

THE ROLE OF THE DRUG AND FOOD CONTROL AGENCY (BPOM) IN THE DISTRIBUTION OF COSMETICS THAT CONTAIN HAZARDOUS SUBSTANCES IN DENPASAR

Anak Agung Sagung Ngurah Indradewi¹⁾, Ni Made Muliati²⁾

¹⁾ Fakultas Hukum, Universitas Dwijendra
e-mail: sagungindradewi@gmail.com

²⁾ Fakultas Hukum, Universitas Dwijendra
e-mail: dekmuliati@gmail.com

ABSTRACT

Many cosmetics are emerging at this time, ranging from make-up equipment such as; lipsticks, powders, mascaras, whitening creams, lotions, etc., which are not balanced by the knowledge of consumers themselves in choosing good, safe, and comfortable cosmetics, as well as the lack of socialization done by the government or companies to the public about dangerous cosmetics on the market. There are a number of cosmetics that contain hazardous ingredients, including Medicinal Chemicals (BKO) that can harm the human body. Based on this background, the writers formulate the problem, namely first what is the role of the Food and Drug Control Agency (BPOM) in the distribution of cosmetics containing hazardous substances in the jurisdiction of Denpasar City. Second, what are the efforts and obstacles of the Food and Drug Control Agency (BPOM) in overcoming the distribution of cosmetics containing dangerous substances in the jurisdiction of Denpasar City. This research uses descriptive empirical legal research. The data source used comes from primary data obtained directly from the research location and secondary data is data obtained from document materials. The data collection technique that the writers use in this study is the snowball method. The data obtained were analyzed by descriptive qualitative. The conclusion of this study is the role of the Food and Drug Control Agency (BPOM) in the distribution of cosmetics containing hazardous substances in the jurisdiction of Denpasar City, that is BPOM supervised cosmetic products starting from the pre market and post market. BPOM's efforts and obstacles in overcoming the distribution of cosmetics were conducting socialization and education to the public, increasing supervision of cosmetic distribution, and taking action against those who distribute cosmetics containing dangerous ingredients, while the obstacle was that the distribution of cosmetics did not go through official channels, so the distribution routes were very wide and varied. Both online, offline, or personally, and cosmetics manufacturers containing dangerous ingredients were mostly illegal, who produced and distributed their products clandestinely or without official documents which made it difficult to trace the source of cosmetics containing dangerous ingredients.

Keywords: Role, Dangerous Cosmetics, BPOM

1. INTRODUCTION

Cosmetics are a form of secondary needs in people's lives. Based on Article 1 point 1 of the Regulation of the Minister of Health of the Republic of Indonesia Number 1176/MenKes/PER/VIII/2010 concerning Notification of Cosmetics, what is meant by "cosmetics are ingredients or preparations intended for use on the outside of the human body (epidermis, hair, nails, lips) and external genital organs) or the teeth and oral mucosa especially for cleaning, deodorizing, changing appearance and/or correcting body odor or protecting or maintaining the body in good condition. The definition of cosmetics, namely, Cosmetics in Greek, namely "kosmetikos" means the skill of decorating, while "kosmos" means decoration (Syarif M. Wasitaatmadja, 2007).

Based on Regulation of the Head of the POM RI Number 2 of 2014 concerning the Second Amendment to Regulation of the head of the POM Agency No. HK.03.1.23.08.11.07517 of 2011 concerning Technical Requirements for Cosmetic Ingredients, there are ingredients included in the list of hazardous materials that are prohibited for use in the manufacture of cosmetics. There are a few cosmetics that contain hazardous ingredients, including Medicinal Chemicals (BKO) that can harm the human body. The drug chemicals (BKO) include K3 red dye, K10 red dye, retinoic acid, mercury, antibiotic-type drugs, dekasamethasone, to hydroquinone.

Dangerous materials (Medicinal Chemicals) in cosmetics, namely medicinal chemicals whose use is prohibited in cosmetic raw materials, because they will damage the organs of the human body. Therefore, the use of medicinal chemicals containing hazardous substances in the manufacture of cosmetics is strictly prohibited. (<https://www.pom.go.id/new/view/more/pers/286>).

Moeljatno uses the term criminal act which he defines as an act that is prohibited by a rule of law, a prohibition which is accompanied by threats (sanctions) in the form of certain crimes, for anyone who violates the prohibition (Adami Chazawi, 2010). Ahmad Miru states that this allowed the distribution of cosmetics to meet market needs which became a business field for business actors, both cosmetics that have distribution permits from the government to those that do not have distribution permits. This is often used as a business area for business actors who have bad intentions due to the weak position of consumers because there is no balanced protection to protect the rights of consumers (2011: 1).

Based on initial data from the Food and Drug Control Agency (BPOM), there were 38 cases of cosmetic product findings containing hazardous substances in Denpasar City in 2019-2021.

In connection with efforts to improve consumer protection and supervision of goods and/or services traded, the Food and Drug Control Agency (BPOM) seeks to make efforts to supervise and warn business actors not to sell cosmetics containing hazardous ingredients and the Food and Drug Control Agency (BPOM) will withdraw harmful cosmetics from the market. The Food and Drug Control Agency (BPOM) carries out supervisory activities which are divided into two, namely inspection and investigation (Gunawan Widjaja and Ahmad Yani, 2000:29).

Criminal law enforcement is an attempt to realize the desires of criminal law into reality, namely criminal law according to Van Hammel is the entire basis or rules adopted by the state in its obligation to enforce the law, namely by prohibiting what is contrary to the law (on recht) and wearing sorrow. (suffering) to those who violate these violations (Sudarto, 2006: 80).

Based on the background of the problem as stated above, several problems can be formulated, including:

- 1) What is the role of the Food and Drug Control Agency (BPOM) in the distribution of cosmetics containing hazardous substances in the jurisdiction of Denpasar City?
- 2) What are the efforts and obstacles of the Food and Drug Control Agency (BPOM) in overcoming the circulation of cosmetics containing dangerous substances in the jurisdiction of Denpasar City?

2. RESEARCH METODOLOGY

The type of research used is empirical legal research (field research) which of course focuses on the behavior of the legal community (law in action). As supporting data from field research that the author did which in this research will be carried out at BPOM Denpasar.

The nature of the research, that this research is descriptive in nature, namely this research precisely describes the characteristics, symptoms with other symptoms in society. Data and data sources come from primary and secondary data, the primary data is data from the field and interviews while the secondary data is primary legal material, which comes from books related to research, while secondary legal material comes from statutory regulations, namely: Laws The 1945 Constitution of the Republic of Indonesia, the Law of the Republic of Indonesia Number 8 of 1999 concerning Consumer Protection, the Regulation of the Minister of Health of the Republic of Indonesia Number 1176/MENKES/PER/VIII/2010 concerning Osmetic Notifications, the Regulation of the Minister of Health Number 472/Menkes/Per/ V/1996 concerning Safeguarding Materials Hazardous to Health. Data collection techniques are carried out using the snowball method. Techniques Analysis and processing of data are carried out by systematizing existing legal materials and systematizing in this case means classifying primary, secondary and tertiary legal data to facilitate analysis work.

3. RELATED RESEARCH/LITERATUR REVIEW

Based on the results of searching the results of previous research and searching some of the literature that has relevance to the research in question, it is hoped that it can provide inspiration for the research conducted. Research on the Role of the Food and Drug Control Agency (BPOM) in the Distribution of Cosmetics Containing Hazardous Substances in the City of Denpasar has never been carried out. The literature review that supports this research is as follows. (Ahmad Miru: 2011) states that the circulation of cosmetics to meet market needs is a business field for business actors, both cosmetics that have a distribution permit from the government to those that do not have a distribution permit, this is often used as a business area for business actors who have bad faith due to a weak consumer position due to the absence of balanced protection to protect the rights of consumers. (Indradewi: 2014) states that economic development is characterized by a flood of various products and/or services to meet the needs of the consumer community, with economic development and increasing lifestyles. Life is getting faster and advances in technology and science have led to rapid changes in cosmetic products. (Celina Tri Siwi Kristiyanti 2018). The Food and Drug Control Agency (BPOM) is an institution in Indonesia that is tasked with supervising the distribution of medicines and food in Indonesia. The functions and duties of this agency resemble those of the Food and Drug Administration (FDA) in the United States.

4. RESULTS AND DISCUSSION

The Role of BPOM in Supervising the Distribution of Cosmetics Containing Dangerous Substances

Regarding control and distribution, it cannot be separated from the word illegal, which means illegal according to the legal dictionary, namely illegal, not based on applicable laws and regulations, contrary to law (Sudarsono, 2015: 12). Monitoring of distribution has broad problems, tends to be complex, and it is a shared responsibility between the government, society as consumers, and business actors. The participation of the community and business actors in supervision is important and needs to be increased. One of the efforts made by the government to monitor and protect public health was the establishment of the Food and Drug Control Agency (BPOM).

An effective and efficient Drug and Food control system (SisPOM) capable of detecting, preventing, and controlling products with the aim of protecting the security, safety and health of consumers both at home and abroad. For this reason, the POM Agency has been formed which has national and international networks as well as law enforcement authority and has high professional credibility.

Supervision carried out by BPOM covers very broad aspects, starting from the process of preparing product and facility standards, evaluating registered products and issuing a Distribution Permit Number (NIE), supervision of marking and advertising, taking and testing of product samples in circulation/facilities of distribution, inspection of production and distribution facilities, supervision of illegal/counterfeit products, up to initial investigations and law enforcement processes against various parties who violate production and distribution methods, as well as distribution of products that do not comply with applicable regulations.

Supervision is the entire process of evaluating the company, with the aim that the company carries out its functions properly and succeeds in achieving its stated goals (Tausasa Editorial Team, 2009: 409). In terminology, supervision is often equated with the term or word "control", "supervision", "monitoring" or "auditing". In the context of the legislature, the word "supervision" is rooted in "oversight" which means observation and direction of an action based on the specified regulatory framework (Putra Erawan, 2014: 8). Supervision is a series of activities to assess by comparing the actual situation with the actual situation (Mufham Al-Amin, 2006:49). Almost the same opinion means that supervision is the process of observing the implementation of all government activities to ensure that all the work being carried out goes according to a predetermined plan (Sujamto, 2006: 15). The participation of the community and business actors in supervision has important meaning and needs to be improved.

According to the Superintendent of Pharmacy and Food, an expert in Denpasar City, November 8, 2022, he said that BPOM's role is in overseeing the distribution of cosmetics containing dangerous substances, namely that BPOM supervises cosmetic products starting from the premarket and post market.

1. Pre-market supervision is carried out through the certification of production facilities that will register/register their products with BPOM and at the time of registration of cosmetic products through a notification system.
2. Post-market supervision is carried out through supervision of cosmetic production and distribution facilities, sampling and testing as well as label evaluation and monitoring of advertisements in circulation (Interview: Kadek Darsini).

Based on the explanation from the Pharmacy and Food Supervisor, on November 8, 2022, in supervising the distribution of cosmetics containing dangerous substances, BPOM conducts supervision by:

- a. Entering any place that is suspected to be used in the production, storage, transportation, and trade of cosmetics to inspect, examine and take samples of everything used in the activities of manufacturing, storage, transportation and trading of cosmetics.
- b. Opening and examining cosmetic packaging; and/or
- c. Examine documents or other records that allegedly contain information regarding the activities of manufacturing, storage, transportation, and trading of cosmetics, including duplicating or quoting the information (interview: Anak Agung Istri Puspitayani).

The Drug and Food control system organized by the Food and Drug Control Agency (BPOM) is a comprehensive process, covering pre-market and post-market supervision, namely:

1. Standardization which is the function of formulating standards, regulations and policies related to drug and food control. Standardization is carried out centrally, intended to avoid differences in standards that might occur because of each province establishing its own standard.
2. Assessment (pre-market) which is product evaluation before obtaining a distribution permit number and finally it can be produced and distributed to consumers. The assessment is carried out centrally, so that products that have distribution permits apply nationally
3. Supervision after circulation (post-market) to see the consistency of product quality, safety and product information is carried out by sampling Drug and Food products in distribution, as well as inspection of Drug and Food production and distribution facilities, monitoring of pharmacovigilance and supervision of labels/marketing and advertisements. Post-market supervision is carried out nationally and is integrated, consistent and standardized. Post-market supervision is carried out nationally and is integrated, consistent and standardized. This supervision involves the Drug and Food Control Agency (BPOM) in 33 provinces and areas that are difficult to reach/borders carried out by the Food and Drug Monitoring Post.
4. Laboratory testing, products that are sampled based on risk are then tested through a laboratory to find out whether the Medicines and Food meet the safety, efficacy/benefits, and quality requirements. The results of this laboratory test are the scientific basis used to determine products that do not meet the requirements to be withdrawn from circulation
5. Law enforcement in the field of drug and food control. Law enforcement is based on evidence from tests, examinations, and initial investigations. The process of law enforcement up to projusticia can end with the imposition of administrative sanctions such as being banned from distribution, withdrawn from circulation, revoked distribution permit, confiscated for destruction.

Pasal 2 Peraturan Kepala BPOM Nomor 14 Tahun 2014 tentang Article 2 Regulation of the Head of BPOM Number 14 of 2014 concerning the Organization and Work Procedure of the Technical Implementation Unit (UPT) within the Food and Drug Supervisory Agency stipulates that the UPT has the task of implementing policies in the field of drug and food control, which includes supervision of therapeutic products, narcotics, psychotropics, addictive substances, traditional medicines, cosmetics, complementary products as well as supervision of food safety and hazardous substances. Then in this study specifically discusses cosmetics that contain harmful substances.

The increasing demand for cosmetics makes manufacturers compete to make and sell cosmetics without paying attention to the ingredients contained therein. Consumers do not seem to get important knowledge about the dangers and consequences that arise when using cosmetics at random without looking at the ingredients and the ingredients contained in these cosmetics.

From 2019-2021, several findings by the Denpasar City of BPOM related to cosmetics containing hazardous substances can be submitted, namely: in 2019 there were 13 cases, in 2020 there were 6 cases, in 2021 there were 19 cases. Based on this data, violations from 2019-2020 decreased, then violations in 2020-2021 increased violations found by BPOM.

Based on Article 8 paragraph (1) of Law No. 8 of 1999 concerning Consumer Protection, it regulates the prohibition of business actors who do not meet or do not comply with the standards required by the provisions of laws and regulations. In terms of the right to food security, which can be seen from the food samples tested, it shows that business actors have committed acts against the law, so if you encounter conflicting business actor actions, it is important to enforce the law.

The Efforts of the Food and Drug Control Agency (BPOM) in Overcoming the Circulation of Cosmetics Containing Dangerous Substances in the Legal Area of Denpasar City.

Behavior that is inconsistent with the norms in society or can be referred to as a deviation from agreed norms can disrupt order and peace in human life (Dewi, A. M. A. T.: 2021). This deviation is usually labeled by society as a violation or even a crime. Crime in human life is a social phenomenon that is always faced by humanity, society, and even the state (Bambang Waluyo: 2014: 1-2).

Distribution of cosmetics is an activity, or a series of activities aimed at transferring, distributing cosmetics. So those who have the right to distribute cosmetics are only certain people who already have a permit. To get a permit as a legal cosmetic product from BPOM must go through a process. Legalization here can mean that the cosmetic product is safe and suitable for use. To obtain a permit, the entrepreneur and the person who administers the cosmetic permit must submit a cosmetic notification to the Food and Drug Control Agency. (Indradewi, A. A. S. N., & Astiti, K. F. S.: 2022: 265-274).

According to G.P. Hoefnagels crime prevention efforts can be broadly divided into two, namely (Barda Namawi: 2010: 46)

- 1) Penal Pathway (Repressive)
Countermeasures through the penal route can also be referred to as efforts made through the criminal law route.
- 2) Non-penal (Preventive) Pathway
This effort is a countermeasure effort that focuses more on preventive properties, namely actions in the form of prevention before a crime occurs.

Based on the writer's analysis coping theory, namely the role of the Denpasar City BPOM in the distribution of cosmetics containing dangerous substances, is included in preventive or non-penal efforts where BPOM acts as a supervisor and if it is proven from the results of supervision that violations are found, then they are delegated to the authorized party to impose sanctions, in this case, it is in the form of penal or law enforcement efforts.

To avoid the negative consequences of using goods and or services, Law number 8 of 1999 concerning Consumer Protection determines various prohibitions for business actors which are regulated in 10 articles. Law number 8 of 1999 concerning Consumer Protection stipulates that the objective of

consumer protection is to elevate the dignity of the consumer's life. For this purpose, various things that have negative consequences from the use of goods and or services must be avoided from the trading activities of business actors.

As an effort to avoid the negative consequences of using these goods and/or services, the law determines various prohibitions as follows: Pursuant to Article 8 of Law number 8 of 1999 concerning Consumer Protection, states that:

- 1) Business actors are prohibited from producing and/or trading goods and/or services that:
 - a). does not meet or does not comply with the required standards and provisions of laws and regulations, b). not in accordance with the net weight, net or net content, and the amount in the count as stated on the label or etiquette of the said goods, c). not in accordance with the size, measure, weight, and amount in the calculation according to the actual size, d). not in accordance with the conditions, guarantees, features, or efficacy as stated in the label, etiquette, or description of the goods and/or services, e). not in accordance with the quality, grade, composition, processing, style, mode, or certain uses as stated on the label or description of the goods and/or services, f). not in accordance with the promise stated in the label, etiquette, description, advertisement, or sales promotion of the said goods and/or services, g). does not include expiration date or period for the best use or utilization of certain goods. h). does not comply with the provisions for producing in a halal manner, as stated in the statement "halal" contained in the label, i). does not put a label or make an explanation of the goods which contains the name of the goods, size, net or net weight/content, composition, rules of use, date of manufacture, side effects, name and address of the business actor and other information for use which according to the provisions must be installed/made, j). does not include information and/or instructions for the use of goods in the Indonesian language in accordance with the provisions of the applicable laws.
- 2) Business actors are prohibited from trading damaged, defective, or used, and tainted goods without providing complete and correct information on the goods in question,
- 3) Entrepreneurs are prohibited from trading damaged, defective, or used and contaminated pharmaceutical and food preparations, with or without providing complete and correct information,
- 4) Business actors who commit violations in paragraphs (1) and (2) are prohibited from trading the said goods and/or services and are required to withdraw them from circulation.

To avoid the negative consequences of using goods and or services, Law number 8 of 1999 concerning Consumer Protection determines various prohibitions for business actors which are regulated in 10 articles. Law number 8 of 1999 concerning Consumer Protection stipulates that the objective of consumer protection is to elevate the dignity of the consumer's life. For this purpose, various things that have negative consequences from the use of goods and or services must be avoided from the trading activities of business actors. The results of supervision are used as a basis for law enforcement, to protect the public from the use of cosmetics that do not meet the terms and conditions.

- 1) Pre-emptive Efforts.
Pre-emptive efforts made by the Food and Drug Control Agency in Denpasar to increase effectiveness in controlling business actors who are still trading cosmetics containing hazardous substances are to routinely conduct socialization and strengthen public information services through print media, electronic media, advertisements, brochures, billboards, or other social media that aims to increase knowledge and awareness about the dangers of cosmetics containing these dangerous substances.

- 2) Preventive Efforts.
Preventive efforts carried out by the Food and Drug Control Agency are conducting regular raids and inspections of places that are considered prone to becoming locations for illegal cosmetic trade so that their presence can be eliminated from society. *Upaya Represif*.
- 3) Repressive Effort
The repressive effort being made is that currently BPOM is trying to lobby the DPR to make a new regulation regarding legal sanctions which can really create a deterrent effect for actors who produce or distribute illegal cosmetics, so that no more perpetrators are only given mandatory reporting sanctions.

Based on the opinion of the Coordinator of the Examination Substances Group on November 8, 2022, he said the efforts made by BPOM to reduce the occurrence of the circulation of cosmetics containing dangerous substances in the Denpasar City area, namely by conducting outreach and education to the public and increasing supervision of the distribution of cosmetics.

- a. Conduct socialization and education to the community
- b. Increasing supervision of cosmetic distribution (interview: Desak Ketut Andika Andayani).

The results of supervision are used as the basis for law enforcement. However, in BPOM's duties there are obstacles from BPOM in overseeing the distribution of cosmetics containing dangerous substances, namely:

- a. Distribution of cosmetics does not go through official channels, so the distribution channels are very wide and varied, both online, offline and in person.
- b. Manufacturers of cosmetics containing hazardous materials, mostly illegal, who produce and distribute their products clandestinely or without official documents, which makes it difficult to trace the source of cosmetics containing hazardous materials.

The results of an interview with, as the Supervisor of Pharmacy and Food, a Madya expert in the City of Denpasar on 8 November 2022, there are several obstacles in handling and preventing the distribution of cosmetics, as follows:

- a. Several cosmetics containing hazardous materials have received a notification number from the POM Agency, even though after the test results contained hazardous materials the product notification number was canceled or even included in the POM Public Warning.
- b. Information regarding the cancellation of notification and public warning numbers did not reach all levels of society. (Interview: Ni Kadek Darsini).

Based on an interview with the Pharmacy and Food Supervisor, November 8, 2022, the obstacles experienced by BPOM came from within (internal) and from outside (external).

1. Internal Barriers

The internal obstacle experienced by BPOM is the limited funds owned by BPOM to control the distribution of BPOM-registered dangerous cosmetics circulating in the community.

2. External Barriers

The external obstacle experienced by BPOM, namely the recognition of Business Actors or Shop Owners. Business actors who do not care and do not comply with applicable legal provisions are especially related to people who use these face cream products when the Denpasar City Health Office already knows that the cosmetics or face creams contain hazardous ingredients, the factory or shop that sells them does not want to make it public that the business actor sells cosmetics or face creams which can be detrimental to society in a long-term effect. (Interview: Anak agung Istri Puspitayani).

Based on the results of the interview with the Substance Inspection Group Coordinator, he said that the distribution of cosmetics containing hazardous substances was difficult to complete because:

- a. There is still consumer demand for cosmetics containing hazardous ingredients because
- b. the beauty effect is faster, while the adverse health effects are not directly felt by consumers and there is a lack of public awareness of the dangers of cosmetics containing hazardous materials.
- c. Not all business actors know the information/list of cosmetic products that contain hazardous ingredients or are withdrawn from circulation.
- d. The sanctions given have not provided a deterrent effect when compared to the economic benefits obtained by the perpetrators (interview: Desak Ketut Andika Andayani). This is because the content of hazardous materials can only be detected by laboratory testing.

5. CONCLUSION

The role of the Food and Drug Control Agency (BPOM) in the distribution of cosmetics containing hazardous substances in the jurisdiction of Denpasar City is to supervise cosmetic products starting from the pre market and post market. Where pre-market supervision is carried out through certification of production facilities that will register/register their products with BPOM as well as when registering cosmetic products through a notification system. As well as post-market supervision is carried out through supervision of cosmetic production and distribution facilities, sampling and testing as well as label evaluation and monitoring of advertisements in distribution.

The efforts and obstacles of the Food and Drug Control Agency (BPOM) in overcoming the distribution of cosmetics containing dangerous substances in the jurisdiction of Denpasar City, namely by conducting socialization and education to the public and increasing supervision of the distribution of cosmetics, by conducting outreach and educating the public, increasing supervision circulation of cosmetics, as well as prosecution of facilities that distribute cosmetics containing dangerous substances such as imposition of sanctions and further prosecution, while the obstacles from BPOM in supervising the distribution of cosmetics containing dangerous substances, namely: that distribution of cosmetics does not go through official channels, so that the distribution channels are very wide and various, both online, offline, and in private, and cosmetic manufacturers containing dangerous ingredients are mostly illegal, who produce and distribute their products clandestinely or without official documents which make it difficult to trace the source of cosmetics because contain hazardous materials.

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Hasil Wawancara

Wawancara dengan Ni Kadek Darsini selaku Pengawas Farmasi dan Makanan ahli Madya Kota Denpasar pada tanggal 8 Nopember 2022 pukul 09.00 wita.

Wawancara dengan Anak Agung Istri Puspitayani selaku Pengawas Farmasi dan Makanan pada tanggal 8 Nopember 2022 pukul 11.00 Wita

Wawancara dengan Desak Ketut Andika Andayani selaku Koordinator Kelompok Substansi Pemeriksaan, pada tanggal 8 Nopember 2022 pukul 13.00 Wita