

Law Enforcement Against Dangerous Pharmaceutical Preparations in the National Health System

¹Dian Puspito Rini, ²Adnan Hamid, ³Pattharawadee Rangsimanop

^{1,2}Universitas Pancasila, Indonesia, ³Rajamangala University Of Technology Krungthep, Thailand

¹5224230012@univpancasila.ac.id, ²adnan_hamid@univpancasila.ac.id,

³Patthrawadee.r@mail.rmutk.ac.th

ABSTRACT

Cosmetic preparations are ingredients that can be used on parts of the body that change a person's appearance. In Indonesia, the discovery of dangerous cosmetic preparations is rampant, based on several Press Releases submitted by the POM Agency. The rise of the discovery of dangerous cosmetic preparations has had a great impact on the health system in Indonesia. The a need for law enforcement against dangerous cosmetic preparations to improve the health system in Indonesia and to achieve the highest degree of health for the community. The purpose of research is to dig up and find a fact that has not existed before. The method used is qualitative literature research. The results of the surveillance research on cosmetic preparations still face obstacles due to limited human resources, large surveillance areas, and the complexity of supervision. The results of the study are the punishments given to business actors who commit cosmetic crimes, with the punishment imposed on the perpetrators being relatively light, so that they do not cause a deterrent effect for business actors. Law enforcement against dangerous cosmetic preparations in Indonesia has not had a deterrent effect on business actors and does not cause fear of committing violations, so that it can be said that it has not been able to realize the highest optimal level of public health.

Keywords: *Pharmaceutical Preparations. Law Enforcement. National Health System.*

Introduction

The National Health System (SKN) was first established in 1982 and then changed to SKN in 2012, which is regulated in Presidential Regulation of the Republic of Indonesia No. 72 of 2012 (Hani P Febriyanti, Rhaina Al Yasin, and Rosa S N Sabrina, et al.2023). Law of the Republic of Indonesia No. 17 of 2023 concerning Health is the legal basis for carrying out positive transportation in the health system in Indonesia. Regulating critical aspects of the health system, including health efforts, health facilities, human resource systems, health financing, and health information systems (Hukumonline, 2024).

This law responds to the development of science and technology in the health sector, global and national health issues, the need to improve the quality of health services for the community, the realization of a better national health system, harmonize with laws related to health, and to create legal certainty and the effectiveness of law enforcement (¹Legislative Body of the House of Representatives-RI,2023). The national health system according to this Law is defined as health management organized by the Indonesian nation in a comprehensive and integrated manner to achieve health development goals. In this legislation, cosmetic preparations fall into the category of pharmaceutical preparations.

Cosmetic preparations themselves are defined as ingredients used on the outer part of the body and are generally used for the purpose of cleaning, protecting, maintaining body fitness and can change a person's appearance. According to its function, cosmetic preparations are divided into 2 (two), as decorative cosmetics (*make-up*) intended to beautify the appearance of facial skin. Cosmetic preparations that are specialized for skin care are better known as *skincare* (Ira, H, & Ira, H,2023). To produce, store, promote, and/or distribute decorative cosmetic preparations and *skincare*, business actors must first have a certification of good

cosmetic manufacturing practices and a distribution permit in the form of a notification issued by the POM Agency.

The public's need for cosmetic preparations in Indonesia is currently increasing. This is because for women, fair and *glowing* skin is a dream and is identified with healthy skin conditions and has aesthetic value. Then, many women with tan and yellow skin are often targeted by bullying. It is strengthened by the social and cultural pressure in society on beauty standards, and the desire to increase self-confidence, as well as the existence of advertisements and social media that show white skin as a symbol of beauty. So many women are willing to do things that can make them have brighter skin, including the use of skin lightening care products, and even perform various medical procedures to turn the skin white, such as doing whitening injections (Taif F. Alzahrani, Shaykhah M. Alotaibi and Albatool A. Alzahrani, et. al.,2025). According to the WHO, demand for skin-lightening care products will reach a peak demand of US\$31.2 billion in 2024 (Cintya Theresia A. M. Sitorus.,2024).

Although skin lightening cosmetic preparations are in great demand and used by the public, in general, skin lightening products have risks to health. There are many cases of skin-lightening cosmetic products in production that do not meet the standards of safety, efficacy and quality of cosmetic ingredients, and are often associated with the use of harmful ingredients such as mercury (Hg), lead (Pb), *hydroquinone* and synthetic dyes (red K10) (Ayu Khurin'in, Anzalna F Arifa, Feri S Budi, et al.,2025). Although these chemical compounds can have a lightening effect on the skin in a relatively short time, their use can accumulate in the body with the properties of these compounds which are carcinogenic and harmful to health (Elvia Rahmawati, Miftakhul Huda, and Ian Firstian Aldhi,2024).

In Indonesia, the preparation of cosmetic products that use harmful ingredients such as mercury (Hg), lead (Pb), *hydroquinone* and synthetic dyes (red K10) is an offense and their use is strictly prohibited by the POM Agency. This ban is in line with WHO's concern about the impact of Hg compounds that have the potential to cause blockage of blood vessels (atherosclerosis), coronary heart disease, stroke, heart attack (myocardial infarction), hypertension, blockage of blood vessels (carotid artery), and heart rhythm disorders (arrhythmias) and are the cause of cardiovascular disease (Yuan-Seng Wu, Ahmed I. Osman, and Mohamed Hosny, et al,2024).

Likewise, *hydroquinone* can cause cancer, irritating dermatitis, melanocyte damage, contact dermatitis, and ochronosis (Stela Regina F, Natielle Moreira C, and Livia Teixeira Oliveira.,2024). Likewise, lead compounds are found in creams, eyeliners, lipsticks, and powders. These compounds can have an impact on developmental delays, cancer, reproductive complications, and harm fetal development for pregnant women (Opoku Gyamfi, James Aboko, and Edward Ankapong,2023).

In recent years, there has been a widespread circulation of cosmetic preparations containing harmful ingredients in Indonesia. A press release submitted by the POM Agency recently found cosmetic preparations that were proven to contain harmful ingredients in as many as 34 cosmetic products. Then, based on the results of sampling and testing activities based on risk analysis conducted by the POM Agency from September 2022 to June 2025, as many as 272 cosmetic preparation products containing harmful ingredients were found in Indonesia.

The rampant circulation of cosmetic preparations containing harmful ingredients is influenced by the high consumer interest in cosmetic preparation products with instant and cheap results. As a result, many business actors tend to use ingredients at low prices and have an instant effect in cosmetic preparation products, but are harmful to the health of those who use these products (Janneta A Pangalila, I Nyoman Putu, and I Gusti A, et al.,2024). This is because public knowledge of cosmetic preparation products that contain harmful ingredients

is still lacking (Dinna Fitria K, Hilya Aulia, Samuel Hadi, et al,2024). On the other hand, the development of e-commerce platforms makes it easier to distribute and purchase cosmetic preparation products without going through strict supervision.

Regarding cosmetic preparations, the government has the authority to carry out supervision of all stages of the circulation of cosmetic preparations, starting from production, distribution, to sales. The supervision aims to ensure that every cosmetic preparation product in circulation meets the requirements of safety, quality, and benefits in accordance with the standards that have been set in laws and regulations. The government's move to withdraw and destroy cosmetic products containing harmful ingredients reflects the seriousness of the issue of cosmetic preparations. International bodies such as the FDA (United States), MFDS (South Korea), and SFDA (Saudi Arabia) also pay great attention to the use of hazardous ingredients in cosmetics, given their impact on human health and safety. In fact, the World Health Organization (WHO) has recommended discontinuing the use of these ingredients to prevent about 30% of diagnosed cancer cases (Radosław Balwierz, Paweł Biernat, and Agatha James.et al,2023).

The problem of the circulation of dangerous cosmetic preparations requires the active role of the National Health System (SKN) in supporting law enforcement over the rampant circulation of cosmetic preparations that use harmful ingredients. In accordance with the national goal of maintaining public safety from the use of unsafe cosmetic preparation products, the enforcement of cosmetic crime laws is the most important in supervising the rampant circulation of cosmetic preparations in order to ensure the safety of users as regulated in several laws and regulations, including the Health Law, the Consumer Protection Law, the POM Agency Regulation, and the Criminal Code.

Looking at the many rulings in the courts of cosmetic crime cases in Indonesia, and the Press Release submitted by the POM Agency, it shows that even though supervision has been carried out by the POM Agency and law enforcement against cosmetic crimes, cosmetic preparations containing harmful ingredients are still widely found. This causes anxiety for people who have difficulty distinguishing which products are safe for health and which are not (Teuku Hafizh Fakhreza, Muhammad Anggara T,2023). This shows that the supervision and law enforcement system is still weak in the case of the circulation of cosmetic preparations containing harmful ingredients. Based on the above, seeing the rise of cosmetic preparations containing harmful ingredients, the research carried out is to examine how the law enforcement of cosmetic preparations containing harmful ingredients in Indonesia in the National Health System. Based on the explanation that has been explained in the introduction, the formulation of the problems in this study that is to be reviewed is:

How is the law enforcement against dangerous cosmetics in Indonesia in the National Health System?

Methods Research

This type of research is qualitative literature research or *library research* that is carried out by collecting data from relevant written sources by studying literature and writings that are closely related to the problems in the research. The problem in this study is related to the enforcement of the law on cosmetics containing harmful ingredients in Indonesia in the National Health System. The research method used is literature research by examining literature materials or secondary data related to the object of study in the form of norms, laws and regulations and decisions. The object of this study is how to enforce the law against cosmetics containing harmful ingredients in Indonesia in the National Health System.

The data source used in the study is sourced from primary data sourced from laws and regulations and court decisions. Meanwhile, the secondary data sources in this study are

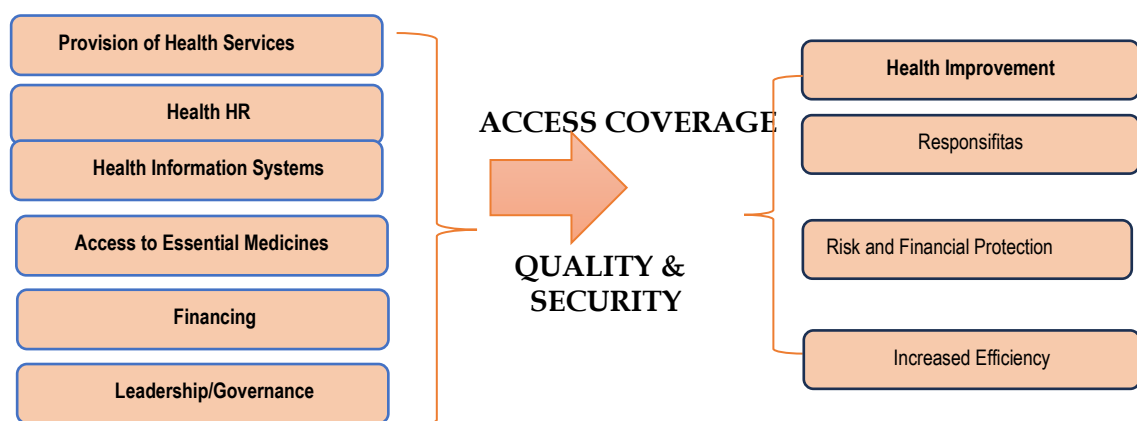
sourced from journals and websites related to the research. The data collection technique used by searching the decision documents, journals and articles it is in is related to the object of research.

Results and Discussion

The originator of the national health system began with the 1978 Alma-Ata Declaration, which emphasized the importance of health services as one of the keys to achieving the development of a country's health. The concept of this health system continued to develop until 2000, with the WHO presenting *The World Health Report 2000* as the beginning of the development of the health system. In the framework of the WHO *Report 2000*, the three main objectives of this system are conveyed, namely *good health*, *responsiveness to the expectations of the population*, and *fairness of financial conscience* (WHO.2023).

In 2007, the WHO conveyed new ideas in the health system with the publication of the document *Strengthening Health Systems to Improve Health Outcomes* as a new foundation for health system development. The 2007 WHO document provides novelty in the framework of the health system by adding several key elements. In a 2007 document, the WHO has changed the three main elements into six main elements known as *the six building blocks*. These elements are the provision of health services (*service delivery*), health workers (*health workforce*), health information system (*health information system*), access to essential medicines (*access to essential medicine*), financing (*financing*), and leadership/governance (*leadership/government*). The objectives of the WHO health system 2007 are divided into 2 levels of objectives, namely *output* and *outcome*. At the output level, the expected goals are access, coverage, quality and security of health services. Meanwhile, in the order of *outcomes*, the expected goals are in the form of improving health status that is equitable and comprehensive, responsive, financial risk protection, and efficiency (WHO,2007).

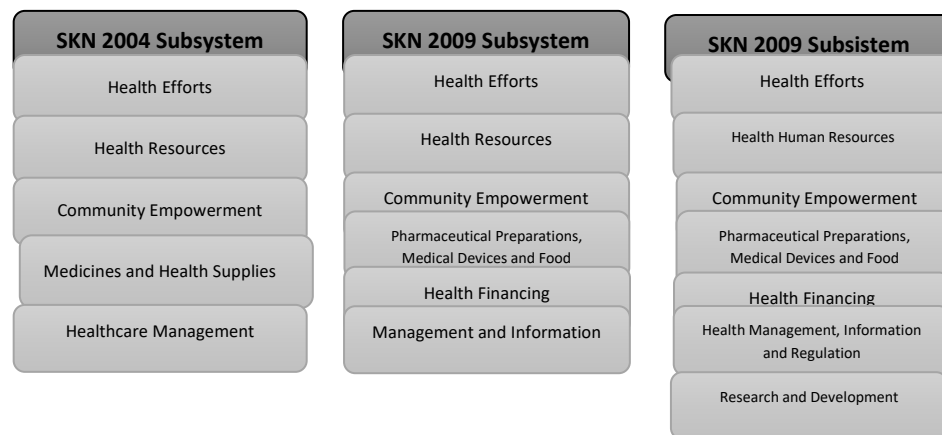
DEVELOPMENT FRAMEWOR PURPOSE HEALTH SYSTEM



Building Block of the Health System Source: WHO (2007)

The development of the global system was responded in stages by the National Health System with the issuance of the 1982 SKN. This SKN has the goal of improvement by considering global economic conditions. Furthermore, the issuance of SKN 2004, the issuance of SKN 2004 takes into account changes after the 1998 political reform and changes in government management after the decentralization policy. In 2009, the SKN was renewed to emphasize the revitalization of primary health services. Continued, the emergence of SKN

2012, which is regulated in Presidential Regulation of the Republic of Indonesia No.72 of 2012. The 2012 SKN still refers to the WHO system framework in 2000. The SKN 2012 has the goal of improving the highest degree of public health. SKN 2012 adopts the main elements of the health system contained in WHO 2007 by adding a community empowerment subsystem as part of this system.



Changes in the National Health Subsystem in Indonesia 2004-2012 Source: Ministry of Health (2004-2009): Government of Indonesia (2012)

The 2023 Health Law Mandate explains health providers. Health providers themselves are the legal basis of the 2012 SKN. Health Providers include Health Efforts, Health Resources, and Health Management. The Health Effort itself aims to realize the highest degree of health for the community, both for individual health efforts and for public health efforts. Meanwhile, Health Resources are intended to be utilized in order to support violations of health efforts. Furthermore, health managers are carried out on health efforts and health resources that aim to ensure the achievement of the highest degree of health (Ministry of National Development Planning/Bappenas,2023).

The 2012 SKN states that the components of health management are arranged in the national health system in the form of subsystems, one of these subsystems is pharmaceutical preparations in the form of cosmetics. The Health Law of 2023 and Government Regulation of 2024 comprehensively regulate pharmaceutical preparations in the form of cosmetics, both in regulation and supervision of pharmaceutical preparation products in the form of cosmetics which aim to ensure the safety and quality of pharmaceutical preparations in the form of cosmetics so that they are safe for the health of users. Health is a human right guaranteed by the constitution as well as the international constitution (Mai Irwansyah B Siagian, Esra E Simatupang, dan Pianus Ddaki, dkk,2025). With this guarantee, the Government has a responsibility to protect citizens' health rights as a form of the state's commitment to improving public health (¹Farina Firda E dan Mie Susanto,2025).

In realizing national health in the cosmetic preparation sector, regulation, supervision, and law enforcement of cosmetic preparations are important points in ensuring legal certainty that the circulating cosmetic preparations are under the provisions and safe for health. In Indonesia, cosmetic preparations are the largest industrial sector, and this sector will always experience significant growth every year. Based on data submitted by the POM Agency, cosmetic preparations registered with the POM Agency reached a total of 50,909 in the past 5 years.

The 2023 Health Law states that every business actor that procures, produces, and/or distributes cosmetic preparations must meet standards and/or requirements, quality, and

quality in the form of a recognized cosmetic codex for cosmetic preparations (Law of the Republic of Indonesia No. 17 of 2023 concerning Health).. This is in line with the provisions in the 2019 POM Agency Regulation, which states that every business actor in the field of cosmetic preparations that procures, produces and distributes cosmetic preparations ensures that the cosmetic preparations meet the requirements of safety, usefulness, and quality in every manufacturing activity until circulation (Regulation of the POM Agency No.23 of 2019). Regarding the quality standards of cosmetic preparations in Indonesia, it is regulated in the 2021 POM Agency Regulation, which states that every cosmetics industry must implement the correct way of making cosmetics (CPKB) to ensure that the raw materials used meet the standards and quality requirements as raw materials for cosmetics, with the existence of a CPKB certificate.

Efforts to ensure that the raw materials used in cosmetic preparations meet the quality standards as raw materials for cosmetics are carried out by the Minister or the POM Agency in sampling and risk analysis testing activities carried out in management facilities owned by the Central Government and Regional Governments. In addition, the beauty industry can be said to have cosmetic preparations that are good if they have production permits and distribution permits. According to the Regulation of the Minister of Health in 2010, cosmetic preparations can only be circulated after having a production permit granted by the Directorate General. Meanwhile, the granting of distribution permits can only be granted after going through a notification process that meets technical requirements (Haya Alyssa S R, N.G.N Renti M Kerti, 2025).

Recently, in Indonesia, there have been widespread cases of cosmetic preparations containing harmful ingredients such as mercury (Hg), lead (Pb), *hydroquinone* and synthetic dyes (red K10). One of the driving factors for the large circulation of cosmetic preparations containing harmful ingredients is the development of technology. It is undeniable that the existence of e-commerce platforms has provided convenience in marketing and selling cosmetic preparations, but it is vulnerable to abuse by irresponsible business actors. Most of the distribution of cosmetic preparations containing harmful ingredients is marketed through e-commerce platforms without going through supervision from the POM Agency (Aprilia V Buloto, Fenti U Puluhulawa, Avelia R.Y.M,2025).

Based on data from *sampling* and testing activities based on risk analysis conducted by the POM Agency from September 2022 to June 2025, the POM Agency has found 272 cosmetic preparation products containing hazardous ingredients. The data, taken based on the notification of the POM Agency in a Press Release on [the https://www.pom.go.id/](https://www.pom.go.id/) website, conveyed the findings of cosmetic preparations containing harmful ingredients as follows:

1. Press Release No.HM.01.1.2.08.25.137 dated August 1, 2025, found as many as 34 cosmetic products containing harmful ingredients.
2. Press Release No.HM.01.1.2.04.25.100 dated April 22, 2025, found as many as 16 cosmetic preparations containing harmful ingredients.
3. Press Release No.HM.01.1.2.03.25.87 dated March 19, 2025, found as many as 6 brands of Tabita and Tabita Glow cosmetic preparations that contain harmful ingredients.
4. Press Release No.HM.01.1.2.12.24.108 dated December 30, 2024, found as many as 69 brands of cosmetic preparations containing harmful ingredients.
5. Press Release No.HM.01.1.1.12.24.99 dated December 3, 2024, found as many as 55 cosmetic preparations containing harmful ingredients
6. Press Release No.HM.01.1.2.12.23.50 dated December 8, 2023, found as many as 181 cosmetic preparations containing harmful ingredients.

Against the rampant circulation of cosmetic preparations containing harmful ingredients in Indonesia, the National Health System has an important role in supervising

cosmetic preparations and enforcing the law against business actors who violate laws and regulations on health and regulations of the POM Agency in the realization of justice, legal certainty, and benefits. The government, through the POM Agency, has full responsibility for supervising cosmetic preparations (Graciela A.P Ananda, 2024). Although the regulations regarding the supervision of the POM Agency have been regulated, in their implementation in the field, they still face obstacles due to limited human resources, a large supervision area, and the complexity of violations. This condition affects why there are still many cosmetic preparations circulating in the community (Rastiawaty, Ismail Alrip, 2024).

Quoted from the POM Agency website, the supervision carried out by the POM Agency includes *pre-market* and *post-market supervision*, whose procedures and mechanisms are as follows (Food and Drug Supervisory Agency (BPOM) 2023).:

a. Pre-market supervision (before the product is marketed).

This supervision is carried out before cosmetic preparations are allowed to be produced and distributed in Indonesia. In this supervision, an evaluation of safety, usefulness, and quality is first carried out. The purpose of this supervision is to provide complete and objective information to the public, to ensure that the use of these cosmetics is safe. The form of *pre-market supervision* carried out by the POM Agency includes certification and registration of cosmetic preparation products, inspection of cosmetic preparation permits from pharmacies, factories, and other facilities that produce cosmetic preparations, information services and public complaints, provision of education and training, and providing appeals to manufacturers, retailers, and the public regarding good and safe cosmetic preparation products.

b. Post-market supervision (after the product has been marketed).

This supervision is carried out by the POM Agency to monitor cosmetic preparation products that have been circulating, including their locations and production facilities. Post-market supervision is carried out through a process, namely: (i). Inspection of facilities and production sites of cosmetic preparations. (ii). Random sampling of cosmetic preparations circulating in the market for laboratory testing. Testing in the laboratory is carried out to determine whether the cosmetic preparation meets the quality standards that have been set in the applicable laws and regulations. This sampling will be intended as research data and to be used in determining whether the product has been standardized based on the requirements or not. If it does not meet the requirements, it is used as a basis for recalling products that are not suitable for distribution.

Furthermore, the National Health System also has an important role in enforcing the law against business actors who violate the principles of justice, legal certainty, and benefits in society. Law enforcement is a rule of law in a tangible form in the field. To create the law, an organizational structure is needed, starting from the courts, the prosecutor's office, the police, and correctional institutions, which are the core institutions of law enforcement formed by a state. According to Satjipto Rahardjo, law enforcement is a process to make legal wishes come true. The essence is that law enforcement is to realize values or rules that contain justice and truth, and it is not a task for law enforcers alone, but the participation of everyone (Rinneke Sara, Amalia C Damayanti and Reno Verne, et al., 2025).

The law enforcement process is an effort made to enforce the value system that already exists in the law itself. Values such as certainty, justice, and the correct usefulness of the law, so that there are no deviations from the true legal values (Podang Peksiadji, Yoyok Ucok, Ernu Widodo, 2025). Soerjono Soekanto stated that law enforcement is an activity of harmonizing the values contained in the applicable norms or rules with behavioral attitudes as a series of final-stage value elaboration to create, maintain, and enforce peace and tranquility in society (Asirah, Andi M Sofyan, Audyna M Muin, 2023).

In Indonesia, law enforcement against cosmetic preparations containing harmful ingredients is divided into 2 stages, namely *non pro Justitia* and *pro Justitia*, namely (Mohammad Eka Purwanto, 2024):

1. Tahap Non pro Justitia.

This law enforcement is carried out through *pre-market* (before market) and post-market (after the product is marketed) supervision, which is carried out by the POM Agency. In this law enforcement, business actors who violate the rules will be subject to administrative sanctions such as prohibition of product distribution, withdrawal from circulation, revocation of distribution permits, and confiscation for destruction.

2. Stages of Pro Justitia.

This law enforcement was carried out after a case of unlawful acts was found that was proven in the Police. In law enforcement at the *pro Justitia* stage is divided into two stages, namely:

- Investigation and non-investigation stages. At the investigation stage, the case submitted has been proven to be further processed by sending files from the Police to the Prosecutor's Office for trial at the District Court in accordance with *the locus delicti*. Seeing the still rampant circulation of cosmetic preparations containing harmful ingredients, existing law enforcement against business actors who commit cosmetic crime crimes is still ineffective and lacks a deterrent effect on business actors.
- Meanwhile, at the non-investigation stage. Business actors whose cases are proven but not considered will not be tried in court, but will be coached and/or given a stern warning letter issued by the Head of the Health Office. Business actors for this case are only sentenced to administrative sanctions or light fines. The considerations for determining whether to conduct an investigation or a non-investigation are:
 - a. The presence of malicious intent indicates that the cosmetics entrepreneur who committed the violation deliberately sold products containing harmful chemicals for financial gain. They may cover up information from the public about the risks of using the product.
 - b. The large volume of goods can influence the decision to conduct an investigation or not. If the amount of evidence is large, an investigation may be required to trace the networks of other perpetrators involved in the sale of cosmetic-specific pharmaceutical preparations containing harmful ingredients.

Law enforcement against the crime of cosmetic preparations containing dangerous ingredients in Indonesia is carried out by law enforcement officials based on laws and regulations that claim to be instruments in ensnaring perpetrators involved in criminal practices, such as:

- 1. Criminal Code (KUHP)** Article 196, which will take effect in 2026, regulates criminal sanctions for perpetrators who produce or distribute cosmetics that do not comply with applicable provisions with a penalty of up to 15 years in prison and a fine of Rp1.5 billion. In addition, Article 204 of the Criminal Code highlights the criminal act of fraud committed by perpetrators by misleading the public as consumers, which can be subject to imprisonment for up to four years. Article 386 of the Criminal Code is also relevant, particularly in cases where cosmetics harm users through untrue or misleading claims. The threat of punishment in this article is up to six years in prison.
- 2. Law of the Republic of Indonesia Number 17 of 2023 concerning Health** Article 435 of this law provides a threat of punishment of up to 12 years in prison and a maximum fine of Rp 5 billion for perpetrators who produce or distribute cosmetics that do not meet safety, benefit, and quality standards.

3. Law of the Republic of Indonesia Number 8 of 1999 concerning Consumer Protection.

Article 62 of the Consumer Protection Law, business actors who trade goods and/or services that do not comply with the required standards can be subject to imprisonment for a maximum of 5 years or a maximum fine of two billion rupiah.

Based on a search of criminal verdicts related to cosmetic crimes in Indonesia obtained from the Directory of the Supreme Court of the Republic of Indonesia, data was obtained that in 2023, the Court has decided 145 criminal cases of cosmetic crimes. For 2024 data, the Court decided 158 cases of cosmetic crimes, while in early 2025, there were 90 cases decided by the court. Based on the data of criminal case decisions related to cosmetic crimes, the punishment imposed on the perpetrators is relatively light, so that it does not have a deterrent effect on business actors and does not cause fear for business actors who violate the law. This shows that the law enforcement system in Indonesia is still weak, law enforcement should be a protector of public health rights.

Looking at the goal of the National Health System (SKN) is the implementation of health development by all components of the nation, in achieving the highest degree of public health. Seeing that the supervision and law enforcement of cosmetics that contain harmful ingredients still does not ensure public safety, it means that the health system has not been fully implemented.

Conclusion

The supervision of cosmetic preparations carried out by the POM Agency currently does not provide guarantees to the public that the cosmetic preparations in circulation are following the requirements and standards of safety and quality of cosmetic ingredients. Likewise, with law enforcement against cosmetic crimes still not having a deterrent effect on business actors and not causing fear, the national health system has not fully protected and provided legal certainty to the public for cosmetic preparations in circulation, according to the requirements and safety standards, and the quality of cosmetic ingredients.

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