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The Role of the Drug and Food Control Agency (BPOM) in Addressing the Distribution of Illegal Cosmetics

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Original Article

Abstract

The beauty industry, while fostering cosmetic advancements, also creates opportunities for unauthorized individuals to market products. This study assesses consumer protection and The Drug and Food Control Agency (BPOM)'s oversight of illicit cosmetics sales. Employing a normative juridical approach with secondary data analysis and a statute and case methodology, the research examines existing legal frameworks. The analysis reveals that Indonesian law, notably Article 142 of the health Law and related statutes, provides legal safeguards for consumers. Violations, such as sales without proper distribution permits, incur civil, administrative, and criminal penalties. BPOM bears the responsibility of monitoring cosmetics distribution but is frequently criticized for negligence. To mitigate this, BPOM should intensify routine and proactive inspections to curb illegal product circulation and uphold community safety standards.

Keywords: *Food, Drug, Illegal Cosmetics, Consumer Protection, BPOM*

Abstrak

Industri kecantikan terus berkembang, mendorong inovasi kosmetik, namun juga membuka celah bagi oknum tak bertanggung jawab untuk memasarkan produk tanpa izin. Penelitian ini mengevaluasi perlindungan konsumen dan tanggung jawab Badan Pengawas Obat dan Makanan (BPOM) dalam mengawasi penjualan kosmetik ilegal. Metode penelitian menggunakan pendekatan yuridis normatif dengan analisis data sekunder dan pendekatan statute serta kasus. Temuan menunjukkan bahwa hukum Indonesia, termasuk Pasal 142 Undang-Undang Kesehatan dan regulasi lainnya, telah menetapkan perlindungan hukum terhadap konsumen. Pelanggaran seperti penjualan tanpa izin edar diancam sanksi perdata, administratif, dan pidana. BPOM bertanggung jawab atas pengawasan peredaran kosmetik, namun sering kali dianggap lalai. Seharusnya, BPOM meningkatkan inspeksi rutin dan proaktif untuk mencegah produk ilegal dan memastikan keamanan produk di masyarakat.

Kata kunci: *Makanan, Obat-obatan, Kosmetik Ilegal, Perlindungan Konsumen, BPOM*

1. INTRODUCTION

The beauty industry in Indonesia has become one of the main pillars of the national economy and is included among the three main priority industries as stipulated in the 2015-2035 National Industrial Development Master Plan (RIPIN). According to data compiled by Statista, this sector is predicted to experience an average annual growth of 5.91%, encompassing skin care and other personal care products.¹ This growth potential indicates that the beauty industry is not only significant from an economic perspective but also holds bright prospects for the future, contributing substantially to job creation and driving innovation within the sector.

The beauty industry is highly competitive, with lifestyle and consumer perceptions of beauty products significantly impacting market dynamics. During the Covid-19 pandemic, there was a notable increase in individuals' interest in performing skin care routines at home. This shift has created opportunities for local brands to showcase their ability to provide products that are not only of comparable quality to international brands but also more affordable. This change has not only heightened awareness of local products but also fostered a strong sense of pride and loyalty among consumers toward domestic brands. Consequently, the national beauty industry is experiencing rapid growth, propelled by increasing support and enthusiasm from local consumers. This phenomenon demonstrates how adaptation to changing market conditions can create new opportunities and drive overall industry development.

Data from The Drug and Food Control Agency (BPOM) indicates that the number of business entities in this sector has increased significantly, from 819 in 2021 to 913 in 2022, reflecting a growth rate of 20.6%.² Further analysis from Statista states that the largest market segment in the national beauty industry is skin care and personal care, with a total market volume reaching USD 3.16 billion in 2022.³ Despite its high demand, particularly among women, the beauty industry reveals that the desire to meet beauty standards is often a priority. However, it is crucial to note that various cosmetic products that fail to meet standards frequently circulate in the market. This is a significant concern as it can negatively impact users, both in terms of health and the effectiveness of the products used.

Although a cosmetic product may be sold at a low price, certain underlying reasons might account for this. One such reason is the possibility that the product is not registered or officially authorized by BPOM.⁴ This potentially indicates that the cosmetics contain harmful ingredients that can jeopardize human health and organs. Additionally, these cosmetic products may lack clear labeling or expiration dates, leaving consumers

¹ Direktorat Jenderal Industri Kimia Farmasi dan Tekstil, "Perkembangan Industri Kosmetik Nasional," Kementerian Perindustrian Republik Indonesia, 2022, <https://www.kemenerin.go.id/ripin>.

² Direktorat Jenderal Industri Kimia Farmasi dan Tekstil.

³ Direktorat Jenderal Industri Kimia Farmasi dan Tekstil.

⁴ Randy Aprilianto, "Product Experience, Outcome Focus, Moments of Truth, Peace of Mind Pengaruhnya Terhadap Customer Satisfaction Dan Customer Loyalty Skin Care Erhaclinic Surabaya" (Widya Mandala Catholic University Surabaya, 2016), <http://repository.ukwms.ac.id/eprint/8427/>.

uninformed about crucial product information. Furthermore, there is a possibility that the product is a counterfeit, mimicking a well-known cosmetic brand but sold at a significantly lower price.

According to Article 1, Point 12 of Law Number 17 of 2023 concerning Health (hereinafter referred to as the “Health Law”), cosmetics are categorized as pharmaceutical preparations because they are considered products related to health. Additionally, the definition of cosmetics, as explained in Article 1, Point 1 of the Explanation of Government Regulation of the Republic of Indonesia Number 72 of 1998 concerning the Safeguarding of Pharmaceutical Preparations and Medical Devices, states that cosmetics are mixtures of materials intended to be applied to the exterior of the body (such as the skin, hair, nails, lips, and external genital organs), as well as the teeth and oral cavity.

The purposes of using cosmetics include cleaning, enhancing attractiveness, altering appearance, maintaining good condition, and improving body odor. However, it is important to note that cosmetics are not intended to treat or cure diseases. The Regulation of the Minister of Health of the Republic of Indonesia Number 1175/MenKes/PER/VIII/2010 concerning Notification of Cosmetics further explains that cosmetics are materials or products designed to be applied to the external parts of the human body, including external genital organs, lips, nails, hair, and skin (epidermis), or on the teeth and oral mucous membranes. The primary purposes of using cosmetics are to provide aroma, cleanse, alter appearance, improve body odor, and maintain or protect the body to keep it in good condition.

Business actors have a responsibility to protect consumer rights by ensuring that the products they sell are safe and of high quality. Unfortunately, many business actors in the cosmetics industry often neglect this responsibility, thereby putting consumers at risk if they are not diligent in choosing cosmetic products. Irresponsible business actors may exploit consumer negligence for personal gain. To address the need for legal certainty and protect consumer rights, the government has established consumer protection laws. These laws are designed to provide clear legal safeguards for consumers and impose sanctions on violators. With this regulation, it is hoped that business actors will pay greater attention to consumer rights, ensuring that consumers can feel safer when using the products they purchase.⁵

The circulation of dangerous beauty products with counterfeit BPOM distribution permits has a clear negative impact on consumers. Many consumers, who do not carefully verify the authenticity of distribution permits, tend to assume that the products they use have undergone the BPOM approval process and are thus safe. This misconception can lead to various health problems, as consumers remain unaware that the product does not meet established safety standards. Consequently, consumers may neglect to check the product’s composition or the authenticity of the distribution permit number listed.

⁵ Theresia Gabriella and Handar Bakhtiar, “Perlindungan Hukum Kepada Konsumen Terkait Peredaran Kosmetik Ilegal,” *Jurnal Panorama Hukum* 8, no. 1 (July 2023): 17–23, <https://doi.org/10.21067/jph.v8i1.8521>.

Although Article 8 of the Consumer Protection Law (UUPK) prohibits business actors from producing and trading damaged, defective, or contaminated goods or services, it does not specifically address the distribution of products with fake permits.⁶ This gap means that legal protection for consumers is not optimal, allowing an increase in the falsification of product distribution permit numbers, which is increasingly concerning.

BPOM plays a crucial role in supervising and addressing the distribution of cosmetic products without proper BPOM permits. Prioritizing the protection of consumer rights, BPOM must take firm action against violators. The significant role of the government and BPOM in maintaining consumer safety and health cannot be overlooked. BPOM, as the agency responsible for regulating and supervising health products, including skin whitening products, must actively detect and take action against illegal products or those with counterfeit permits.

Based on the background discussed above, the objectives of this research include:

- a) to review consumer protection measures for products that do not have a permit from the BPOM;
- b) to examine the responsibility of BPOM as an institution that monitors product distribution by producers.

2. RESEARCH METHODOLOGY

In this research, normative juridical methods are adopted. As explained by Peter Mahmud Marzuki,⁷ this approach is used to identify various legal regulations, principles, and doctrines relevant to addressing the legal issues at hand. It involves an in-depth analysis of legal sources such as statutes, court decisions, and other legal documents to provide a comprehensive understanding of the problem being researched. This method aims to analyze applicable law and understand its implications for the issue under investigation. By using this approach, researchers can gain a profound understanding of the legal framework governing a particular subject and evaluate how these rules and principles can be applied in the specific context being studied.

To support the research process, both a statutory approach and a case approach are utilized. The statutory approach, involves a thorough examination of all relevant laws related to the legal issue under discussion. This approach allows researchers to understand the applicable legal framework, evaluate the legal implications, and gain a deeper understanding of the relevant legal context.⁸ Additionally, a case approach is used, involving the study of cases that are relevant or similar to the problem being researched. By analyzing these cases, researchers can identify legal precedents, decision patterns, and

⁶ Anak Agung Ngurah Naga Sena and Dewa Gde Rudy, "Perlindungan Konsumen Terkait Peredaran Produk Pemutih Badan Dengan Izin Edar BPOM Palsu," *Jurnal Thengkyang* 8, no. 1 (2023): 1–11, <https://jurnal.unisti.ac.id/thengkyang/article/view/156>.

⁷ Peter Mahmud Marzuki, *Penelitian Hukum*, 19th ed. (Jakarta: Prenada Media Group, 2019), <https://prenadamedia.com/product/penelitian-hukum-edisi-revisi/>.

⁸ I Made Pasek Diantha, Ni Ketut Supasti Dharmawan, and I Gede Artha, *Metode Penelitian Hukum Dan Penulisan Disertasi* (Denpasar: Swastu Nulus, 2018).

strategies used in resolving similar issues. These two approaches enable researchers to develop an in-depth analysis of legal protection regarding the circulation of counterfeit permits for cosmetic products and the responsibility of BPOM in safeguarding consumers from various threats.

In this research, researchers will collect information and data related to consumer protection issues concerning illegal cosmetics in Indonesian society through literature review methods. This collection method aims to provide a comprehensive picture of consumer protection within the context of Indonesian positive law, ensuring that the data collected is systematically structured and analyzed using qualitative analysis methods. The data is sorted and grouped based on its relevance to the research problem and its accuracy. The data compilation process is carried out meticulously to ensure that all collected information aligns with the research objectives. Each piece of data is thoroughly analyzed to understand its implications and significance within the context of the research being conducted.

3. RESEARCH RESULTS AND DISCUSSION

3.1 Consumer Protection Against Sales of Illegal Cosmetics

In essence, God created humans in perfect form. However, it is common for women to desire improvements in their appearance. They seek to enhance their beauty, requiring more than just natural attributes. This desire has led to the proliferation of various beauty products in modern society. The development of beauty products, particularly in the field of cosmetics, has seen many women willing to spend substantial amounts of money to purchase various types of cosmetics to enhance their appearance. Consequently, free trade, especially in the cosmetics market, is expanding rapidly due to the high public demand for beauty products.

The rapid growth of free trade has led to increased sales of various cosmetic products in the market. This phenomenon demonstrates that with the increasingly open global market, cosmetic products have greater access to be bought and sold. With the fast-paced growth of free trade, beauty products can easily reach consumers worldwide. The heightened demand for cosmetic products encourages manufacturers to create diverse beauty products that attract consumers' attention. As market competition intensifies, manufacturers strive to offer innovations and product variations that can meet consumer desires.

However, this phenomenon has also attracted the attention of unscrupulous business actors who perceive an opportunity amidst the high demand for cosmetic products. These irresponsible business actors see potential profits without considering the consequences of using unsafe or unregistered ingredients and possibly engaging in practices detrimental to consumers. This highlights that within the cosmetics industry, there are individuals who opt for shortcuts to achieve profit, disregarding the negative impacts that may ensue. These irresponsible business actors exploit this situation by selling illegal cosmetic products at

low prices that do not meet standards and have not been certified by BPOM.⁹ Consumers' ignorance of the risks associated with using illegal cosmetics allows these products to remain in demand, even though they may not be aware of the potential side effects, which can include various skin diseases if used long-term. Unregistered and inadequately tested illegal cosmetics can pose serious health risks to users.¹⁰

Illegal or dangerous cosmetics refer to products that contain mixtures of ingredients that are legally permitted but exceed the quantity or quality standards recognized or regulated by law, as well as cosmetics containing ingredients prohibited for use in cosmetics due to not meeting safety and efficacy requirements. These products do not comply with the legal provisions or recognized safety standards. In practice, the use of such ingredients in cosmetics, whether they exceed the permitted amounts or are on the list of prohibited ingredients, can result in harm to the health and safety of the user.

The existence of unlicensed products also presents challenges for the government in addressing their distribution and increasing public awareness of the importance of using cosmetic products that have been tested and officially registered by competent authorities. In response, the health Law regulates the prohibition of distributing illegal cosmetics, as stated in Article 138, which prohibits business actors from engaging in activities involving pharmaceutical preparations that do not meet the required safety and effectiveness standards. This provision aligns with Article 8, paragraph (1), letter a of the Consumer Protection Law (PK Law), which prohibits business actors from selling goods that do not meet the standards set by statutory regulations. This provision not only protects consumer rights but also encourages business actors to ensure that their products comply with legal requirements.

Article 2, paragraph (1) of BPOM Regulation Number 12 of 2020 concerning Procedures for Submitting Cosmetics Notifications (hereinafter referred to as "BPOM Regulation Number 12 of 2020") mandates that all parties involved in the cosmetics industry ensure that the cosmetic products produced and distributed domestically, or imported for distribution within Indonesia, meet established standards of safety, efficacy, quality, labeling, and claims. Producers, distributors, and importers must ensure that the cosmetic products they market comply with these provisions, guaranteeing that the products are safe to use, beneficial for consumers, of adequate quality, and have clear labels and claims that reflect reality.

This provision aims to protect consumers from risks that may arise due to the use of cosmetics that are unsafe or do not meet specified requirements. Pharmaceutical preparations, including cosmetics, may not be marketed or sold without undergoing a

⁹ Neri Widya Ramailis and Deki Putra Wandu, "Peran BPOM Kota Pekanbaru Dalam Mengawasi Perdagangan Kosmetik Illegal," *Sisi Lain Realita* 3, no. 2 (August 2019): 20–39, [https://doi.org/10.25299/sisilainrealita.2018.vol3\(2\).3708](https://doi.org/10.25299/sisilainrealita.2018.vol3(2).3708).

¹⁰ I Komang Triana Diantara, Ida Ayu Putu Widiati, and Ni Made Sukaryati Karma, "Penerapan Sanksi Pidana Terhadap Pelaku Tindak Pidana Yang Mengedarkan Kosmetika Tanpa Izin Edar: Study Kasus Pengadilan Negeri Gianyar Nomor Pekara 132/Pid.Sus/2018 PN Gin," *Jurnal Analogi Hukum* 2, no. 2 (2020): 264–69, <https://doi.org/10.22225/ah.2.2.2020.264-269>.

licensing process determined by the relevant authorities. Cosmetics typically contain various chemicals that need to be carefully inspected, involving testing and analysis to ensure safety. This inspection ensures that each component in the product does not cause dangerous side effects and complies with established safety standards.¹¹

The Health Law, Article 142, paragraph (4), stipulates the standard obligations and requirements that must be fulfilled to obtain a marketing permit. This article states that cosmetic products must meet a number of standards and requirements, including quality, safety, and technical provisions determined by BPOM, to be sold and marketed in Indonesia. Cosmetic products must comply with established regulations regarding quality, safety, and ingredient compliance. This ensures consumer protection from the risks posed by substandard cosmetic products and enhances public trust in the cosmetics available on the market.

Paragraph (5) of Article 142 of the health Law emphasizes that the ingredients used in cosmetic products must meet the same quality standards and criteria as pharmaceutical ingredients, such as natural ingredients for medicines, health supplements, quasi-medicines, and other specific items that have undergone a risk evaluation. This underscores the importance of ensuring that cosmetic products have gone through a risk evaluation process and meet the quality requirements to avoid health risks for users. Fulfillment of these quality requirements must align with recognized standards or statutory provisions. Additionally, the implementation of this regulation aims to protect consumers from products whose safety is not guaranteed and encourages the cosmetics industry to prioritize the safety and quality of their products.

The provisions outlined in Article 142, paragraphs (4) and (5) of the health Law, and Article 3, paragraphs (1) and (2) of Minister of Health Regulation Number 1176/Menkes/Per/VIII/2010 regarding Cosmetic Notifications underscore the necessity for every cosmetic product to obtain a distribution permit from the Ministry of Health before being marketed. The notification serves as official documentation granting distribution permission. This procedural step mandates compliance with Good Cosmetic Manufacturing Practices (CPKB) and various technical requirements, encompassing product safety, materials, labeling, and claimed benefits. The issuance of this notification signifies the completion of administrative procedures and conferral of approval. Marketing authorization recipients can thereby confirm compliance with all prerequisites and proceed with authorized activities.

These requirements also extend to individuals or entities involved in the production or distribution of pharmaceutical products, medical devices, or household health equipment, who must possess a business permit issued by the Central or Regional Government in accordance with their respective jurisdictions. Acquisition of this permit necessitates adherence to norms, standards, procedures, and criteria stipulated by statutory

¹¹ Asri Wakkary, "Tindak Pidana Pemalsuan Obat Dalam Peraturan Perundang-Undangan Di Indonesia Berdasarkan Undang-Undang Nomor 36 Tahun 2009 Tentang Kesehatan," *Lex Privatum* 4, no. 5 (2016): 21–27, <https://ejournal.unsrat.ac.id/index.php/lexprivatum/article/view/12637>.

regulations. Moreover, business actors are obligated to include a registration number from the POM Agency on each product¹², ensuring conformity with specified safety and quality standards to safeguard consumer health and safety.

Non-compliance with established safety, effectiveness, or quality standards may result in administrative sanctions against the responsible party, as outlined in the business license regulations. These sanctions, ranging from fines to revocation of business permits or restrictions on business activities, aim to uphold product safety and societal benefit while encouraging adherence to established standards by business actors.

3.2 The Legal Responsibility of Business Actors Selling Illegal Cosmetics

When discussing liability, it is essential to assess whether any losses arise from the utilization of goods or services provided by business actors by consumers. This pertains to the legal obligation that business actors must assume towards consumers for any adverse effects that may occur due to the use or consumption of the goods and services they offer.¹³ Legal responsibility entails the duty of an individual or entity to adhere to and enforce various rules and regulations established within the legal framework.¹⁴

Article 19, paragraph (1) of the Consumer Protection Law (UUPK) delineates the responsibility of business actors, which includes compensating consumers for various losses incurred. This encompasses damage to goods, environmental harm, and other losses experienced by consumers resulting from the use or consumption of goods and/or services produced or traded by the business actor. Concerning the legal liability of business actors selling cosmetics unlawfully and lacking distribution permits, the liability that may be sought is categorized into three aspects: administrative accountability, criminal liability, and civil accountability.

a) Accountability from the Criminal Aspect

Pharmaceutical products such as cosmetics cannot be freely distributed and sold without undergoing licensing procedures established by the authorities. This is because cosmetic products typically contain chemicals that necessitate scrutiny and testing to ascertain their safety and efficacy for consumers. Individuals who engage in the sale of cosmetics without official permission may be subject to criminal sanctions in accordance

¹² Isdiana Syafitri and Atika Sandra Dewi, "Analisis Perlindungan Hukum Terhadap Konsumen Atas Produk Skincare Ilegal," *Juripol: Jurnal Institusi Polgan* 5, no. 2 (August 2022): 124–33, <https://doi.org/10.33395/juripol.v5i2.11697>.

¹³ Desiana Ahmad and Mutia Cherawaty Thalib, "Tanggung Jawab Hukum Pelaku Usaha Terhadap Peredaran Kosmetik Yang Tidak Memiliki Izin Edar," *Jurnal Legalitas* 12, no. 2 (2019): 104–13, <https://doi.org/10.33756/jelta.v12i2.5797>.

¹⁴ I Made Surya Kartika and AA Sagung Wiratni Darmadi, "Tanggung Jawab Pelaku Usaha Periklanan Dalam Memberikan Informasi Yang Lengkap Dan Benar," *Kertha Semaya: Journal Ilmu Hukum* 4, no. 1 (2016): 1–5, <https://ojs.unud.ac.id/index.php/kerthasemaya/article/view/13381>.

with applicable legal provisions, including various regulations governing this matter, such as:

1) Health Law

Article 435 of the Health Law mandates that individuals involved in the production or distribution of Pharmaceutical Preparations and/or Medical Devices failing to meet the standards and requirements for safety, efficacy/benefits, and quality as stipulated in Article 138, paragraphs (2) and (3) of the Health Law may face criminal penalties. The prescribed punishment consists of imprisonment for up to 12 years or a fine of up to IDR 5,000,000,000.00 (five billion rupiah). Through the enactment of the recently passed health law, which supersedes the previous legislation, the government has imposed stringent sanctions on offenders to serve as a deterrent and foster compliance with existing regulations. These penalties, encompassing both imprisonment and fines, underscore the government's commitment to upholding stringent health standards and ensuring the safety, efficacy, and quality of all pharmaceutical products and medical devices available on the market.

2) Consumer Protection Health Law (UUPK)

Article 62, paragraph (1) of the UUPK stipulates that violations of several provisions within this law, including Article 8 of the UUPK, may result in sanctions such as imprisonment for a maximum period of five years. Additionally, violators may be liable for fines not exceeding two billion rupiah. This provision aims to deter offenders and safeguard consumer rights by ensuring that severe violations are met with appropriate penalties. Article 8 of the UUPK itself prohibits business actors from manufacturing or trading goods and/or services that fail to meet or comply with required standards, posing risks to consumers. In Article 8, paragraph (1), letter a of the UUPK, it explicitly states that business actors are forbidden from producing and/or trading goods and/or services that do not meet or comply with the required standards and provisions of statutory regulations. In the case of business actors selling cosmetics unlawfully or without distribution permits, who market cosmetic products without official permits both online and offline, they clearly contravene the provisions outlined in Article 8, paragraph (1), letter a of the UUPK, rendering them liable to imprisonment for a maximum of five years or a fine of two billion rupiah.

b) Accountability from Administrative Aspects

Business actors engaged in the sale of illegal cosmetics or those lacking distribution permits, who market cosmetic products without official permits, will incur various administrative sanctions as additional penalties, as stipulated in Article 63 of the UUPK. Firstly, they may receive a written warning. BPOM possesses the authority to issue official

warning letters to such business actors found to be involved for the first time in the sale of cosmetic products lacking official permits. This measure aims to afford these business actors the opportunity to cease their illicit activities promptly and adhere to relevant regulations. Through this written warning, it is anticipated that they will recognize their transgressions and take requisite corrective measures to ensure that all products sold undergo an evaluation process and obtain approval from the POM, thereby guaranteeing consumer safety and health.

Secondly, temporary suspension of activities leading to consumer losses may be imposed. Should the violation persist or the business actor fail to implement corrective measures within the specified timeframe, BPOM is authorized to mandate a temporary suspension of product sales or distribution activities detrimental to consumers. This action seeks to safeguard consumer rights and safety against potential hazards or further losses resulting from products or business practices not in compliance with applicable standards.

Thirdly, compensation for losses will be enforced. The administrative sanction imposed on business actors violating Article 60, paragraph (2) of the UUPK involves compensation for losses, capped at Rp. 200,000,000 (two hundred million rupiah). The Consumer Dispute Resolution Agency (BPSK) holds the authority to determine or impose administrative sanctions. Therefore, if a business violates consumer rights pursuant to Article 60, paragraph (2), BPSK may impose sanctions in the form of predetermined compensation for losses. This sanction aims to deter business actors from committing violations and deliver justice to consumers adversely affected.

Fourth, product withdrawal is another measure undertaken by BPOM. Should BPOM ascertain that a cosmetic product poses potential health risks to users or fails to meet the prescribed licensing requirements, they possess the authority to promptly issue a withdrawal order. This measure aims to ensure that only safe and legally compliant products are available to the public. This withdrawal encompasses the entire distribution chain, from manufacturer to retailer, thereby ensuring that the product is no longer accessible to consumers.

Following this, revocation of business permits represents the ultimate recourse. In instances where violations are severe or recurrent, BPOM is empowered to revoke the distribution permit for problematic cosmetic products. Furthermore, BPOM may also proceed to revoke the business license of the implicated company. This action is undertaken to ensure that cosmetic products circulating in the market adhere to established safety and quality standards, thereby affording maximum protection to consumers against potential risks stemming from non-compliant products.

c) Liability from Civil Aspects

The Civil Code delineates regulations governing consumers' rights to pursue legal action against cosmetic manufacturers whose products contain hazardous ingredients capable of inducing dependency or adverse effects on users. Articles 1365 and 1371 of the Civil Code elaborate on this matter extensively, granting consumers the authority to initiate

civil lawsuits in cases where loss arises from the use of unsafe cosmetic products. Business actors who knowingly sell cosmetics without a distribution permit may incur losses for consumers, rendering them liable for unlawful acts.¹⁵ Consequently, consumers possess the legal entitlement to advocate for the safety and quality of the products they utilize, as well as to pursue legal recourse against business actors responsible for products failing to meet established safety standards.

3.3 BPOM's Accountability Regarding Business Actors Selling Illegal Cosmetics

Cosmetics are mandated not to contain harmful ingredients. To ensure consumer safety, cosmetics available on the market must adhere to the standards delineated in BPOM Regulation Number 44 of 2013, governing aesthetic requirements on labels. This underscores the commitment to furnish consumers with clear and transparent information concerning the cosmetic products they utilize. This regulation underscores a collective endeavor to uphold the safety of cosmetic products and shield consumers from potential hazards stemming from the use of perilous ingredients. Furthermore, it underscores the significance of transparency within the cosmetics industry, which forms an integral component of consumer protection efforts.¹⁶

In this scenario, the principal responsibility does not rest with BPOM. Should cosmetics be found to contain potentially hazardous substances, BPOM's mandate primarily involves supervising distribution by involved parties in the process. The primary responsibility lies with the end user. Should cosmetics be discovered to contain hazardous substances, BPOM holds the authority to seize the product, and upon securing permission from investigators, the product may be disposed of by incinerating it in a landfill. BPOM's role primarily centers on monitoring products and food to ensure their safety and quality.¹⁷

In executing its supervisory duties, BPOM is endowed with several functions delineated in Article 3 of Presidential Regulation No. 80 of 2017 concerning The Drug and Food Control Agency (hereinafter referred to as "PP No. 80 of 2017"). In fulfilling these functions, BPOM is vested with authority as stipulated in Article 4 of the PP. One of BPOM's principal functions is to establish norms and quality standards for products in circulation. Additionally, BPOM is tasked with conducting supervision prior to a product's market circulation, as well as during its circulation. This is aimed at safeguarding consumers against adverse effects, such as whitening products sold with counterfeit distribution

¹⁵ Juan Matheus and Ariawan Gunadi, "Pembentukan Lembaga Pengawas Perlindungan Data Pribadi Di Era Ekonomi Digital: Kajian Perbandingan Dengan KPPU," *Justisi* 10, no. 1 (2024): 20–35, <https://doi.org/10.33506/jurnaljustisi.v10i1.2757>.

¹⁶ I Made Satya Wiguna and Pande Yogantara, "Pemalsuan Terhadap Nomor Izin Edar Produk Kosmetik Ditinjau Dari Perspektif Hukum Pidana Di Indonesia," *Kertha Negara: Journal Ilmu Hukum* 10, no. 6 (2022): 525–34, <https://ojs.unud.ac.id/index.php/kerthanegara/article/view/94114>.

¹⁷ Luh Cahya Bungan Natah and Marwanto Marwanto, "Perlindungan Hukum Terhadap Konsumen Yang Mengonsumsi Produk Kosmetik Impor Ilegal Yang Mengandung Bahan Berbahaya," *Kertha Semaya: Journal Ilmu Hukum* 8, no. 2 (2020): 207–21, <https://ojs.unud.ac.id/index.php/kerthasemaya/article/view/57267>.

permits. BPOM underscores that it employs two primary approaches to safeguard consumers, namely preventive measures and repressive measures. Preventive measures encompass initiatives to forestall the entry of products failing to meet safety and quality standards into the market, while repressive measures involve responding to products already in circulation suspected of jeopardizing consumers, including issuing distribution permits for illicit products.

Preventive actions are measures taken to proactively mitigate the likelihood of illicit conduct by business entities in falsifying distribution permit numbers issued by BPOM. This endeavor can be realized through the establishment of a Drug and Food Monitoring System (SISPOM), as well as the establishment of BPOM in various provinces across Indonesia. Conversely, repressive measures constitute a response to criminal or deviant acts that have transpired, with the objective of furnishing legal safeguarding for consumers. The execution of this initiative entails the deployment of officers and enforcers from the BPOM, encompassing inspectors, investigators, as well as researchers and informants associated with drugs and food. BPOM is empowered to take decisive actions in addressing violations related to drugs and food, including the rescission of distribution permits, the recall of products in circulation, and potentially initiating legal proceedings.¹⁸

The oversight of the circulation of cosmetic products containing hazardous ingredients within the community primarily aims at ensuring product quality and safety. BPOM assumes responsibility for this oversight, which is bifurcated into two modalities. Firstly, the POM employs a “pre-market” paradigm, where it monitors all facets of cosmetic production, spanning from raw materials to the manufacturing process of finished products. The “pre-market” concept denotes the process of surveillance, evaluation, and testing of the quality and safety of a cosmetic product before it is sanctioned for release into the market. Within this framework, regulatory bodies such as the POM conduct a series of assessments on cosmetic products, encompassing ingredient testing and verifying compliance with established safety standards.¹⁹ The objective of this pre-market assessment is to ascertain that products slated for public consumption have undergone rigorous evaluation procedures and merit trust for their safety. Consequently, consumers can harbor a sense of assurance and confidence when utilizing cosmetic products available on the market.

Secondly, BPOM also conducts post-marketing surveillance, wherein they monitor products already in circulation on the market to ensure compliance with established safety and quality standards. “Post-marketing” surveillance denotes a regulatory process executed

¹⁸ Theresia Louize Pesulima, Jenny Kristiana Matuankotta, and Sarah Selfina Kuahaty, “Perlindungan Konsumen Terhadap Peredaran Produk Kesehatan Ilegal Di Era Pandemi Covid-19 Di Kota Ambon,” *Sasi* 27, no. 2 (June 2021): 160–71, <https://doi.org/10.47268/sasi.v27i2.453>.

¹⁹ Fatma Riska Fitrianiingsih Dai, Ramdhan Kasim, and Nurmin K Martam, “Perlindungan Hukum Bagi Konsumen Terhadap Peredaran Kosmetik Ilegal,” in *Semantech: Seminar Nasional Teknologi, Sains Dan Humaniora*, vol. 1, 2019, 316–31, <https://jurnal.poligon.ac.id/index.php/semantech/article/view/498>.

subsequent to the distribution of a cosmetic product to the public.²⁰ This oversight encompasses diverse activities, including inspections of production and distribution facilities, monitoring adverse effects resulting from cosmetic usage, sampling and laboratory testing of products already in circulation, as well as evaluating and monitoring cosmetic advertising and promotional campaigns.²¹ Additionally, BPOM disseminates information to the public through educational initiatives and public advisories. In executing this surveillance, BPOM possesses legal authority (*ius poenandi*) to intervene if cosmetics are found to contain hazardous ingredients.²² Hazardous products are subject to confiscation, and upon obtaining approval from the judiciary, investigators proceed to dispose of the products by incineration at a designated final disposal site. The supervisory measures undertaken by the POM Agency aim to uphold the safety of cosmetic products and safeguard consumers from the hazards posed by products that fail to meet safety standards.

Nevertheless, to ensure the continual enhancement of the safety and quality of cosmetic products in circulation, the oversight and authority delegated to BPOM are deemed insufficient. BPOM frequently encounters challenges in guaranteeing that all cosmetics available in Indonesia conform to established standards. Evident weaknesses in this monitoring framework are highlighted in the instance of trading cosmetics without a distribution permit, involving Samantha Laura D. Fanggidae as the defendant, as documented in Ende District Court Decision Number 22/Pid.Sus/2021/PN.End. During the investigation, it was ascertained that 68 beauty products lacked distribution permits. This scenario underscores the existence of cosmetic products that have managed to elude BPOM surveillance, suggesting that BPOM has yet to fully accomplish its obligations in safeguarding consumers from unsafe and substandard products.

The root of this issue lies in the fact that BPOM's actions were prompted by the defendant's failure to comply with the issued guidance summons. BPOM's approach, which primarily entailed conducting shop inspections post non-compliance, was deemed sluggish and ineffective. Consequently, this delay led to numerous consumers falling victim to the sale of cosmetic products lacking distribution permits. Irrespective of whether business actors attend coaching sessions regularly or not, BPOM should exhibit a more proactive and expeditious response in identifying potential violations. Procrastination in addressing these suspicions only prolongs the process and heightens risks for consumers. Thus, BPOM is perceived as negligent in fulfilling its functions adequately. To mitigate

²⁰ Imam Cahyono, Marsitiningih Marsitiningih, and Selamat Widodo, "Peran Badan Pengawas Obat Dan Makanan Terhadap Peredaran Obat Tradisional Yang Mengandung Bahan Kimia Obat Berbahaya Dalam Perlindungan Konsumen," *Kosmik Hukum* 19, no. 2 (August 2020): 110–17, <https://doi.org/10.30595/kosmikhukum.v19i2.8216>.

²¹ Dai, Kasim, and Martam, "Perlindungan Hukum Bagi Konsumen Terhadap Peredaran Kosmetik Ilegal."

²² Ela Oktavia Putri and Yunita Reykasari, "Perlindungan Konsumen Terhadap Peredaran Produk Kosmetik Mengandung Bahan Berbahaya Yang Merugikan Konsumen (Studi Analisis Produk Kosmetik Temulawak New Day & Night Cream Beauty Whitening)," *Indonesian Journal of Law and Justice* 1, no. 2 (December 2023): 1–19, <https://doi.org/10.47134/ijlj.v1i2.2012>.

this, BPOM should conduct routine and proactive inspections to deter the circulation of illicit products and ensure the safety of products in the market. By implementing stricter and systematic supervisory measures, BPOM can effectively safeguard the public from the hazards posed by non-compliant cosmetic products.

Moreover, guidance from BPOM plays a pivotal role in enhancing public awareness concerning cosmetics or other beauty products sold at discounted prices. This educational initiative aims to cultivate a more discerning and skeptical attitude among the public towards products sold at unusually low prices, as such items often fail to meet established safety and quality standards. Through this guidance, BPOM can furnish clear information regarding the hazards associated with using beauty products lacking distribution permits and educate the public on the importance of verifying distribution permits prior to purchase. Consequently, individuals will exercise greater caution and can steer clear of products posing potential health risks.

4. CONCLUSION

Based on the research findings, it comes to the following conclusions:

- 4.1. Consumers and business actors have different consequences as follows:
 - a. Consumers are indeed afforded legal protection by various regulations, including Articles 138 and 142 of the Health Law, Article 2 paragraph (1) of BPOM Regulation Number 12 of 2020, BPOM Regulation Number 44 of 2013, and other pertinent regulations that unequivocally prohibit the distribution of cosmetics lacking a valid permit. Article 142 of the Health Law delineates the obligatory standards and prerequisites for securing a distribution permit, while Article 8 paragraph (1) letter a of the UUPK prohibits business actors from trading goods that fail to meet prescribed standards and regulatory provisions. Furthermore, Article 142 paragraphs (4) and (5) of the Health Law, alongside Article 3 paragraphs (1) and (2) of Minister of Health Regulation Number 1176/Menkes/Per/VIII/2010, mandate that all cosmetic products must obtain a distribution permit from the Ministry of Health before being marketed, among other regulations.
 - b. Business actors found guilty of vending cosmetics without a distribution permit may face imprisonment under various legal provisions such as Article 435 of the Health Law and Article 62 paragraph (1) of the UUPK. Moreover, unscrupulous business actors engaged in selling cosmetics without a distribution permit, who market such products without official authorization, are liable to encounter diverse administrative sanctions as supplementary penalties, as stipulated in Article 63 of the UUPK.

- 4.2. To forestall the recirculation of cosmetics lacking distribution permits, BPOM, as the overseeing body for medicines and food in Indonesia, assumes a pivotal role in regulating and monitoring the distribution of cosmetics within society. Nonetheless, BPOM's supervisory performance often falls short of optimal standards, as evidenced in the Ende District Court Decision Number 22/Pid.Sus/2021/PN.End. Ideally, BPOM should conduct regular and proactive inspections to forestall the proliferation of illicit products and ensure the safety of products available on the market, thereby enabling consumers to utilize said products with confidence and peace of mind.

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