

Liability Of Business Actors To Consumers Who Are Harmed Due To The Use Of Skincare Products Whose Distribution Licenses Have Been Revoked (Case Study Hn-Hetty Nugrahati Skincare Products)

Kezia Br Manalu¹; Roida Nababan²; Besty Habeahan³.

Faculty of Law, HKBP Nommensen University Medan

kezia.manalu@student.uhn.ac.id, roida.nababan@uhn.ac.id, bestyhabeahan@gmail.com

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Abstract

The circulation of dangerous skincare products whose distribution permits have been revoked, as in the case of HN (Hetty Nugrahati) skincare products, poses a serious threat to public health and demands strict legal accountability from business actors. This study aims to analyze the form of business actors' responsibility towards consumers who experience health losses based on Law Number 17 of 2023 concerning Health, and to examine the role of the Food and Drug Monitoring Agency (BPOM) in supervising cosmetic products that violate technical requirements. The research method used is descriptive juridical with a case study approach. Data analysis was conducted qualitatively descriptive juridical by reviewing relevant primary and secondary legal materials. The results of the study indicate that business actors bear absolute responsibility (strict liability) to provide compensation for health damage suffered by consumers due to the use of products that do not meet safety standards. BPOM plays an important role through pre-market and post-market supervision functions, providing public warnings, and revoking distribution permits to ensure legal certainty. However, coordination in the mechanism for providing consumer compensation is still not optimal. It is recommended that BPOM strengthen the inspection system to prevent administrative negligence and that business actors be more proactive in fulfilling consumers' right to compensation.

Key Words : *Strict Liability, Consumer Protection, Skincare, BPOM, Distribution Permit.*

A. Introduction

Skincare is a skin care product that is included in the cosmetic category, as defined in Law Number 17 of 2023 concerning Health, which is an ingredient or preparation intended for use on the outside of the human body, such as the epidermis (skin), with the aim of cleansing, protecting, maintaining good condition, neutralizing skin tone, nourishing the skin on the face or beautifying facial skin.¹ Skincare products have a variety of products such as *day cream, night cream, lotion, serum, mask, sunscreen, moisturizer, and toner* which

¹ Ahmadi Miru & Sutarman Yodo. *Consumer Protection Law*, (Jakarta: PT. Raja Grafindo Persada, 2014).

are designed as daily skin care. Skincare has become more focused because these products are often widely consumed by the public, so it can increase the risk of consumer losses (such as skin irritation, allergies, or damage to health) if the product does not meet safety standards. The revocation of the distribution permit for skincare products can occur if it is proven that they contain harmful ingredients, such as mercury or irritants, that cause harm to consumers, thus giving rise to legal liability for business actors. Based on the Health Law and Law Number 8 of 1999 concerning Consumer Protection.²

A distribution permit is an official approval from the Food and Drug Supervisory Agency (BPOM) to distribute skincare or cosmetic products, in Indonesian territory. BPOM is a non-ministerial government agency tasked with supervising the safety, quality, and efficacy of health products, medicines, and cosmetics, as regulated in the Health Law and Presidential Regulation Number 80 of 2017 concerning the Food and Drug Control Agency. Revocation of a distribution permit occurs if the product is proven to have violated a provision, such as containing prohibited ingredients, unsafe, or posing a health risk based on consumer reports or surveillance findings.³ The revocation of distribution permits by BPOM is the main trigger for consumer losses due to skincare products, which then raises the responsibility of business actors. Based on the Consumer Protection Law Number 8 of 1999 Article 7, business actors have an absolute responsibility (*strict liability*) to compensate for losses suffered, both material and immaterial, and require product recall and compensation.⁴

Based on Positive Law, Law Number 8 of 1999 concerning Consumer Protection is a positive legal instrument that regulates the responsibilities of business actors (*strict liability principle*) and provides a comprehensive legal framework to protect consumer rights, including the right to product safety, the right to correct and clear information, and the right to compensation for losses suffered due to the use of defective or dangerous products.⁵ This protection mechanism is regulated in Law Number 8 of 1999 Article 4 and Article 19, which requires business actors to be legally responsible for the products they produce or distribute, through civil liability. This principle is regulated to provide justice for consumers who have been harmed due to the use of skincare products that have had their distribution permits revoked.⁶ Therefore, Law Number 8 of 1999 is to strengthen and fulfill the rights of consumers from these cases in order to solve problems fairly and quickly.⁷

² Wicaksono, B. P., & Suryono, A. "Legal Protection for HN (Hetty Nugrahati) Skincare Users Who Are Not Registered with BPOM". Journal of Customary Law, Vol. 1 No. 1 (2024), pp. 1-10.

³ Pangaribuan, L. "Cosmetic Side Effects and Their Treatment for Women". Journal of Prosperous Healthy Families, Vol. 15, No. 2 (2017), pp. 20-28.

⁴ Law Number 17 of 2023 concerning Health

⁵ Permana, D.P., & Kamal, U. "Consumer Legal Protection of Skincare Products with Microneedle Applicators Revoked for Distribution". Nomos : Journal of Legal Sciences Research, Vol. 5, No. 2 (2025), pp. 363-373.

⁶ Lestari, Y. P. I., Dina Azizah, Dhea Indah Cahyani, & Dita Putri Aulia. "Education on Dangerous Creams Containing Mercury & How to Check BPOM for SMAN 1 Alalak Students". ABDIKAN: Journal of Community Service in the Field of Science and Technology, Vol. 2, No. 1 (2023), pp. 23-30.

⁷ Law Number 8 of 1999 concerning Consumer Protection

On the other hand, the Presidential Regulation of the Republic of Indonesia Number 80 of 2017 concerning the Food and Drug Control Agency in this study is very important to analyze the extent of the effectiveness of the BPOM supervisory function, which often only acts after thousands of victims have fallen.⁸ This regulation gives full authority to BPOM to carry out *pre-market* (before circulation) and *post-market* (after circulation) supervision, this is also regulated in Article 3 paragraph (1) letter d, but in the case of Skincare HN-(Hetty Nugrahati) there is a large gap in the initial inspection system for hazardous ingredients such as mercury. Using this regulation, the study will highlight whether BPOM has maximized its enforcement and coordination functions, or whether there has been administrative negligence that allowed products without valid permits to circulate widely and endanger thousands of people before their distribution permits were finally revoked.

The use of Presidential Regulation Number 80 of 2017 concerning the Food and Drug Control Agency in this study is based on revealing the relationship between weak state supervision and the emergence of mass consumer losses.⁹ Broadly, this study places the Presidential Regulation not only as a legal text, but as a tool to test the responsibility of the bureaucracy in protecting the public, because without strict supervision as mandated by this Presidential Regulation, consumers' rights to compensation are often ignored because business actors feel that there is no strong legal pressure from the government's administrative side.¹⁰

The HN-(Hetty Nugrahati) Skincare Product Case Study serves as a relevant empirical illustration. In October 2023, BPOM revoked the distribution permit for this product based on Law Number 17 of 2023 concerning Health Article 98 paragraph (1), because it was found to contain harmful substances such as mercury that exceeds the safe limit (more than 1 ppm) and unregistered chemicals that have the potential to cause chronic skin irritation or hormonal disorders.¹¹ The case involved thousands of consumers who had used the product before the revocation of the distribution permit, with reports of health losses such as skin rashes and tissue damage, as well as material losses due to the purchase of the product. Although BPOM has issued warnings and product recalls, the compensation mechanism for consumers is often not optimal, because business actors such as distributor company HN-(Hetty Nugrahati) have not been proactive in providing compensation.¹²

⁸ Permana, D.P., & Kamal, U. "Consumer Legal Protection of Skincare Products with Microneedle Applicators Revoked for Distribution". *Nomos : Journal of Legal Sciences Research*, Vol. 5, No. 2 (2025), pp. 363–373.

⁹ Johannes Galuh Bimantara, Fajar Ramadhan, Asitya Diveranta, Sekar Gandhiwangi, Harry Susilo. "Illegal Cosmetics With Mercury Sold Over-the-Counter in the Market". *Retrieved May 20 (2024)*, <https://www.kompas.id/artikel/kosmetik-ilegal-bermerkuri-dijual-bebas-di-pasaran>.

¹⁰ Cellina Tri Siwi Kristiyanti. *Consumer Protection Law*, (Jakarta: Sinar Grafika, 2009).

¹¹ Taufikkurrahman. "Alternative Dispute Resolution (ADR) in Consumer Dispute Resolution". *Stain Pamekasan Journal*: Volume 2, Number 1 (2015), pp. 22-43.

¹² Mega Lusi Sartika, Sakti Ritonga., & Muhammad Jailani. "Dr. Richard Lee's Youtube Channel Framing Analysis on the Safety and Marketing Strategy of HN Products". *Journal of Sibatik*, Vol. 2, No. 4 (2023), pp. 1347-1354.

In 2022, BPOM began receiving mass reports from various consumers regarding serious side effects due to the use of HN (Hetty Nugrahati) skincare products, including severe skin irritation, allergic reactions, chemical burns, and even systemic health disorders, which are suspected to be caused by ingredients such as hydroquinone and mercury that exceed safe tolerance limits.¹³ An in-depth investigation by BPOM revealed that HN products did not have a valid distribution permit and did not meet the requirements for pre-market testing, thus violating the provisions of Law Number 17 of 2023 concerning Health. This finding became the basis for BPOM to start the process of revoking distribution permits, which emphasized the importance of continuous supervision of *skincare products* that have been distributed.¹⁴

This Legal Research aims to provide clear legal solutions regarding the mechanism of fair compensation for consumers and evaluate the role of BPOM, thereby making a significant contribution to strengthening the enforcement of consumer protection laws in the pharmaceutical sector. Therefore, this study is expected to provide practical legal recommendations to strengthen consumer protection, prevent the recurrence of similar cases, and increase the effectiveness of BPOM supervision.¹⁵

The choice of this title was driven by its practical urgency and high legal relevance, because the phenomenon of revoking the distribution license of skincare products, such as the case of *Skincare HN*, directly threatens consumer safety and causes serious losses. The main reason for conducting this research is to analyze in depth the extent to which the responsibility of business actors can be enforced in Indonesia, especially in the context of products that are proven to contain harmful substances and the revocation of the distribution license. This study is different from the previous study which only highlighted the aspect of illegal cosmetic circulation in general, this study specifically analyzes the application of the principle of strict *liability* to business actors after the revocation of distribution permits by BPOM, as well as examining the effectiveness of administrative supervision in the perspective of Presidential Regulation Number 80 of 2017. *The research gap* in this study is that there is no proactive compensation mechanism from business actors after administrative actions by BPOM, so an analysis is needed on the application of *the strict liability* principle.

B. Research Methods

This research focuses on laws and regulations in Indonesia with justice for consumers against the civil liability of business actors (*strict liability*) for losses suffered by consumers

¹³ Salbiah, W., Junaida, E., & Amilia, S. "The Influence of Product Knowledge and Quality Perception on HN Skincare Purchase Decisions in Langsa City". *Scientific Journal of Applied Managerial Students*, Vol 3, No. 3 (2023), pp. 582-587.

¹⁴ Eleanora & Fransiska N. "Proof of Product Liability to Consumers Related to Hidden Defects." *Morality Journal of Legal Sciences*, Vol. 9, No. 2 (2023), p. 170.

¹⁵ Julianti, S & Sutihat, S & Hidayat, S. "Analytical Quality of HN Skincare Products (Henny Nugrahati)". *Journal of Economic Research and Publications*, Vol. 2, No. 2 (2024), pp. 219-229.

due to *skincare products* that have had their distribution permits revoked by the Food and Drug Supervisory Agency (BPOM).¹⁶

1. Types of Research

This study uses a descriptive juridical qualitative data analysis method. Descriptive juridical research is a method of legal research that aims to provide a systematic description, explanation, and analysis of written legal principles, rules, and norms. This descriptive juridical research is related to the statute *approach* and the *case approach*.¹⁷ The data and sources of data and materials used in this study are:

2. Primary Legal Material

Primary legal material is legal material that is authoritative, meaning it has authority. Primary legal materials consist of legislation, official records or treatises in the making of Laws and Judges' Decisions.¹⁸

For this study, primary legal materials are binding legal sources, sourced from, among others:

- a. Law Number 17 of 2023 concerning Health (especially Article 1, Article 98 paragraph (1) concerning the Revocation of Distribution Permits for Health Products such as *Skincare*).
- b. Law Number 8 of 1999 concerning Consumer Protection (especially Article 4, Article 5, Article 7, Article 19 concerning Consumer Rights and Responsibilities).
- c. Presidential Regulation of the Republic of Indonesia Number 80 of 2017 concerning the Food and Drug Control Agency.
- d. BPOM Regulation Number 25 of 2025 concerning Technical Requirements for Cosmetic Ingredients.

3. Secondary Legal Materials

Secondary legal materials are legal materials that do not have direct binding power, but function to provide explanations, analysis, and interpretations of primary legal materials for all publications on law that are not official documents.¹⁹

For this study, the secondary legal materials are:

- a) Textbooks (literature) and doctrines (opinions of legal experts) on civil law, consumer protection law, principles of legal certainty, principles of legal justice and consumer rights law.
- b) Legal scientific journals, articles, and papers relevant to the research topic.

4. Tertiary Legal Materials

Tertiary legal materials are one of the legal research that is currently not only limited to physical books, but also includes information sources from the web, websites, and the internet that are used as search and interpretation tools. This source includes

¹⁶ Muhaimin. "Legal Research Methods. Mataram University Press, (Mataram, 2020), p. 65.

¹⁷ Sigit Sapto Nugroho, Anik Tri Haryani & Farkhani. "Legal Research Methodology". (Oase Pustaka Surakarta : 2020), p. 66.

¹⁸ Presidential Regulation Number 80 of 2017 concerning the Food and Drug Control Agency.

¹⁹ Amiruddin & Zainal Asikin. *Introduction to Legal Research Methods*, (Jakarta: Rajawali Pers, 2019), p. 67

access to the institution's official website such as the BPOM check page to verify the revocation of distribution permits online.²⁰

Untuk penelitian ini, bahan hukum tersier adalah :

- a) Legal dictionary.
 - b) Legal encyclopedia, seeking information about the protection of consumers who are harmed by the use of HN-(Hetty Nugrahati) skincare products whose distribution licenses have been revoked.
 - c) The internet (web) and official website regarding information on the case of HN-(Hetty Nugrahati) skincare products and the Food and Drug Control Agency (BPOM) Institution.
5. Data Collection

Data collection is carried out through *library research* and case study *techniques*, which are in accordance with the type of descriptive juridical research.²¹ Literature study techniques involve collecting legal materials from primary sources (laws and related regulations), secondary (literature and jurisprudence), and tertiary (legal dictionaries) through digital access such as the official BPOM website, and online law libraries. Case study techniques were used to collect empirical data on the revocation of the distribution license of HN-(Hetty Nugrahati) skincare products, including the Food and Drug Control Agency's 2023 report, verified media news, and public documentation of consumer losses.²²

C. Results and Discussion

1. The Responsibility of Business Actors to Consumers Who Suffer Losses Due to the Use of Skincare Products Whose Distribution Licenses Have Been Revoked Based on Positive Law

Business Actors or Producers are often defined as entrepreneurs who produce goods and services. This definition includes business owners and professional retailers, i.e. any person or entity involved in the provision of goods or services to consumers.²³ Business actors do not only include individuals and manufacturers, but also distributors, exporters, importers and retailers. Business actors are also responsible for negative consequences that can harm society. Business Actors are regulated in Law Number 8 of 1999 concerning Consumer Protection.²⁴

Legal Responsibility is part of the concept of legal obligation. The principle of liability is an important part of consumer protection law. In the case of consumer rights violations, caution is required in analyzing who should be responsible and the extent of the liability that can be imposed on the parties concerned.²⁵

²⁰ Soerjono Soekanto. "Introduction to Legal Research", (University of Indonesia, Jakarta, 1986).

²¹ Jaholden, "Basic Concepts of Legal Research", (CV. Prima Library Medan, 2021).

²² Bambang Sunggono. *Legal Research Methodology*, (Jakarta: Raja Grafindo Persada, 2015), p. 114.

²³ *Ibid.*

²⁴ Shidarta, *Indonesian Consumer Protection Law*, PT Grasindo, (Jakarta, 2000), p. 59.

²⁵ Abdulkadir Muhammad, *Indonesian Corporate Law*. (Citra Aditya Bakti, 2010), p. 503.

Based on a Case Study of Skincare Products HN-(Hetty Nugrahati) is a series of skin care products that include facial cleanser, *toner*, *day cream*, and *night cream*.²⁶ With just a few uses, this cream promises to make the skin smoother, brighter, and more beautiful. In addition, this whitening *lotion* is also believed to be able to overcome various skin problems such as treating acne, removing dark spots, whitening the skin, shrinking pores, and protecting the skin from UV radiation and so on. Toner and facial soap are the only products that contain methanol.²⁷ Because methanol cannot be utilized, this amount exceeds the threshold allowed by the Food and Drug Control Agency. When viewed from the negative side, mercury should not be used in *skincare*. Although often stored in containers without labels, items containing mercury often do not have labels. Therefore, consumers are not aware that the mercury content in the products they use can harm their health and skin.²⁸

Side effects in the use of mercury cream, whether *day cream* or *night cream* do not appear immediately, usually appear within 6 months to 1 year.²⁹ What's even more dangerous is that once mercury is applied to the face or into the body, it's very difficult and almost impossible to remove. Therefore, skincare products that contain mercury can cause the skin to become red, itchy, blackened, and burning.³⁰

The responsibility of business actors who sell skincare products that do not have a distribution permit and contain harmful ingredients is based on the principle of strict *liability*.³¹ Based on the principle of positive legal responsibility, business actors must be responsible to consumers who feel disadvantaged by *skincare* products sold by these business actors. This principle of strict *liability* aims to prevent business actors from committing fraud that can result in losses for every consumer who uses the product.³²

This responsibility can be in the form of civil liability. Regarding the Consumer Protection Law, Article 19 of Law Number 8 of 1999 concerning Consumer Protection regulates the responsibilities of business actors.³³ Based on the research conducted on the responsibility of business actors for the products distributed, business actors are required to provide responsibility to consumers as stated in Article 19 of Law Number 8 of 1999 concerning Consumer Protection, namely:

- a. Business actors are responsible for providing compensation for damage, pollution, and consumer losses resulting from consuming goods or services produced or traded.
- b. Compensation as intended in paragraph (1) may be in the form of a refund or

²⁶ *Ibid.*

²⁷ Diary Rahma, *consider this before using HN*. Retrieved May 12, 2024, <https://www.rahmaediary.com/2021/02/pertimbangkan-ini-sebelum-pakai-cream-hn.html>.

²⁸ Zulham. *Consumer Protection Law*. (Jakarta: Kencana Prenada Media Group, 2019), pp. 18-55.

²⁹ *Ibid.*

³⁰ Ariana Heidyana. *Signs of Face Damage due to Mercury*. Retrieved May 24, 2022, <https://www.klikdokter.com/info-sehat/kulit/tanda-tanda-wajah-rusak-karena-merkuri>.

³¹ *Ibid.*

³² Christian, C. T. S. *Consumer Protection Law*. (Jakarta: Sinar Grafika, 2022), p. 97.

³³ Prasetyo, A. B. "Synchronization of Provisions for Consumer Compensation According to the Civil Code and the Consumer Protection Law". *Journal of Private Law*, Vol. 8, No. 2 (2020), pp. 210-225.

replacement of goods or services of the same or equivalent value, or health care and compensation in accordance with the provisions of the applicable laws and regulations.

- c. The provision of compensation is carried out within a grace period of 7 (seven) days after the date of the transaction.
- d. The award of compensation as intended in paragraphs (1) and (2) does not eliminate the possibility of criminal prosecution based on further evidence of guilt regarding the existence of elements of guilt.

This shows that the liability of business actors who commit negligence in their business practices is limited to what has been stipulated in Article 19 of the Consumer Protection Law, where consumers who feel aggrieved can ask for compensation in the form of refunds, or replacement of goods or services of the same type or value, or health care. The research is also different from previous research that discussed illegal cosmetics in general, this study focuses on the application of real damages after the revocation of distribution licenses using the principle of absolute responsibility.³⁴

The following are the principles of responsibility of business actors:

2. The Principle of Responsibility Based on the Element of Fault

The principle of *liability based on fault* is a principle that is quite applicable in criminal and civil law. In the Civil Code, especially Articles 1365, 1366, and 1367, this principle is firmly enforced. This principle states that a person can only be held legally accountable if there is an element of wrongdoing in his actions.³⁵

1) The Presumptive Principle To Always Be Responsible

This principle states that the defendant is always held liable (*presumption of liability principle*), until they can prove that the defendant is guilty.³⁶ Currently, the burden of reverse proof (*omkering van bewijslast*) is still acceptable with the principle of presumption to always be responsible. The basis of the theory of reverse burden of proof theory is that a person is presumed guilty, until they can prove otherwise. This is certainly contrary to the legal principle of the *presumption of innocence* which is commonly known in law. However, if applied to the consumer case it becomes clear that, this principle is quite relevant.³⁷

2) The Presumptive Principle of Not Always Being Responsible

This principle is the opposite of the principle of presumption to always be responsible. The *presumption of nonliability principle* is only known in the very limited scope of consumer transactions, and such a restriction is usually common sense justified.³⁸

3) Absolute Responsibility Principle

³⁴ Law Number 8 of 1999 Article 19 concerning Consumer Protection

³⁵ Erna Ferrinadewi, "Product Attributes Considered in Cosmetic Purchases and Their Influence on Consumer Satisfaction in Surabaya". Petra University Surabaya: Vol. 7, No. 2 (2005). pp. 139-151.

³⁶ *Ibid.*

³⁷ *Ibid*, p. 61.

³⁸ *Ibid.*

The principle of *strict liability* is often equated with the principle of *absolute liability*. However, some experts distinguish between the two terms. There is an opinion that says that responsibility is a principle that establishes fault as an indeterminate factor.³⁹ However, there are exceptions that allow for exemption from liability. On the contrary, absolute liability is the principle of responsibility without fault and without exception.⁴⁰

4) Liability with Limitations

The principle of *limitation of liability* is very much liked by business actors to be included as a clause of exemption from liability in the contract agreement they make. In the film printing agreement, it is stipulated that if the film to be printed is lost or damaged (including the fault of the employee), then the consumer is only limited to ten times the price of one new roll of film.⁴¹

Based on the application of these articles, it is very relevant to the case study of Skincare HN (Hetty Nugrahati) which has had its distribution permit revoked by BPOM because it contains harmful ingredients such as mercury and hydroquinone.⁴² Juridically, the revocation of the distribution license is authentic evidence that the product does not meet safety standards, so that consumers can claim material and immaterial damages through a civil lawsuit or dispute resolution body. This emphasizes that civil law serves as an instrument to force business actors to take full responsibility for products that threaten public safety.⁴³

3. The Role of BPOM in Supervising Distribution Permits for Skincare Products That Are Detrimental to Consumers According to Presidential Regulation of the Republic of Indonesia Number 80 of 2017 concerning the Food and Drug Control Agency

The Food and Drug Control Agency (BPOM) is an institution that has the responsibility and power to protect consumers from drug and food products. One of them is skincare which is also under its protection. In the Regulation of the Food and Drug Control Agency Number 2 of 2020 concerning the Supervision of the Production and Circulation of Cosmetics or *Skincare*, a *skincare* that is distributed in the community, *skincare* must have a distribution permit from the Food and Drug Control Agency.⁴⁴ Skincare products that have been registered with the Food and Drug Control Agency can be ensured to be safe, of quality, and meet their claims of benefits and

³⁹ Siahaan, N. H. T. "Consumer Law: Consumer Protection and Product Liability". (Jakarta: Erlangga, 2020), p. 140.

⁴⁰ *Ibid*, p. 63.

⁴¹ *Ibid*, p. 65.

⁴² Jaang, Syaharie, "Analysis of Legal Protection for Consumers Based on the Principle of Justice." Journal of Law and Human Rights Wara Ciencias, Vol. 2, No. 05 (2023), pp. 335-341.

⁴³ Hutagalung, S. M. "Juridical Analysis of Civil Liability of Online Cosmetics Business Actors Who Do Not Have a Distribution License". Scientific Journal of Law Enforcement, Vol. 8, No. 1 (2021), pp. 56-65.

⁴⁴ Prayuti, Yuyut. "Consumer Protection in Online Health Product Transactions: An Analysis of Regulations and Practices". Syntax Idea, Vol. 6, No. 4 (2024), pp. 1274-1284.

health. In the regulation of the Food and Drug Control Agency Number 25 of 2025 regarding ingredients used in compositions that meet the requirements for use.⁴⁵

Based on Presidential Regulation Number 80 of 2017 concerning the Food and Drug Supervisory Agency (BPOM) in Article 3 Paragraphs (1), (2), and (3) in carrying out drug and food supervision, it is stated that the Food and Drug Supervisory Agency (BPOM) carries out its functions.⁴⁶ Here are its functions:

In carrying out the task of drug and food supervision, the Food and Drug Supervisory Agency (BPOM) carries out its functions, namely:

- a. Formulation of national policies in the field of drug and food control.
- b. Implementing national policies in the field of drug and food control.
- c. Preparation and determination of norms, standards, procedures, and criteria in the field of supervision before circulation and supervision during circulation.
- d. The implementation of supervision before circulation and supervision during circulation.
- e. Coordination of the implementation of drug and food supervision with the government, both the central government and local governments.

Based on the case of Skincare HN (Hetty Nugrahati), this product began to receive serious attention from the Food and Drug Control Agency (BPOM) in 2022 after the emergence of mass reports from consumers who experienced severe side effects. Research conducted by BPOM revealed the fact that HN (Hetty Nurgahati) Skincare products contain banned harmful chemicals, especially mercury and hydroquinone. The mercury found in the product exceeded the safe threshold, while the toner and facial soap products were found to contain methanol that exceeded the permissible limit. These ingredients are very dangerous because they are difficult to remove from the body and can cause permanent side effects such as darkening of the skin, burning, redness of the skin, and health problems.⁴⁷

As a form of administrative law enforcement, BPOM officially revoked the distribution permit for *HN Skincare* products in October 2023. This revocation decision is based on Article 98 paragraph (1) of Law Number 17 of 2023 concerning Health, because the product is proven to contain harmful ingredients and unregistered chemicals.⁴⁸ In addition, BPOM's research confirms that HN products do not meet the pre-market testing standards required by the state.⁴⁹ After the revocation of the distribution permit, BPOM carried out a repressive function by issuing *public warnings*

⁴⁵ BPOM RI, Regulation of the Food and Drug Supervisory Agency of the Republic of Indonesia Number 23 of 2019 concerning Technical Requirements for Cosmetic Ingredients.

⁴⁶ *Ibid.*

⁴⁷ *Ibid.*

⁴⁸ Putri Nur Anisa & Tatty Aryani Ramli. "Implementation of Cosmetic Supervision Regulations Without Distribution Permits in Trade Through Electronic Systems as an Effort to Protect Consumers". *Journal of Legal Research*, Vol. 1, No. 2 (2022), pp. 93-100.

⁴⁹ Barkatullah, A. H. *Consumer Protection Law*. Theoretical Studies and the Development of Thought. (Bandung: Nusa Media, 2019), p. 128.

and ordering the withdrawal of products from all regions of Indonesia. BPOM also acts as an authority that ensures legal certainty by conducting post-market *control* to detect toxic substances and coordinating with law enforcement officials to ensure that these dangerous products are completely lost from circulation. However, this effort often faces challenges because the compensation mechanism for thousands of consumers is not optimal due to the lack of proactivity of HN's distribution permit in providing compensation.⁵⁰

Overall, the role of BPOM in the case of Skincare HN is very important as an instrument to protect the public from large health risks. The revocation of the distribution permit by BPOM serves as legally valid evidence that the product is not safe, then provides a strong basis for consumers to demand strict *liability* from business actors. In the future, the effectiveness of BPOM needs to be strengthened through stricter supervision to prevent administrative negligence that allows products without a valid distribution permit to circulate widely and endanger thousands of consumers before legal action is taken.⁵¹

D. Conclusion

The responsibility of business actors is a legal obligation to bear all consequences and provide compensation for risks arising from *the skincare* products they distribute, which in the context of Law Number 17 of 2023 concerning Health is categorized as strict *liability*. Based on this principle, HN *skincare product business actors* whose distribution licenses have been revoked and are obliged to provide full compensation for health losses experienced by thousands of consumers without requiring consumers to prove the existence of an element of manufacturer error, so that consumers can demand material and immaterial damages through a civil lawsuit or dispute resolution agency. The enforcement of this responsibility is absolute because the product is proven to violate the safety standards of pharmaceutical preparations, so that business actors can legally be burdened with the responsibility to restore consumer rights as a direct impact of the circulation of dangerous products.

The role of the Food and Drug Supervisory Agency (BPOM) in supervising the distribution of *skincare products* that are detrimental to consumers is carried out through preventive and repressive supervision functions in accordance with the applicable skincare material technical standards. BPOM plays an important role in conducting post-market *control* to detect the content of hazardous substances and taking strict administrative action in the form of revocation of distribution permits for products that threaten public safety. In addition, BPOM functions as an authority that ensures legal certainty by coordinating with law enforcement officials to ensure that dangerous products are no longer circulating in the

⁵⁰ Ngabito, Rafyanka I P. "Analysis of Legal Liability for the Distribution of Skincare Products Proven to be Overclaimed." *Journal of Law Development and Justice Review*, Vol. 7, No. 3 (2025), pp. 263-275.

⁵¹ Arief, A. S., & Yuliana, N. "Legal Protection for Consumers for the Circulation of Cosmetics Containing Harmful Ingredients (Mercury) Reviewed from the Consumer Protection Law". *Lex Generalis Legal Journal*, Vol. 2, No. 5 (2021), pp. 421-438.

community, as well as providing education to consumers to be protected from the risk of using *dangerous skincare* in the future. This requires regulatory harmonization between the Health Law and the Consumer Protection Law related to the compensation system (loss to consumers).

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