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Implementation of Bpom's Authority In Issuing Distribution Permits And Supervising Skincare Products

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Abstract: This research examines how the Food and Drug Supervisory Agency (BPOM) carries out its authority to give distribution permits and supervise the sale of skincare products in Indonesia. This study applies a juridical-normative approach, applying relevant laws and secondary data from official BPOM documents and reports. The research results indicate that the skincare distribution permits are explicitly regulated in Law (Undang-Undang) No. 36 of 2009 concerning Health, and Law (Undang-Undang) No. 8 of 1999 concerning Consumer Protection, and BPOM Regulation No. 12 of 2020 concerning Procedures for Submitting Cosmetic Notifications. The process of obtaining approval of a product involves submitting a product notification, undergoing BPOM evaluation, obtaining a notification number, and fulfilling the post-approval requirements. From an administrative law perspective, the procedure shows the principles of good governance, whereas from a commercial law perspective, a distribution permit serves as a legal requirement for selling products. In practice this process still encounters many significant challenges, often leading to the widespread use of illegal products without permits. The discovery of harmful skincare and cosmetics valued at billions of rupiah and the difficulty of monitoring online sales across platforms illustrate major regulatory problems. Therefore, providing effective legal protection for consumers in Indonesia. Therefore, stronger supervision and cooperation between sectors are needed to give better legal protection for consumers in Indonesia.

Keyword: BPOM, cosmetics, skincare, supervision

INTRODUCTION

Skincare, or skin care products, are a type of cosmetics formulated to maintain the skin's health, cleanliness, and appearance of the skin. According to BPOM (the Indonesian Food and Drug Authority), cosmetics are substances or preparations intended to be used on the external parts of the human body, including the skin, with the purpose of cleaning, perfuming, altering appearance, or maintaining the body in good condition. Over time, skincare has evolved beyond just aesthetics; it now plays a vital role in maintaining skin health, driven by the increasing public awareness of healthy living.

The types of skincare products available on the market are quite diverse, including cleansers, toners, moisturizers, sunscreens, as well as specialized care products such as serums, masks, and anti-aging creams. These products typically contain active ingredients such as vitamin C, niacinamide, hyaluronic acid, retinol, and salicylic acid, which are beneficial for skin care. However, many skincare products have been found to contain harmful substances such as mercury, hydroquinone, and resorcinol, which, if used without supervision, can pose serious health risks ranging from irritation to organ damage (BPOM, 2025).

To protect consumers from such risks, Indonesia has implemented several regulations. Law Number 36 of 2009 on Health affirms the government's obligation to ensure the safety, quality, and efficacy of health products. Law Number 8 of 1999 on Consumer Protection grants consumers the right to comfort, safety, and security in consuming goods and/or services. Technically, BPOM Regulation Number 12 of 2020 on Procedures for Submitting Cosmetic Notifications requires every skincare to undergo an evaluation and notification process before being authorized for sale.

BPOM (Badan Pengawas Obat dan Makanan) plays an important role in this system. As a non-departmental government agency under the president, BPOM regulates and supervises all stages of production, distribution, and marketing of drugs, food, and cosmetics to ensure consumer safety (Abd. Aziz.,2020). Its authority includes issuing distribution permits, establishing standards for ingredients, monitoring compliance with regulations, and taking administrative actions against violations. BPOM's supervision extends beyond inspecting finished products; it covers the entire production process, including raw materials, production facilities, documentation, and product packaging. This comprehensive approach aims to prevent harmful products from reaching consumers while supporting a fair and competitive business environment (Aziz & Musyafa'ah, 2020).

In reality, several issues still persist. Many skincare products are still being distributed without official approval, particularly through online marketplaces. BPOM continues to find illegal products containing harmful ingredients. In a joint operation in 2025, BPOM uncovered the circulation of illegal cosmetics worth IDR 31.7 billion—more than ten times higher than the previous year (BPOM, 2025).

Theoretically, this study is supported by Administrative Law theory, particularly the concept of government authority *(Kewenangan Pemerintahan)*, which explains that every government agency must act based only within the powers given to it by law. Additionally, the research draws upon Consumer Protection Theory, which emphasizes the state's duty to protect citizens from harmful or unsafe products. These sets of theories serve as the foundation to analyze the legitimacy and effectiveness of BPOM's authority in implementing its supervisory functions.

This research aims to analyze the implementation of BPOM's authority in issuing distribution permits and supervising skincare product marketing in Indonesia, by examining its legal basis, procedural implementation, and the challenges in enforcement. The study also seeks to evaluate the effectiveness of BPOM's supervision mechanisms and provide recommendations to strengthen consumer protection and regulatory compliance in the cosmetics sector.

METHOD

In this study *"Implementation of BPOM's Authority in Issuing Distributions Permits and Supervising Skincare Products,"* the author uses a qualitative research method with a juridical-normative. This method was selected because the study focuses on analyzing the authority of the Indonesian Food and Drug Administration (BPOM) as regulated by laws and its implementation in the supervision of skincare products in Indonesia.

The juridical-normative approach is applied to examine existing written legal norms, according to Law No. 36 of 2009 on Health, Law No. 18 of 2012 on Food, Law No. 33 of 2014 on Halal Product Assurance, Law No. 8 of 1999 on Consumer Protection, as well as BPOM's technical regulations concerning the issuance and supervision of drug and food circulation permits.

This study utilizes secondary data such as official BPOM documents, monitoring reports, and publications from credible media sources to provide an factual overview of the challenges faced by BPOM especially in addressing the ongoing circulation of illegal skincare products. This approach enables the author to evaluate how BPOM's authority has been implemented in accordance with the law and to evaluate its effectiveness in ensuring legal protection for consumers.

The analysis uses deductive reasoning techniques, starting from general legal norms and regulations, then applied to specific cases and practices of BPOM's authority in the skincare industry. This technique allows the researcher to evaluate whether the implementation of BPOM's authority aligns with the principles of legality, consumer protection, and administrative accountability.

RESULTS AND DISCUSSION

Legal Regulation on the Approval and Supervision of Skincare Products

A distribution permit acts as an important role ensuring that skincare products entering the market are safe, effective, and meet established quality standards. It serves as a legal filter that prevents the distribution of dangerous or prohibited products.Through this the Indonesian National Agency of Drug and Food Control (BPOM) protects public health by ensuring that all skincare products meet the required standards before being sold to consumers.

a. Law Number 36 of 2009 on Health, Article 106 paragraph (1)**,** which states that pharmaceutical preparations, including cosmetics, may only be distributed after obtaining official authorization. Thus, official authorization serves as a fundamental requirement for the distribution of skincare including cosmetic products. This establishes distribution permit as a mandatory legal for cosmetic products, including skincare, to be marketed.
b. Law Number 8 of 1999 on Consumer Protection, Article 8, prohibits businesses from manufacturing or selling products that do not meet safety standards or do not have the necessary legal approval. This forms legal protection for consumers.
c. BPOM Regulation Number 12 of 2020 on Procedures for Submitting Cosmetic Notifications serves as the technical basis outlining how a skincare product can obtain marketing authorization through the notification mechanism.

A research done by Isdiana Syafitri and Atika Sandra Dewi (2022) highlights the legal protection provided to consumers against illegal skincare products. The study explains that consumers are entitled to safety, accurate information, and compensation when harmed by unsafe or illegal products, as regulated under Articles 4 and 8 of the Consumer Protection Law (UU No. 8/1999). Protection measures include administrative sanctions, criminal penalties, and civil actions such as compensation claims. BPOM plays a critical role in this system by monitoring, sampling, and, if necessary, withdrawing unsafe skincare products from the market, as evidenced by the identification of numerous products containing mercury in 2021. These measures ensure that unauthorized products are prevented from harming consumers and reinforce the importance of distribution permits as a gatekeeping mechanism for safe skincare circulation.

Moreover, these violations of cosmetic regulations are subject to strict legal consequences, violations can result in both criminal and administrative sanctions. Products without proper BPOM registration or that fail safety standards may be subjected to laboratory testing, and producers or sellers can face criminal sanctions including fines up to

Rp1.500.000.000 and imprisonment up to 10–15 years, as regulated under the Health Law and BPOM decrees (Wardani, 2019).

Implementation of Product Approval Procedures for Skincare Products

The study done by (Madugula et al.,2023) demonstrates that social media significantly influences consumer behavior in selecting skincare products, particularly among young adults such as medical students. Approximately 22.9% of participants reported being influenced by social media in their purchasing decisions, while 33.4% were influenced by friends and family. This shows that consumers are often exposed to new skincare products before they are properly verified for safety, quality, and labeling.

This situation highlights the critical importance of BPOM's product approval procedures, laboratory testing, and ongoing monitoring are crucial components in maintaining product safety, efficacy, and truthful advertising, especially skincare has been rapidly growing online in the online market. Pre-market evaluation, such as verification of ingredient safety, labeling compliance, and quality assessment, ensures that products meet legal standards before distribution. Also post-market supervision, including online monitoring of social media and e-commerce platforms, is essential to prevent the circulation of illegal or unsafe skincare products that are widely promoted online.

These legal regulations not only establish the requirement for distributing skincare products but also the procedural requirements that must be fulfilled by manufacturer and skincare companies :

a. Notification Submission: Manufacturers or importers are required to submit an application to BPOM along with documents related to the product's safety, quality, labeling, and claims.Legal basis: Articles 2, 4, and 7 of BPOM Regulation Number 12 of 2020 on Procedures for Submitting Cosmetic Notifications.
b. BPOM Evaluation: BPOM conducts an evaluation of the product's ingredient composition, safety of use, labeling compliance, and adherence to quality standards. Legal basis: Article 28 paragraph (1) of BPOM Regulation Number 12 of 2020 states that verification includes aspects of safety, quality, claims, and labeling of cosmetics.
c. Issuance of Notification Number: If the product meets all the requirements BPOM proceeds to the issuance of a notification number. This number is required to appear on the packaging to indicate that the product meets legal standards. Legal basis: Article 29 paragraph (1) of BPOM Regulation Number 12 of 2020 states that once the certification results have met the required standards, the applicant will be notified and provided with the official notification number.
d. Post-Market Authorization Obligations: Manufacturers and companies must maintain product quality, report any changes in composition, and take responsibility for any cause effects that may harm consumers.Legal basis: Article 41 of BPOM Regulation Number 12 of 2020 regulates the validity period of the notification (three years) and the mandates for renewal. In addition, BPOM Head Regulation Number HK.03.1.23.12.11.10051 of 2011 on the Mechanism for Monitoring Adverse Effects of Cosmetics (MESKOS) requires manufacturers and companies to report any adverse effects.

In addition to its authority in granting marketing authorization, BPOM also carries out post-market supervision to ensure that skincare products already in circulation continue to meet safety, quality, and efficacy standards. In practice, BPOM's supervision is divided into two main mechanisms: pre-market supervision and post-market supervision.

1. Pre-Market Supervision

   Pre-market supervision is carried out before a product is released to the market. BPOM evaluates the documents submitted by manufacturers or importers, including the product formula, data on the safety of active ingredients, production quality, and labeling used

(BPOM, 2020). If necessary, BPOM may also conduct laboratory tests to ensure that the product's claims correspond to its actual composition. However, pre-market supervision has limitations, as the number of products entering the market is very large, while BPOM's inspection capacity remains limited. This situation creates opportunities for some illegal products to slip through and circulate without a valid product license. This preventive supervision aims to screen products from the outset to prevent potential risks to consumers and it is regulated in *BPOM Regulation No. 18 of 2015,* and certifying cosmetic production facilities to ensure compliance with legal production standards.

2. Post-Market Supervision

Based on Presidential Regulation Number 80 of 2017 concerning the Food and Drug Monitoring Agency, Article 3, Post-market supervision is carried out after the product has been distributed to the public. This supervision is repressive, aiming to act against products that violate regulations. Furthermore, according to (Imam Suyudi et al.,2022), BPOM's role does not end at pre-market approval. BPOM actively conducts post-market supervision by sampling products in the market, monitoring advertisements, inspecting production facilities, and overseeing distribution processes. This post-market supervision ensures that products maintain their quality and safety even after entering the market implemented by BPOM include:

1. inspections of production, distribution, and retail facilities.
2. Cyber patrols to detect the sale of illegal skincare products on online marketplaces and social media platforms.
3. Product recalls if the products are found to contain hazardous substances or lack marketing authorization.
4. Administrative sanctions, such as written warnings, suspension of production, revocation of marketing authorization, and referral of cases for criminal prosecution if the violations are deemed severe.

BPOM role and function According to Presidential Decree Number 80 of 2017, BPOM carries out functions such as preparing national policies, implementing and coordinating pre- and post-market supervision, providing technical guidance, taking action against violations, managing state property, and providing substantive support to organizational elements. These functions ensure continuous monitoring, enhance consumer protection, and maintain compliance in the cosmetic industry (Andira & Muhammad, 2024).

From the perspective of Administrative Law, this process represents a form of public service. BPOM acts as the administrative authority that provides legal certainty to manufacturers and skincare companies. The notification procedure also reflects the general principles of good governance (AUPB), including transparency (through the online system), accuracy (through the evaluation of technical documents), legal certainty (through the issuance of the notification number).

From a Commercial Law perspective, product license functions as a requirement for trade legality. Skincare products without distribution permits are categorized as illegal, which makes their sales contracts legally defective. In practice, many consumers suffer losses after purchasing unlicensed products sold at low prices on online marketplaces. This situation shows that license approval from BPOM is necessary for the legal sale of products in the cosmetics industry.

Table 1. *Skincare Brands Detected to by BPOM Contain harmful Substances in Indonesia (2022–2025)*

Year/ Period	Amount of skincare products found my BPOM	Examples of Skincare brand

September 2022 - October 2023	181 items	ELCY BEAUTY, GLOWINGIN, R&D GLOW etc.
End of Oktober- November 2024	235 items 69 brands	Lameila, Aichun Beauty, Tanako etc.
Februari10–18 2025	4.334 items/varian kosmetik 91 brands	Acne Forte, 24k essence, Glow express etc.

Source: BPOM RI

The increasing number of skincare products and brands detected by BPOM containing harmful substances from 2022 to 2025 indicates a challenge in regulating and supervising the skincare and cosmetic industry, particularly due to the rapid expansion of online and imported cosmetic distribution in Indonesia. This situation highlights weaknesses in market surveillance mechanisms, as well as the need for stricter enforcement of product safety standards. The rapid expansion of online marketplaces and the influx of imported cosmetic products have made it more difficult for authorities to monitor product circulation and verify compliance with BPOM's safety requirements. Consequently, this issue not only threatens consumer health and safety but also undermines public trust in regulatory institutions and the cosmetic industry as a whole.

CONCLUSION

Based on the results of this research on The Implementation of BPOM's Authority in regarding Distribution Permits and Supervising Skincare Products in Indonesia lead to the following conclusions. The authority of BPOM, the National Agency for Drug and Food Control, is regulated under Law No. 36 of 2009 concerning Health. Law No. 8 of 1999 on Consumer Protection, and Presidential Regulation No. 80 of 2017 on BPOM, further elaborated through BPOM Regulation No. 12 of 2020 and BPOM Regulation No. 18 of 2024. These laws and regulations provide legal legitimacy for BPOM to regulate, supervise, and act against violations. Implementation of Distribution Permit is also the issuance of distribution permits is carried out through a cosmetic notification mechanism, which includes the submission of required documents, BPOM's evaluation process, and the issuance of a notification number. This procedure reflects the principles of legal certainty, transparency, and accuracy, and serves as a requirement for the legality of trade activities under commercial law.

Supervision and Effectiveness BPOM conducts both pre-market and post-market supervision, including cyber patrols on digital platforms. The Intensification Operation conducted in 2025 uncovered illegal cosmetic products valued at Rp 31.7 billion, demonstrating increased supervisory activity. However, its overall effectiveness remains limited due to cross-border online trade, limited human resources, and low consumer literacy regarding product legality. From the perspective of Administrative Law, BPOM's exercise of authority is in accordance with the principle of legality, although improvements are needed in the digital monitoring system. From the perspective of Commercial Law, weak law enforcement against illegal business actors has led to market injustice and reduced the competitiveness of compliant industries.

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