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Administrative Criminal Reform In Providing Accountability For Skincare Actors That Haven't Registered With Bpom

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Abstract: This research aims to analyze the problem of skincare products circulating without the approval of the Indonesian Food and Drug Administration (BPOM), which has a serious impact on public health and undermines consumer confidence. The main focus of this research is on the legal aspects and fraud risks faced by businesses running illegal skincare businesses. The methodology used in this research is the normative juridical method, which examines the application of two legal principles, namely strict liability and vicarious liability, in the legal context of selling illegal cosmetic products. This research illustrates the difference between the two principles, where strict liability does not require proof of malicious intent, while vicarious liability involves the responsibility of another party through a legal relationship. This research lies in emphasizing the role of BPOM in law enforcement and legal compliance as well as the importance of public awareness in preventing discrimination against illegal cosmetic products. The research also highlights the administrative and criminal sanctions that business owners can face under Article 36 of the 2009 Health Law. The research shows that business owners who operate products without BPOM approval may be subject to severe sanctions, both administratively and criminally. In addition, if consumers suffer losses due to unsafe products, manufacturers or distributors may be required to provide compensation. This research emphasizes the importance of consumer protection as well as the responsibility of manufacturers and distributors for the products they sell. Law enforcement in Indonesia, especially through BPOM regulations, should be strengthened to ensure the safety and quality of cosmetic products on the market. This research makes a significant contribution in understanding the legal implications of selling illegal cosmetic products and the importance of regulation in protecting public health.

Keywords: Accountability; Skincare; Dangerous; BPOM

Abstrak: Penelitian ini bertujuan untuk menganalisis masalah produk perawatan kulit yang beredar tanpa persetujuan Badan Pengawas Obat dan Makanan (BPOM) Indonesia, yang berdampak serius terhadap kesehatan masyarakat dan merusak kepercayaan konsumen. Fokus utama dari penelitian ini adalah pada aspek hukum dan risiko penipuan yang dihadapi oleh pelaku usaha yang menjalankan bisnis perawatan kulit ilegal. Metodologi yang digunakan dalam penelitian ini adalah **metode yuridis normatif**, yang mengkaji penerapan dua prinsip hukum, yaitu *strict liability* dan *vicarious liability*, dalam konteks hukum penjualan produk kosmetik ilegal. Penelitian ini menggambarkan perbedaan antara kedua prinsip tersebut, di mana *strict liability* tidak memerlukan pembuktian niat jahat, sedangkan *vicarious liability* melibatkan tanggung jawab pihak lain melalui hubungan hukum. Penelitian ini terletak pada penekanan terhadap peran BPOM dalam penegakan hukum dan kepatuhan hukum serta pentingnya kesadaran masyarakat dalam mencegah diskriminasi terhadap

produk kosmetik ilegal. **Penelitian ini juga menyoroti** sanksi administratif dan pidana yang dapat dihadapi oleh pemilik usaha berdasarkan Pasal 36 Undang-Undang Kesehatan 2009. **Penelitian menunjukkan bahwa** pemilik bisnis yang mengoperasikan produk tanpa persetujuan BPOM dapat dikenakan sanksi yang berat, baik secara administratif maupun pidana. Selain itu, jika konsumen mengalami kerugian akibat produk yang tidak aman, produsen atau distributor dapat diminta untuk memberikan kompensasi. **Penelitian ini menekankan** pentingnya perlindungan konsumen serta tanggung jawab produsen dan distributor terhadap produk yang mereka jual. Penegakan hukum di Indonesia, terutama melalui regulasi BPOM, harus diperkuat untuk memastikan keamanan dan kualitas produk kosmetik yang beredar di pasaran. Penelitian ini memberikan kontribusi signifikan dalam memahami implikasi hukum dari penjualan produk kosmetik ilegal dan pentingnya regulasi dalam melindungi kesehatan masyarakat.

Kata Kunci: Pertanggungjawaban; Skincare; Berbahaya; BPOM

INTRODUCTION

Nowadays appearance is one of the important factors in various ways of life and work, so that all groups, both men and women, are very interested in their appearance and make everything more attractive. One effort to make the appearance more attractive is to use cosmetic products, one of which is skin care. Skincare is a cosmetic that is identical to skin care, especially skin and body.¹ Skin care products on the market has become a basic need for most society, particularly women. It's not surprising that's demand for skin care products is increasing and diverse every year. The beauty industry in Indonesia has become one of the main pillars of the national economy and is included in the three main priority industries as stipulated in the National Industrial Development Master Plan (RIPIN) 2015-2035. According to data compiled by Statista, the sector is predicted to experience an average annual growth of 5.91%, covering skincare and other personal care products. This growth potential shows that the beauty industry is not only significant from an economic perspective but also has bright prospects for the future, contributing greatly to job creation and driving innovation within the sector.² Very profitable sales and a wide target market have led to the proliferation of skin care products with different functions and benefits. However, it should be noted that the manufacture and sale of skin care products cannot be done carelessly. Unfortunately, marketers are taking advantage of this opportunity by targeting consumers looking for low prices products with instant gratification. If you pay attention, the growth in sales of skin care products is increasingly concerning. The proliferation of various unregistered or uncertified care ingredients sold to the public by commercial operators can be harmful to those who use them. The main example is skin irritation due to illegal use of skin care products.³

¹ Sri Windarti et al., "Kebiasaan Pemakaian Skincare Santri Putri Pesantren Kyai Syarifuddin Lumajang," *Jurnal Tata Rias* 11, no. 1 (2022): 123–30.

² Novi Christi and Gatot P Soemartono, "The Role of the Drug and Food Control Agency (BPOM) in Addressing the Distribution of Illegal Cosmetics," *Jurnal Ilmu Hukum Kyadiren* 6, no. 1 (2024): 9–24, <https://doi.org/10.46924/jihk.v5i2.203>.

³ Susanti Sembiring and Bisma Putra Pratama, "Perlindungan Terhadap Konsumen Kosmetik Ilegal Yang Mengandung Zat Berbahaya," *Jurnal Ilmiah Ekotrans & Erudisi* 2, no. 1 (2022): 83–87.

Generally, dangerous cosmetic preparations do not mention their composition. Entrepreneurs only emphasize that the products they sell provide results in a short time. On average, women are easily tempted by commercial offers with cheap prices and fast results without paying attention to the contents of the product. Not paying attention to the bad effects felt after using the product. Indonesia is a country of law, where all activities of people's lives must be regulated by applicable laws and regulations, including those in the cosmetics industry.⁴ In line with the increasing needs of the beauty industry in Indonesia and the innovation of cosmetic products that continue to develop, claims as one of the attractions of cosmetics continue to develop and innovate. "Regulation of the Minister of Health No. 1176 / MENKES / PER / VIII / 2010 Concerning cosmetic notifications that must be met by every business actor in conducting promotions".⁵ The circulation of skincare cosmetics in the marking of their skincare. The implementation of cosmetic notifications is Indonesia's commitment in its agreement on ASEAN Harmonization. In the ASEAN sector, it has an impact on changes in the cosmetic business climate in Indonesia.

Regulation of the Food and Drug Administration (BPOM) No. 3 of 2022 Article 2; "Cosmetic claims, hereinafter referred to as claims, are statements in the form of information regarding the benefits, safety, and/or other statements related to cosmetics". Stating that business actors are required to ensure that cosmetics distributed in the territory of Indonesia meet the technical requirements for claims. Claims as referred to in "Article 3 of BPOM Regulation No. 3 of 2022; The technical requirements for claims as referred to in Article 2 include claims on markings and claims on advertisements, claims on markings and claims on advertisements as referred to in paragraph (1) must meet the following criteria: a. legal compliance; b. truth; c. honesty; d. justice; e. can be proven; f. clear and easy to understand; and g. may not claim to be a medicine or intended to prevent a disease, in addition to having to fulfill the criteria as referred to in paragraph (2), Business actors in determining Claims on Markings and Claims on Advertisements are also required to refer to the Claim guidelines as set out in the Attachment which is an integral part of these Agency Regulations."⁶

The distribution of illegal cosmetics or cosmetics without permission from Food and Drug Administration (BPOM) is still a major problem in Indonesia. Obtaining a license from BPOM does take a considerable amount of time, especially since it involves a careful evaluation process of the safety, quality, and effectiveness of the product being produced. This process includes not only the collection of necessary documents but also laboratory testing to ensure that the product meets the set standards.⁷ One example of a case that often occurs is the sale of skin care products that are not registered with BPOM and the sale of illegal skin care

⁴ Indra Silfiyah, "Peran Pemerintah Dalam Pemberantasan Perdagangan Kosmetik Berbahaya Melalui E-Commerce" (Universitas 17 Agustus 1945, 2022).

⁵ Tambahan Lembaran, "Menteri Kesehatan Republik Indonesia. Peraturan Menteri Kesehatan Republik Indonesia Nomor 1176/MenKes/Per/VIII/2010.," *Peraturan Menteri Kesehatan Republik Indonesia*, no. 397 (2010): 1–10.

⁶ Kepala Badan, Pengawas Obat, and Makanan, "Peraturan Badan Pengawas Obat Dan Makanan Nomor 3 Tahun 2022 Tentang Persyaratan Teknis Klaim Kosmetika Dengan Rahmat Tuhan Yang Maha Esa Kepala Badan Pengawas Obat Dan Makanan," no. 8 (2022).

⁷ Concerning Health et al., "A r t i c l e i n f o a b s t r a c T" 2, no. 2 (2023): 383–400.

products can cause various negative impacts for consumers, such as skin irritation, allergies and even poisoning. In recent years, there has been a rise in skincare sales cases products that doesn't have a BPOM distribution permit. These cases show that the legal protection provided to consumers is not effective enough to prevent the circulation of dangerous skin care products. Therefore, there needs to be more effective legal protection for traders who sell skin care products that have no distribution license from BPOM.⁸

"Article 1 number 4 of Law No. 36 of 2009 concerning Health", skincare is included in the type of pharmaceutical preparations. Cosmetics based on "Article 1 number 1 Explanation of Government Regulation of the Republic of Indonesia Number 72 of 1998 concerning the Security of Pharmaceutical Preparations and Medical Devices".⁹ In connection with the widespread circulation of cosmetic products, the government and the Food and Drug Administration of the Republic of Indonesia (BPOM RI) have set requirements for cosmetic businesses, namely cosmetic product distribution permits, as a public need. products launched since 2011. As a form of good faith of entrepreneurs, entrepreneurs must comply with prevailing laws and regulations in Indonesia in their economic activities. One thing that needs to be fulfilled by businesses is consumers. "According to the Consumer Protection Law (UUPK)", consumers have right to accept guarantees for services and goods offered to them. Therefore, business actors must fulfill their obligations by providing right, clear and truthful information about condition and warranty from product or service and explanation of its usage, repair and maintenance.¹⁰

Skin care products containing hazardous chemicals can cause dangerous side effects for consumers, because one test claims a well-known brand in the industrial world. Therefore, effective legal protection is required to prevent the circulation of skin care products that are not fulfilled health standards. To protecting the public from dangerous skin care products, retailers who sell skin care products without a distribution permit from the Food and Drug Administration (BPOM) should be prosecuted. Disobedience of traders and users in doing business can cause conflict between users and traders. This conflict can be stated as the responsibility of one party who does not obtain their rights due to the other party does not fulfill their obligations, for example, user losses after using a certain object. The main example is skin irritation caused by the use of illegal skin care products. Disputes between business actors and users that initially arise due to consumer transactions with business actors.¹¹

BPOM is again following up on reports from the public regarding allegations of illegal cosmetic production practices without a Distribution Permit (TIE) and containing ingredients

⁸ Satria Agung Mujib, Permana Putra, and Wahyu Prawesthi, "Criminal Acts of Circulating Cosmetics Without a Distribution Permit and Not Meeting the Standards of Safety Requirements," *International Journal of Multicultural and Multireligious Understanding*, 2023, 381–86, <http://ijmmu.comhttp://dx.doi.org/10.18415/ijmmu.v10i2.4445>.

⁹ Peraturan Pemerintah Republik Indonesia, "Peraturan Pemerintah Republik Indonesia Nomor 72 Tahun 1998 Tentang Pengamanan Sediaan Farmasi Dan Alat Kesehatan," *Republik Indonesia*, 1998, 1–61.

¹⁰ Theresia Gabriella and Handar Bakhtiar, "Perlindungan Hukum Kepada Konsumen Terkait Peredaran Kosmetik Ilegal," *Jurnal Panorama Hukum* 8, no. 1 (2023): 17–23.

¹¹ Dewi Wahyuni Mustafa, Sulaeman Sagoni, and Besse Muqita Dewi, "LEGAL : Journal of Law" 2, no. 2 (2023): 46–55.

prohibited in cosmetics. The illegal cosmetic products were found from an illegal cosmetic factory in Elang Laut Warehouse with the address Sentra Industri 1 and 2 Block I1/28, RT 02/ RW 03, North Jakarta. In detail, the evidence that was secured included raw materials in the form of chemical drugs such as Hydroquinone, Retinoic Acid, Dexamethasone, Mometasone Furoate, Salicylic Acid, Fluocinolone, Metronidazole, Ketoconazole, Betamethasone, and Tranexamic Acid. Based on an investigation into the production facilities of the illegal cosmetics, it is suspected that a crime has occurred. First, namely "producing or distributing pharmaceutical medicine and/or medical equipment who does not have business license as intended in Article 197 Jo. Article 106 paragraph (1) of the Republic of Indonesia Law Number 36 of 2009 concerning Health as amended by the Government Regulation in Lieu of Law Number 2 of 2022 concerning Job Creation with a maximum prison sentence of 15 (fifteen) years and a maximum fine of IDR 1 billion". Second, namely "producing or distributing pharmaceutical preparations that does not meet the standards and/or security requirements, usefulness or benefits, and quality as referred to in Article 196 Jo. Article 98 paragraph (2) and paragraph (3) of the Republic of Indonesia Law Number 36 of 2009 concerning Health".¹² "This crime is punishable by a maximum of 10 (ten) years imprisonment and a maximum fine of IDR 1 billion. Third, namely trading goods that do not fulfill or disobey to the required standard and the provisions of laws and regulations as referred to in Article 62 paragraph (1) Jo. Article 8 paragraph (1) letter a of Law of the Republic of Indonesia Number 8 of 1999 concerning Consumer Protection. This crime is punishable by a maximum of 5 (five) years imprisonment or a maximum fine of IDR 2 billion."¹³

According to many cases, the writer is interested in raising the title entitled "Criminal Administrative Reform in Providing Accountability for Skincare Sellers Who Have Not Been BPOM", from the title, several problems certainly arise where many sellers/owners do not make claims/tests of products to be sold, so that in this case, when using skincare, the consumer's face becomes flecked, acne, pimples, or other facial irritations. If you see the dangers that arise due to compositions that have not been tested by BPOM, the author urges readers to increase literacy and increase knowledge and insight.

METHOD

¹² Indonesia, "Undang-Undang Republik Indonesia Nomor 36 Tahun 2009 Tentang Kesehatan" 19, no. 19 (2009): 19.

¹³ BADANPOM, "BPOM Tindak Pabrik Kosmetika Ilegal Yang Diduga Mengandung Bahan Dilarang," BADANPOM, 2023, <https://www.pom.go.id/siaran-pers/bpom-tindak-pabrik-kosmetika-ilegal-yang-diduga-mengandung-bahan-dilarang>.

Based on the problems described in this study, this research uses normative juridical legal research methods (legal research). This research prioritizes the understanding that law as a rule or norm that exists in the life of society as a basis for the behavior of each individual, this research becomes a process to answer the legal issues at hand by analyzing legal principles, legal rules, and legal doctrine.

The approach method used is the statute approach. The statutory approach is carried out by analyzing the provisions of the law relating to the concept of skincare products and the responsibilities of business actors related to skincare products.

Legal material collection techniques using literature studies (library research), carried out by combining all existing legal materials (primary, secondary, and tertiary legal materials), which in processing the legal materials will be selected legal materials that have a relationship with the problems studied, which are then analyzed logically and systematically. Legal materials will be analyzed by applying the prescriptive analysis method, by presenting arguments from the results of the research on how what is right, wrong or what is not.

DISCUSSION

Criminal Liability for Skincare Sellers Who Do Not Have BPOM Registration in Indonesia

1. Criminal Liability of Skincare Company Corporations

In the dualistic teaching, there is a separation between criminal acts and criminal responsibility. The teaching on responsibility is based on the teaching on actions, where there is a close relationship between the two aspects, especially related to blameworthiness. This blameworthiness is subjective, namely an assessment of a person's subjective state when committing a crime. Within the framework of criminal law, the brainchild of criminal responsibility is strongly associated with the idea of no crime without fault, as regulated in Article 36 of the Criminal Code. This principle emphasizes that an criminal act can only be subject to responsibility if there is an element of fault on the part of the perpetrator, which can be either intentional or negligent. Often, the approach used is the *psychologisch schuldbecrip*, which emphasizes the offender's mental condition at the time of committing the crime. Here, proof of intent or negligence is required as a condition for criminal responsibility. The normative approach in determining guilt is based on an assessment of the criminal act itself, regardless of the offender's psychological condition. Fault is not only limited to intent and negligence, but can include other conditions that reflect the blameworthiness of the act from a legal perspective. In the corporate context, this concept of fault is even expanded so that a company can be held criminally liable even though there was no intent or negligence on the part of its management, as stated in Perma No. 13 of 2016.¹⁴

¹⁴ Mahkamah Agung Republik Indonesia, "Peraturan Mahkamah Agung Nomor 13 Tahun 2016 Tentang Tata Cara Penanganan Perkara Tindak Pidana Oleh Korporasi," *Ketua Mahkamah Agung RI*, 2016, https://www.pta-bengkulu.go.id/images/pdf_trans_perkara/sk_kma_26_2012.pdf.

Article 37 of the Criminal Code regulates strict liability, where a person or corporation can be subject to criminal penalties even though there is no evidence of fault. This applies especially in the context of *strict liability* and *vicarious liability*. In strict liability, the fulfillment of the elements of a crime is sufficient to prosecute the perpetrator, regardless of whether or not there is fault. Meanwhile, *vicarious liability* requires superiors or employers to be held accountable for the crimes that their subordinates in the context of their work or on their orders.¹⁵

Reasons for forgiveness in criminal law are conditions in which a criminal act is not accountable to the perpetrator, even though the act fulfills the elements of a crime. Reasons for forgiveness are rooted in circumstances that force the perpetrator to commit a crime against his will. In this context, the judge is given the discretion to forgive the perpetrator based on the circumstances surrounding the crime committed. Article 42 of the Criminal Code regulates coercive power as a reason for forgiveness such as absolute coercive power, where the perpetrator does not have free will due to the presence of a force that cannot be restrained. Then relative coercive power, which occurs due to threats or pressure that cannot be avoided. In this case, actions taken to save a greater interest are considered forgivable.

Article 43 of the Criminal Code regulates excessive self-defense. This situation occurs when the act of defense is no longer proportional to the attack received, whether physical violence or other threats. Even though the act is excessive, the perpetrator can be forgiven because of the great mental pressure as a result of the attack experienced. Article 44 of the Criminal Code emphasizes that the implementation of an official order given without authority is not subject to criminal penalties if it is done out in good faith. This condition applies if the perpetrator reasonably thought that's order was legitimate, or the action was still within the scope of official duties. This provides protection for employees or executors of orders who act in good faith even though their orders are illegitimate.

According to Article 45 of the Criminal Code, corporations may be vulnerable to criminal acts, whether in the form of a legal entity (such as PT, foundations, cooperatives) and non-legal entities (firms, CVs). This regulation is not only limited to economic crimes but also opens up opportunities for corporations to be involved in political crimes or terrorism. In terms of corporate crimes, the Criminal Code states that managers who have functional positions in the corporate structure can be subject to criminal penalties. Managers, order givers, controllers, and beneficial owners in a corporation are responsible for criminal acts committed by the corporation. Article 49 of the Criminal Code limits criminal liability to people who act on behalf of the corporation or in the interests of the corporation. This exception is given to individuals who take action based on employment relationships or authority granted by the corporation.

Corporate criminal liability in national law is regulated by the provision that responsibility can be given to the management, the corporation, or both simultaneously.

¹⁵ Kharisma Wulan Fadhila, "Reformasi Hukum Pidana Dan Pertanggungjawaban Korporasi Dalam UU KUHP 2023," *Action Research Literate* 8, no. 3 (2024): 649–57.

Based on Article 48 of the Criminal Code, the requirements for demanding corporate criminal liability include the existence of a crime that occurs within the scope of business, the corporation obtains illegal profits, and the violation is accepted as corporate policy. In addition, a corporation can be held liable if it fails to take preventive measures or intentionally allows a crime to occur. In the context of normative errors, corporate liability is measured through violations of the standard of care, standard operating procedure, and standard of liability. Justification and excuses can be submitted by the management or beneficial owner, as long as they have a direct connection to the crime charged. The implementation of this provision emphasizes the importance of proper and selective application of the law to ensure that corporations are not immune from criminal liability.

2. Administrative Sanctions Regulations

Tabel 1. Bpom Regulation

BPOM REGULATION NUMBER 3 OF 2022

“Number (1) and (2) of Article 5, wich say as follows:

- (1) Notification Number Owners who breach the conditions mentioned in Article 3 paragraph (3), and/or Article 4 will face administrative fines, as will business actors who are not notification number owners.
- (2) The following are examples of administrative sanctions mentioned in paragraph (1):
 - a. written warning;
 - b. withdrawal;
 - c. destruction;
 - d. temporary suspension of activities;
 - e. cancellation or revocation of notification number;
 - f. public announcement to the public; and/or
 - g. recommendations to related agencies as a follow-up to the results of supervision.”

Tabel 2.Law Of The Republic Of Indonesia Number 36 Of 2009

LAW OF THE REPUBLIC OF INDONESIA NUMBER 36 OF 2009

“Article 98 number (3) which reads as follows:

- (3) Government regulations governing the distribution and acquisition of medical equipment and pharmaceutical preparations shall adhere to the pharmaceutical service quality requirements.”

“Article 106 which reads as follows:

- (1) Distribution permits are required before pharmaceutical preparations and medical equipment may be supplied.

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- (2) Information and labeling related to medical devices and pharmaceutical preparations must be truthful, impartial, and comprehensive.
- (3) In the event that pharmaceutical preparations and medical devices that have received distribution permits are later found to not meet quality, safety, or efficacy requirements, the government has the authority to revoke those permits, order their withdrawal from circulation, and confiscate and destroy the products in compliance with applicable laws and regulations.”
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“Article 196 which reads as follows:

A maximum sentence of 10 (ten) years in prison and a maximum fine of IDR 1,000,000,000.00 (one billion rupiah) awaits anyone who knowingly manufactures or distributes pharmaceutical preparations and/or medical devices that do not adhere to the standards and/or requirements for safety, efficacy or benefits, and quality as mentioned in Article 98 paragraph (2) and paragraph (3).”

“Article 197 which reads as follows:

The maximum penalty for producing or distributing pharmaceutical preparations and/or medical devices without the distribution permit mentioned in Article 106 paragraph (1) is IDR 1,500,000,000.00 (one billion five hundred million rupiah) in addition to a maximum prison sentence of 15 (fifteen) years.”

Tabel 3. Law Of The Republic Of Indonesia Number 8 Of 1999

LAW OF THE REPUBLIC OF INDONESIA NUMBER 8 OF 1999

“Article 4 which reads as follows:

The following are the rights of consumers:

1. the right to pleasant, secure, and safe consumption of products and/or services;
 2. the right to select goods and/or services and to get such goods and/or services in line with the exchange value, conditions, and guarantees offered;
 3. the right to accurate, transparent, and truthful information on the state and guarantee of products and/or services;
 4. the right to have grievances and suggestions about the utilized goods and/or services taken into consideration;
 5. the right to consumer protection advocacy, protection, and appropriate efforts to resolve disputes;
 6. the right to consumer education and guidance;
 7. the right to be treated fairly and without discrimination;
 8. the right to replacement, damages, or compensation if the goods or services are not as described in the agreement;
 9. rights governed by other statutory provisions.”
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“Letter (f) of Article 7 states the following:

f. provide damages, reimbursement, and/or substitution for losses brought about by the usage, use, and utilization of traded products and/or services;"

"Article 8 paragraph (1) letter an states:

(1) Business actors are not allowed to produce, trade, or otherwise deal in products or services that:

a. do not adhere to the necessary standards and legal requirements;"

"According to Article 62 paragraph (1):

(1) business actors who violate the provisions mentioned in Article 8, Article 9, Article 10, Article 13 paragraph (2), Article 15, Article 17 paragraph (1) letters a, b, c, e, paragraph (2), and Article 18 may face a maximum sentence of five (five) years in prison or a maximum fine of IDR 2,000,000,000.00 (two billion rupiah)."

3. Criminal Sanctions Regulation

Tabel 4. Bpom Regulations And Law Of The Republic Of Indonesia

BPOM REGULATIONS	LAW OF THE REPUBLIC OF INDONESIA NUMBER 36 OF 2009 CONCERNING HEALTH
None / not specifically set	"Article 196 which reads as follows: A maximum sentence of 10 (ten) years in prison and a maximum fine of IDR 1,000,000,000.00 (one billion rupiah) awaits anyone who knowingly manufactures or distributes pharmaceutical preparations and/or medical devices that do not adhere to the standards and/or requirements for safety, efficacy or benefits, and quality as mentioned in Article 98 paragraph (2) and paragraph (3)." "Article 197 which reads as follows: The maximum penalty for producing or distributing pharmaceutical preparations and/or medical devices without the distribution permit mentioned in Article 106 paragraph (1) is IDR

1,500,000,000.00 (one billion five hundred million rupiah) in addition to a maximum prison sentence of 15 (fifteen) years.”

In the legal context, two important liability principles are *strict liability* and *vicarious liability*, each of which has different characteristics and applications. The principle of *strict liability* applies to cases where the perpetrator can be punished without the need to prove fault or malice. This liability is directly related to the act that caused the harm, thus requiring the perpetrator to be responsible for the consequences of that act, regardless of whether or not they had the intention to break the law. The application of this principle is often found in regulations relating to dangerous products, where consumer safety is a top priority.¹⁶

On the other hand, *vicarious liability* requires proof of the fault of the party who committed the detrimental act. In this case, the other party can be held responsible based on their legal relationship with the perpetrator who committed the act. Even though the third party did not directly commit the violation, they can be held responsible if the act occurred within the scope of their duties or employment relationship. This principle aims to protect the injured third party by providing assurance that they can obtain compensation even though the direct perpetrator does not have the resources to pay.¹⁷

By understanding these two principles in detail, we can evaluate how they apply in the broader legal context, and the implications they have for legal protection for individuals and society as a whole. By combining these two principles, we can improve the effectiveness of public health surveillance and protection. *Strict liability* provides a threat of severe and strict penalties, while *Vicarious liability* allows others to be held responsible based on their relationship. Thus, we can ensure that cosmetic sellers who do not meet safety standards will be punished strictly and effectively.

In this case, the health law in Indonesia applies criminal sanctions based on the principle of strict liability, which means that violators can be punished without having to prove malicious intent or negligence. This approach provides a strong deterrent effect on cosmetic sellers who do not meet safety standards, given the threat of significant penalties. In this context, the health law serves as a more assertive and comprehensive law enforcement instrument. In contrast, regulations by the Food and Drug Administration (BPOM) tend to provide administrative sanctions, which are lighter and focus on administrative compliance, such as revocation of permits or fines. Thus, the health law has a higher relevance in protecting public health compared to BPOM regulations, which may

¹⁶ Andri Gunawan Wibisana, “Undang-Undang Cipta Kerja Dan Strict Liability,” *Bina Hukum Lingkungan* 5, no. 3 (2021): 494–522.

¹⁷ Grace Yurico Bawole, “Analisis Hukum Terhadap Bentuk Pertanggungjawaban Pidana Berdasarkan Konsep Strict Liability Dan Vicarious Liability,” *Lex Et Societatis* 6, no. 8 (2019).

be less effective in providing adequate sanctions for violations in the cosmetics sector.¹⁸

Business actors also have an obligation to be responsible for products that harm consumers. An expanding range of skin care products has been made possible by the growth of the cosmetics sector. This increase in conditions often causes traders to sell their products without proper supervision, resulting in losses for consumers. Business actors who produce goods or services are responsible for the entire production cycle, including purchasing raw materials, production, and quality control. This responsibility includes strict supervision of every step of the production process. In other words, business actors who produce goods or services focus more on creating goods or services from start to finish.

The responsibility of entrepreneurs is an obligation that must be complied with and which binds the actions of entrepreneurs in managing their business, this concept is known as product liability which shows responsibility in relation to the products produced.¹⁹The principle of product liability is that the manufacturer or seller of a product has an obligation to ensure that using the product is safe and doesn't result in unwanted damage to consumers. If the product is problematic and causes damage, the company can take legal action and be held financially responsible for the consequences.²⁰

Businesses that pose a risk and sell cosmetics without a permission are required to follow the principle of absolute liability. In accordance with the principle of absolute liability, business actors must be responsible for consumers who feel disadvantaged by the products they sell. This principle of absolute liability ensures that entrepreneurs do not repeat fraud in the sale of cosmetic products that can cause losses to consumers. The responsibilities of business owners who manufacture and sell illicit cosmetics without a distribution license and whose goods don't adhere to safety regulations.²¹ And cosmetics are one of the pharmaceutical products, then the person is charged with Article 196, 197 in conjunction with Article 106, concerning quality as referred to in Article 98 paragraph (2) of Law Number 36 of 2009 concerning Health which reads: "every person who does not have the expertise and authority is prohibited from procuring, storing, managing, promoting, and distributing drugs and materials that have medicinal properties." And Article 98 paragraph (3) of Law Number 36 of 2009 concerning Health which reads: "provisions regarding the procurement, storage, processing, promotion, distribution, pharmaceutical preparations and medical devices must meet the pharmaceutical service quality standards stipulated by Government Regulation." In addition, if a defective product

¹⁸ Melina Gabrila Winata, "Perlindungan Hukum Bagi Korban Pengguna Produk Kosmetik Ilegal Berbahaya," *Sapientia Et Virtus* 7, no. 1 (2022): 34–43, <https://doi.org/10.37477/sev.v7i1.343>.

¹⁹ I Gst AA Sintiana Dewi, Ketut Sudiarmaka, And Dewa Gede Sudika Mangku, "Implementation of Product Liability Provisions for Consumers of Goods Delivery Services (Case Study at PT. Tiki Jalur Nugraha Ekakurir (JNE) Singaraja Branch)," *Jurnal Komunitas Yustisia* 3, No. 1 (2020): 25–36.

²⁰ Miftahul Haq and Dedy Felandry, "Prinsip Strict Liability Pelaku Usaha Dalam Rangka Mewujudkan Asas Keadilan Dan Kepastian Hukum Bagi Konsumen Berdasarkan Undang-Undang Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen," *Jotika Research in Business Law* 3, no. 2 (2024): 86–96.

²¹ Tri Setiady, "Perlindungan Hukum Terhadap Konsumen Dalam Pelanggaran Ketentuan Label Pangan Yang Dilakukan Pelaku Usaha Berdasarkan Undang-Undang No. 8 Tahun 1999 Tentang Perlindungan Konsumen," *Jurnal Yustitia* Vol.1, no. 8 (2019): 105–12.

occurs, the trader must be responsible for replacing or repairing the product. Entrepreneurs are fully responsible for the products they sell or distribute. Article 7 letter f of the UUPK reads "Providing compensation, damages and/or reimbursement for losses due to the use, use and utilization of goods and/or services traded."²² Here, the trader bears the liability for any losses caused by products produced or marketed by the trader, in which case consumers who use the trader's goods or services are harmed.

In addition to the type of liability, it is important to raise awareness and education to business owners so that they understand the importance of business operations management and compliance with existing regulations. It is hoped that by raising awareness and understanding, illegal skincare trade practices will be reduced and consumer health will improve. It is hoped that this clear and effective criminal guideline will help create a more honest, reliable and ethical skincare industry among those who do not yet have BPOM certification. Therefore, it is very important to always consider the legality of the skincare products that will be used.²³

Parameters of Criminalization in Administrative Criminal Reform

The regulation of criminal law outside the Criminal Code (*codification*) has given birth to special criminal law that can be regulated in, first, the special criminal law in the health sector. Second, the administrative law with criminal sanctions (*administrative penal law*). Administrative criminal law aims to utilize criminal law sanctions to support the effectiveness of administrative legal norms. This is because of its different and non-independent nature, so it is possible to be regulated outside the codification (*Criminal Code*) in a complementary manner.

Muladi's view always contains exceptions, namely for provisions on criminal acts that are administrative in nature and can be eliminated from punishment due to a "permit". The crime then grew and developed into an independent despicable act (*mala per se*) so that it is regulated in the Criminal Code. According to Andi Hamzah's view, Indonesia has actually deviated far from global rules. This is because our legislative authority is too diligent in making administrative laws and regulations with severe criminal sanctions. In fact, criminal sanctions in administrative laws should not be too severe, for example with a fine or imprisonment (*old Criminal Code*) which is no longer regulated in the new Criminal Code. Adi Hamzah's view seems quite rational because with the threat of severe imprisonment (over 5 years), there is a legal loophole. Unscrupulous officers have the potential to abuse their authority.

For example, an official may detain an individual as a coercive measure that does not always have to be carried out. As a result, there is a risk of transactional practices that hurt the public's sense of justice. Therefore, law enforcement of the criminal sanctioned

²² Presiden Republik Indonesia, "Undang-Undang Republik Indonesia Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen," *Peraturan Pemerintah Republik Indonesia* 2003, no. 1 (1999): 1–46.

²³ Larashati Putri and Moch Najib Imanullah, "Proceeding of Conference on Law and Social Studies Perlindungan Konsumen Terhadap Produk Kosmetik Tanpa Izin Edar Dari Badan Pengawas Obat Dan Makanan (BPOM)," n.d., <http://prosiding.unipma.ac.id/index.php/COLaS>.

administrative law needs to pay attention to several parameters. First, the regulation of criminal sanctions should be an alternative between imprisonment or fines. In its implementation, additional penalties can be imposed if it is considered not to have fulfilled the purpose of punishment. Second, the imposition of criminal sanctions for the criminal sanctioned administrative law should be the last option or *ultimum remedium*. This is because criminal sanctions must be the last resort if other legal sanctions turn out to be unable to enforce a criminal law norm. Finally, a gradation of criminal sanction provisions must be made in stages. In law enforcement for acts that are minor and do not endanger the public, administrative sanctions need to be prioritized as a substitute for criminal sanctions, considering the logical consequences of *ultimum remedium*.

Legal action by the public to prevent the spread of illegal cosmetics is an important part of protecting consumer rights, maintaining product safety and ensuring strict regulation of the cosmetics industry. In many countries, cosmetic products must undergo testing and approval by agencies such as the Food and Drug Administration (BPOM) or similar agencies before being sold to the public. However, it is not uncommon to find illegal cosmetics that violate regulations and can endanger the health of consumers. In situations like this, the public can take various legal measures to resolve the problem. One of the most important efforts is to report illegal cosmetics to the relevant authorities such as BPOM.²⁴ This notification is the first step to initiate further investigation into the suspected product. Authorities can take action such as confiscating the product, imposing fines on manufacturers or distributors who violate the rules, or removing the product from the market. Because the rampant circulation of illegal skincare products without BPOM distribution permits is a serious problem that can threaten public health. Therefore, the government through the Food and Drug Administration (BPOM) applies strict regulations on skincare products and takes firm action against violators. Selling skincare products that are not registered with the Food and Drug Administration (BPOM) can have serious legal consequences.²⁵

The sale of skin care products that are not registered with BPOM violates the provisions of Articles 106 and 197 of Health Law Number 36 of 2009. Violation of this can result in administrative sanctions such as revocation of permits and withdrawal of products from the market. In this case, the seller must also be responsible for consumers who are harmed due to the use of skin care products that are not registered with BPOM and can demand responsibility and compensation from the manufacturer. This is based on Article 1365 of the Civil Code, which stipulates that the party that caused the loss must make up for it if their wrongdoing results in injury to another person.²⁶ Consumer protection against skincare products that are not registered with BPOM is very important. The maker or distributor of illicit cosmetics may be sued by the general population. The public may be

²⁴ Fitrah Zaki Amri, "Penegakan Hukum Terhadap Pelaku Penjualan Kosmetik Illegal Secara Online Oleh Balai Besar Pengawas Obat Dan Makanan (BPOM) Pekanbaru," 2020.

²⁵ Lervony Fridela, "Perlindungan Konsumen Atas Pemenuhan Hak Informasi Produk Kosmetik Impor Ilegal Yang Diendorse Oleh Selebgram Di Pekanbaru, Riau," 2019.

²⁶ Burgerlijk Wetboek, "KUHP: Kitab UU Hukum Perdata," 2007.

compensated in this action for damages brought on by the use of illicit cosmetics. The public has several options for filing complaints besides litigation with BPSK as an alternative dispute resolution that is not adversarial. BPSK acts as an intermediary between consumers and manufacturers or sellers of illegal cosmetic products to reach a mutually satisfactory agreement.²⁷

CONCLUSION

In the field of criminal law, it underlines the importance of the existence of an element of error, either intentional or negligent, as a basis for criminal punishment. In addition, the concept of *strict liability* and *vicarious liability* shows the flexibility of the law in demanding accountability, especially for business actors and corporations, where subjective error is no longer the main requirement. This is especially relevant in cases of violations of health regulations, especially the cosmetics industry, which respects the strict responsibility concept in order to protect consumer safety. Corporate criminal regulations, which allow for criminal liability of corporations and their managers, emphasize the importance of compliance with operational standards and product liability. In this case, business actors who violate product safety standards, especially related to illegal cosmetics, can be held accountable without requiring proof of guilt. This creates a deterrent effect and encourages stricter compliance with existing regulations. Therefore, increasing legal awareness and effective law enforcement are essential to ensure consumer safety and prevent abuse in the trade of pharmaceutical and cosmetic products. Special criminal law has been created as a result of the evolution of criminal law outside the criminal code, especially in the administrative field, which aims to support the effectiveness of administrative norms through criminal sanctions. The principle of *ultimum remedium* emphasizes that criminal sanctions are only applied as a last resort if administrative sanctions are ineffective. Andi Hamzah's criticism shows that criminal sanctions in administrative legislation in Indonesia tend to be too severe, have the potential to be misused, and should be more proportional. In the context of illegal cosmetic products, criminal and administrative sanctions are needed to protect consumers. The sale of cosmetics that are not registered with the BPOM may face penalties in line with the Health Law Number 36 of 2009.

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²⁷ Hanum Rahmaniar Helmi, "Eksistensi Badan Penyelesaian Sengketa Konsumen Dalam Memutus Sengketa Konsumen Di Indonesia," *Jurnal Hukum Acara Perdata ADHAPER* 1, no. 1 (2015): 77–89.

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