while the imposition of an additional penalty is optional (facultative).
- b. The imposition of a principal penalty does not necessarily require an additional penalty, but the imposition of an additional penalty cannot occur without a principal penalty.
- c. A principal penalty, when it has acquired final legal force (in kracht van gewijsde zaak), requires an enforcement action (execution).

In relation to the distribution of cosmetics without a BPOM permit, the principal penalty can include imprisonment. Actions against violations and criminal offenses related to the distribution of cosmetics without a valid permit are regulated in Article 435 of Law No. 17 of 2023 on Health, which states:

Anyone who manufactures or distributes Pharmaceutical Preparations and/or Medical Devices that do not meet the standards and/or safety, efficacy/benefit, and quality requirements as referred to in Articles 138 paragraph (2) and (3) shall be subject to a prison sentence of up to 12 (twelve) years or a fine of up to IDR 5,000,000,000.00 (five billion rupiah). This article contains several elements of a criminal offense, which are:

1. Subjective elements: intentionally.
2. Objective elements:
 - a. The act: producing or distributing;
 - b. The object: pharmaceutical preparations and/or medical devices without a distribution permit as referred to in Articles 138 paragraph (2) and (3).

Looking at the objective elements of the offense, there are two actions: producing or distributing, meaning the perpetrator may carry out the act of producing or distributing, or both. The object of these actions is pharmaceutical preparations and/or medical devices. According to Article 1, number 12 of Law No. 17 of 2023 on Health, pharmaceutical preparations are "drugs, drug materials, herbal medicines, including herbal medicine materials, cosmetics, health supplements, and quasi-drugs." Furthermore, Article 1, number 13 of the same law defines medical devices as "instruments, apparatus, machines, equipment, implants, reagents, and in vitro calibrators, software, as well as materials or similar items used on humans for medical purposes and do not achieve their primary function through pharmacological, immunological, or metabolic processes.

The unlawful nature of this act lies in the object, namely pharmaceutical preparations and/or medical devices that are produced or distributed by the perpetrator without a distribution permit, as stipulated in Article 435 of Law No. 17 of 2023 on Health, which requires that before distributing pharmaceutical preparations and/or medical devices, a distribution permit must be obtained. Violating this legal obligation constitutes a criminal act, turning administrative

violations, which carry administrative prohibitions, into criminal unlawful acts. Based on criminal law provisions, the act of producing or distributing cosmetic products without a distribution permit, as mentioned in Article 435 of Law No. 36 of 2009 on Health, with the term "every person" meaning that producers, contract manufacturers, and distributors who violate the provisions of Article 138 paragraph (2) of Law No. 17 of 2023 on Health, can be sentenced to a maximum of 12 (twelve) years in prison and a fine of up to IDR 500,000,000.00 (five hundred million rupiah).

2. Civil Liability

The forms of liability for business actors in the circulation of cosmetics without a distribution permit include compensating for the losses from the purchased goods, refunding money equivalent to the purchase of the cosmetic product, and covering the medical expenses for consumers who experience facial damage after using the cosmetic product. This responsibility can take the form of civil liability. In relation to the Consumer Protection Law, Article 19 of the Consumer Protection Law regulates the liability of business actors. For the responsibility of business actors regarding the products they distribute, they must provide compensation to consumers as outlined in Article 19 of the Consumer Protection Law.

The liability of business actors who are negligent in their business activities is outlined in Article 19 of the Consumer Protection Law, which is in the form of civil liability. Consumers who feel harmed can request compensation in the form of a refund, replacement of goods and/or services of the same kind or equal value, or health treatment and/or compensation. If the violation results in unlawful acts, the sanctions imposed will be related to Articles 1365, 1366, and 1367 of the Civil Code, which state: Article 1365 of the Civil Code: "Any act that violates the law and causes harm to others obligates the person who causes the harm, due to their fault, to compensate for that harm."

Claims for compensation based on unlawful acts do not require an agreement between the business actor and the consumer, so a claim for compensation can be made by any party who suffers harm, even if no agreement ever existed between the producer and the consumer. To claim compensation, the harm must result from an unlawful act. The compensation may take the form of a refund or replacement of goods and/or services of the same kind or equal value, as well as health treatment and/or compensation in accordance with applicable regulations. Therefore, it is expected that business actors who engage in marketing and sales transactions comply with all regulations set by the state of Indonesia and avoid committing violations or unlawful acts that cause harm to any party, ensuring justice and welfare for all citizens.

3. Administrative Liability

The form of responsibility imposed on a subject who commits administrative errors includes warnings, either verbal or written, revocation of permits, and business closure. In the perspective of public law, the legal action is carried out by a position, which is an institution with its own scope of work, established for a long period, and tasked with carrying out duties and authority. The person who performs these duties and exercises this authority on behalf of the position is referred to as the official.

In principle, administrative legal responsibility arises from violations of administrative provisions. Regarding the imposition of administrative sanctions for criminal acts in the field of cosmetics, pharmaceuticals, and food, the act of producing or distributing pharmaceutical preparations, such as cosmetics, without a distribution permit, can result in penalties ranging from the lightest to the heaviest, depending on the act committed. The heaviest administrative sanctions are likely to be more effective when compared to the imposition of criminal sanctions. The administrative sanctions for the distribution of cosmetics without a BPOM (Food and Drug Supervisory Agency) permit are regulated in Article 13 paragraph (1) of the Head of BPOM Regulation No. HK.03.1.23.12.11.1005 of 2011 concerning the Supervision of Cosmetics Production and Distribution, which states:

(1) Violations of criminal acts in the field of cosmetics may be subject to administrative sanctions in the form of:

- a. A written warning;
- b. Temporary prohibition from distributing cosmetics;
- c. Withdrawal of cosmetics that do not meet safety, efficacy, quality, and labeling requirements from circulation;
- d. Destruction of cosmetics;
- e. Temporary cessation of production and import activities;
- f. Cancellation of notification;
- g. Temporary closure of online access for submitting notification requests.

The lightest administrative sanction is a written warning, which serves as the initial step in the series of subsequent administrative sanctions. Since administrative sanctions are progressive, a warning sanction will first be applied. If there is no response after the warning, the next level of administrative sanctions will be imposed. The written warning must provide clear instructions on what the person receiving it must do to avoid further action by the administrative authority, in this case, the Food and Drug Supervisory Agency (BPOM). The written warning must also have legal certainty, meaning the person receiving the warning understands exactly what needs to be done and the consequences if they fail to comply.

There are two main reasons for imposing administrative sanctions for violations in the field of cosmetics, pharmaceuticals, and food, as follows:

1. The party involved fails to comply with the restrictions, requirements, or regulations, which are then linked to violations of the distribution permit regulations for cosmetic, pharmaceutical, and food products;
2. The party involved, when applying for a distribution permit, provides incorrect or incomplete data or information to the BPOM officials, causing the data to become inconsistent.

Producing or distributing pharmaceutical preparations such as cosmetics without a distribution permit may result in administrative sanctions.

Whether the party involved is a producer, contract manufacturer, or distributor, administrative sanctions can be imposed according to the provisions of Article 13, paragraph (1) of the Head of BPOM Regulation No. HK.03.1.23.12.11.1005 of 2011 concerning the Supervision of Cosmetics Production and Distribution.

CONCLUSION

Cosmetic products to be circulated must have a cosmetic notification. With this notification, the public can be assured that the cosmetic product they intend to use is guaranteed in terms of quality and safety and will not cause harmful skin damage to consumers in the future. The submission of cosmetic notifications begins through the OSS portal, which will then integrate with the Food and Drug Supervisory Agency (BPOM) system on the official BPOM cosmetic notification website. This system will process requirements, payments, verification, evaluation, and then provide a notification of approval or rejection. Afterward, it will return to the OSS system if the requirements have been met, and the license will be issued on the OSS portal.

Legal responsibility for individuals involved in the distribution of cosmetics without a BPOM distribution permit, in cases of circulating cosmetics without a distribution permit, may be held accountable legally in the form of criminal liability and administrative responsibility as follows: criminal sanctions include imprisonment for up to 12 (twelve) years and a fine of up to IDR 500,000,000.00 (five hundred million rupiahs), while administrative responsibilities include: written warnings, temporary bans on distributing cosmetics, withdrawal of cosmetics that do not meet safety, benefits, quality, and labeling requirements, destruction of cosmetics,

temporary cessation of production and import activities, cancellation of notifications, and temporary closure of online access.

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