

Legal Analysis of Doctors' Authority in Cosmetic Manufacturing

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Abstract

This research aims to find out about the regulations for dispensing cosmetics in Indonesian law. This is related to the use of cosmetics which has become a part and cannot be separated from human life. Cosmetics are used as care products to maintain health and beautify oneself, the development of cosmetics is also very fast. This is proven by the emergence of various types of cosmetics, ranging from traditional cosmetics that use natural ingredients to modern cosmetics made with today's advanced technology. With this diverse choice, cosmetic consumers prefer cosmetic products formulated by doctors at beauty clinics on the basis of feeling comfortable and safe in their use. However, in its development, a doctor's authority has been questioned in dispensing cosmetics. If the cosmetics prepared by the doctor cause harm to consumers, what can consumers do? This research is normative research. The result of this research is that doctors do not have the authority to mix cosmetics. The cosmetic compounding process may only be carried out by pharmaceutical personnel consisting of Pharmacists and Pharmaceutical Technical Personnel. So, if consumers feel they have been harmed, they can file a lawsuit claiming an unlawful act, which is based on the Consumer Protection Law.

Keywords: Mixed Cosmetics; Beauty clinic; Doctor; Consumer protection

1. INTRODUCTION

The legal framework in Indonesia that regulates cosmetics and consumer protection is quite comprehensive. Law Number 8 of 1999 concerning Consumer Protection is the foundation that guarantees consumer rights, including the right to correct and honest information and the right to receive compensation for losses resulting from the consumption of goods or services. In addition, the Republic of Indonesia food and drug Supervisory Agency (BPOM) Regulation Number 21 of 2019 specifically regulates the registration and supervision of cosmetics circulating in Indonesia, ensuring that every cosmetic product sold meets the specified safety standards. Meanwhile, the responsibilities of medical professionals, including in the context of cosmetology, are regulated in Law Number 29 of 2004 concerning Medical Practice, which explains the standards that doctors must adhere to in carrying out their medical practice. Furthermore, further provisions regarding medical service standards can also be found in regulations issued by the Ministry of Health and medical professional organizations. Cosmetics have been one of the main needs of women since ancient times, this started about twelve thousand years ago when the Ancient Egyptians discovered the healing effects of perfume, from this point on the cosmetics industry rose to a higher level and became an important part of the nation's beliefs. Ancient Egypt. Cosmetics are used as care products to maintain health and beautify oneself, so the development of cosmetics is considered very fast. This is proven by the emergence of various types of cosmetics, ranging from traditional cosmetics that use natural ingredients to modern cosmetics made with today's advanced technology. The definition of cosmetics is regulated in the Regulation of the Minister of Health of the Republic of Indonesia No. 445/ MenKes/Permenkes/1998 concerning Ingredients, Colorants, Substratum, Preservatives and Sunscreen in Cosmetics, namely Cosmetics are preparations or mixtures of ingredients that are ready to be used on the outside of the body (epidermis, hair, nails, lips and genital organs external parts), teeth and oral cavity to clean, increase attractiveness, change appearance, protect it so that it remains in good condition, improve body odor but is not intended to treat or cure a disease. The definition of cosmetics is then contained in 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, Cosmetics are materials or preparations intended for use on the outside of the human body (epidermis, hair, nails, lips). and external genital organs) or teeth and oral mucosa, especially to clean, perfume, change the appearance and/or improve body odor or protect or maintain the body in good condition. The definition of cosmetics according to Retno Iswari T. is ingredients or a mixture of ingredients to be rubbed, attached, sprinkled, sprayed, inserted or poured on the body or parts of the body with the aim of cleaning, maintaining, increasing attractiveness or changing the appearance and is not included in the class of drugs. When referring to the definition contained in the Republic of Indonesia Minister of Health Regulation no. 445/ MenKes/Permenkes/1998 cosmetics are preparations or combinations of ingredients that are ready to be used on the outside of the body (epidermis, hair, nails, lips and external genital organs), teeth and oral cavity to clean, increase attractiveness, change appearance, protects to stay in good condition, improves body odor but is not intended to treat or cure a disease." The term doctor-mixed cosmetics is intended for cosmetics that are specifically formulated by doctors and sold at beauty clinics, not cosmetics that are sold freely on the market.

The emergence of various kinds of cosmetics available on the market means that consumers are faced with many choices of cosmetics, each with its own type and properties. Conditions like this require consumers to be more selective in choosing which cosmetics to use, whether the cosmetics are safe to use, whether the cosmetics cause side effects. Questions that arise like this, and the lack of knowledge that consumers have about cosmetics, make them very careful in choosing the cosmetics to use. To answer this uncertainty, consumers have an alternative, namely by using cosmetics specially formulated by a beauty doctor. Cosmetics formulated by doctors also vary, but facial care creams such as whitening cream have recently become the choice of women. This is of course to get a perfect appearance on the face. Apart from comfort and safety reasons, low prices are also the main factor in choosing a doctor's cream when compared to well-known brand cosmetic products. "Cream is a semi-solid preparation containing one or more cosmetic ingredients dissolved or dispersed in a suitable base material, in the form of a thick emulsion containing not less than 60% (sixty percent) water intended for external use." The existence of beauty clinics is an option for people to get the cosmetics formulated by doctors that they want. Beauty clinics provide a variety of cosmetics and facial treatments. To get cosmetics or treatments that suit facial conditions, consumers are provided with doctor services provided by beauty clinics. The role of doctors at beauty clinics is to provide consultations on beauty problems experienced by consumers by providing appropriate beauty care solutions. Without a doctor and consultation at a beauty clinic, consumers are often confused about choosing cosmetics and the type of treatment, because the treatment they choose may not suit the beauty condition they are experiencing. The cosmetics provided are often cosmetics in the form of creams that are formulated by doctors themselves and provided by beauty clinics. However, because consumer trust in doctors is very high, consumers often don't care whether a doctor has the competence to mix their own cosmetics. Consumers often assume that cosmetics formulated by doctors have a higher level of safety than other cosmetics on the market. Even though consumers have the right to know information about the raw materials for making cosmetics formulated by doctors as regulated in Article 4 letter c of Law no. 8 of 1999 concerning Consumer Protection that consumers have the right to correct, clear and honest information regarding the condition and guarantee of goods and/or services. The Consumer Protection Law also regulates consumer rights, namely those regulated in Article 4 letter a of the Consumer Protection Law which determines that consumers have the right to comfort, security and safety in consuming goods and/or services. In the Regulation of the Head of the Food and Drug Supervisory Agency of the Republic of Indonesia Number HK.00.05.4.3870 concerning Guidelines for Good Cosmetic Manufacturing Methods, it is stated that personnel who work in the cosmetics industry must have knowledge, experience, skills and abilities that are appropriate to their duties and functions, and are available in sufficient quantities. They must be in good health and able to handle the tasks assigned to them.

It is also stated that all personnel directly involved in manufacturing activities must be trained in carrying out manufacturing in accordance with the principles of Good Manufacturing Practices. So if doctors who mix cosmetics are linked to this regulation, doctors provided by beauty clinics are also required to undergo training in accordance with the guiding principles for good cosmetics manufacturing. If doctors are not given training before dispensing cosmetics, then the doctor will not only violate statutory regulations, but there are concerns that the cosmetics that are formulated will cause harm to consumers. Fulfilling the requirements for doctors to take training in dispensing cosmetics is a manifestation of fulfilling Article 7 letter d of Law Number 8 of 1999 concerning Consumer Protection, namely that business actors are obliged to guarantee the quality of goods and/or services produced and/or traded based on the provisions on quality standards for goods and/or or applicable services. One case of cosmetic doctors causing harm to cosmetic occurred in 2013, this was experienced by a woman with the initials BB. Before doing facial treatment and using BB facial cream it was

fine but the next day, BB found several red spots on her face. The clinic said that this was a reaction on BB's face due to sensitive skin. Because he was afraid, BB consulted with doctor 1 who worked at the clinic. The doctor said that the spots were ordinary acne, but it turned out that the cream given by the doctor had expired and actually made BB's skin condition worse. When BB went to doctor 2, BB found out that the acne she was suffering from was not ordinary acne and the ingredients in the cream could worsen BB's skin condition.

2. METHODOLOGY

The normative juridical research method in the research entitled "Judicial Review of Doctors' Authority in Dispensing Cosmetics" was carried out through several systematic steps. First, this research identifies and examines laws and regulations that are relevant to doctors' authority in dispensing cosmetics, including but not limited to the Medical Practice Law, Health Law, and other related regulations. Second, an analysis of legal doctrine and theory related to medical practice and cosmetic regulation is carried out, to understand the legal basis and limits of doctors' authority in this context. Apart from that, this research also examines relevant jurisprudence or court decisions, to see how the law is applied in real cases related to the authority of doctors in dispensing cosmetics. This analysis aims to identify legal gaps or contradictions in existing regulations and their implications for medical practice and the cosmetics industry.

3. RESULTS AND DISCUSSION

Legality of Doctors in Dispensing Cosmetics

Law No. 17 of 2023 concerning Health presents a new framework for the regulation of health practices in Indonesia, including medical practices. With this law, the definition and scope of medical practice, including the competence and authority of doctors in dispensing cosmetics, has undergone significant normative changes. According to article 1 paragraph (6) Medical Personnel is every person who dedicates themselves to the field of Health and has a professional attitude, knowledge and skills through medical or dental professional education who requires authority to carry out Health Efforts. Medical personnel are defined as individuals who are dedicated to the health sector with professional attitudes, knowledge and skills obtained through medical or dental education, with the authority to carry out health efforts. This designation does not explicitly define doctors, but emphasizes broad professional competence in the health sector. Article 182 paragraph (2) Medical Personnel and Health Personnel as referred to in paragraph (1) include Medical Personnel who have competence in the field of family medicine and Health Personnel who have competence in the field of community health. expands the definition of medical personnel and health workers to include those who have competence in the fields of family medicine and community health, indicating that this law recognizes and respects specialization and sub-specialization in health practice. This provides a framework for doctors to develop competence in various fields, including potential in dispensing and offering cosmetic products, as long as this is in accordance with relevant education, training and professional standards.

Article 173

(1) Health Service Facilities are required to:

- a. provide broad access to service needs, education, research and service development in the Health sector;
- b. providing quality health services and prioritizing patient safety;
- c. maintain medical records;
- d. send reports on the results of services, education, research and development to the Central Government with a copy to the Regional Government via the Health Information System;
- e. make efforts to utilize the results of services, education, research and development in the Health sector;
- f. integrating services, education, research and development in a system as an effort to overcome health problems in the region; and
- g. create standard operational procedures by referring to Health Service standards.

Article 173 regulates the obligations of health service facilities, which include providing broad access to services, education, research and development in the health sector, as well as emphasizing quality health services and patient safety. This indirectly supports the development and use of innovation in medical practice, including in the field of cosmetics, as long as it meets established operational standards and prioritizes patient safety. Law No. 17 of 2023 also stipulates that all matters that have not been regulated in this law will be further regulated in Government Regulations. This opens up opportunities for the government to develop more specific regulations regarding the practice of dispensing cosmetics by doctors, including the requirements, procedures and limits that must be complied with to ensure the safety, efficacy and quality of cosmetic products offered to the public. In

the context of the legality of doctors in dispensing cosmetics, more detailed and specific regulations are needed to bridge the gap between medical competence and practical needs in providing safe cosmetic products. This regulation must consider aspects of training, certification, and inter-professional collaboration, such as between doctors and pharmacists, to ensure that the cosmetic products formulated not only meet aesthetic needs but also strict health standards. Article 1 Paragraph (27) Registration is the official recording of Medical Personnel and Health Personnel which have a competency certificate and/or professional certificate. Paragraph (28) Registration Certificate, hereinafter abbreviated as STR, is written evidence given to Medical Personnel and Health Workers who have been registered. And in paragraph (29) Practice Permit Letter, hereinafter abbreviated as SIP, is written evidence given to Medical Personnel and Health Personnel. as a grant of authority to carry out practice.

Therefore, in carrying out cosmetic dispensing activities, there needs to be legality which guarantees that the activities carried out by the doctor do not constitute an unlawful act. This is one way of fulfilling consumer rights, namely the right to obtain comfort when using cosmetic products formulated by doctors. Apart from fulfilling consumer rights, the legality of dispensing is needed by doctors so that doctors do not violate the provisions of Article 8 paragraph (1) letter a of the Consumer Protection Law. If cosmetics are formulated by a doctor who does not have the requirements as regulated in PP No. 51 of 2009 concerning Pharmaceuticals, then this can be said to be producing and/or trading goods that do not meet or are not in accordance with the required standards and provisions of statutory regulations. Generally, doctors who work in beauty clinics have the title Sp.KK, which stands for Skin and Venereology Specialist. There are also specialist doctors who are more concentrated in the field of beauty and cosmetics. Doctors who are more concentrated in the field of beauty and cosmetics must receive special training as intended in Article 1 point 8 of the Indonesian Medical Council Regulation Number 6 of 2011 concerning Registration of Doctors and Dentists which states that an Additional Qualification Certificate is a letter of recognition of the additional abilities of a Doctor/ Dentists in order to strengthen certain competencies to carry out Medical Practice throughout Indonesia which are published by the relevant Collegium after completing education and/or training in the context of lifelong learning. Furthermore, Article 1 number 14 of the Indonesian Medical Council Regulation Number 6 of 2011 concerning Registration of Doctors and Dentists also states that Continuous Education and Training Programs are education and training programs organized by Professional Organizations and other institutions that are accredited by Professional Organizations in order to absorb developments medical/dental science and technology. One of the trainings in Indonesia is provided by the Medical Aesthetics Institute (Lemdik) founded by Anggi Y. Utami which has been accredited by the Indonesian Doctors Association (IDI) and the Jakarta Provincial Government. This institution provides Medical Beauty and Aesthetics Courses, namely training and skills that combine medical knowledge with artistic skin beauty procedures. 11 This training can be attended by doctors and general public who want to learn and practice the basics of skin beauty, how to use beauty tools, and basic knowledge about concocting beauty creams and others. 12 Participants who take the full course will receive a 'Basic to Advance Medical Aesthetic' national education certificate.

The training received by the doctor still does not provide legality for the doctor to mix cosmetics. This training serves to obtain an additional qualification certificate as a letter of recognition of a doctor's additional abilities in order to strengthen certain competencies for carrying out medical practice. So that the activity of dispensing medicines remains the competence of pharmaceutical staff in accordance with Republic of Indonesia Government Regulation Number 51 of 2009 concerning Pharmaceutical Work. General Chairperson of the Association of Indonesian Dermatology and Venereology Specialists (Perdoski) for the 2014-2017 period, Syarief Hidayat, stated that in fact there is no term 'aesthetic doctor'. The term 'aesthetic doctor' is used by general practitioners who take short-term courses abroad to learn certain procedures, such as laser or botox. These courses are not obtained through formal education. This is different from the Sp.KK degree which is obtained through formal education. Skin and genital specialist doctors and general practitioners have their respective competencies which are regulated in the Indonesian Doctor Competency Standards (SKDI). Every action carried out by a doctor must refer to the SKDI, if they carry out actions outside their competence, it can be said to be malpractice. The Association of Indonesian Dermatology and Venereology Specialists (Perdoski) also does not have the authority to take action or prohibit this. What Perdoski can do is make a report if there are doctors who practice outside their competence. The authority to take action or prohibit it lies with the Health Service.

Rights and Obligations of Beauty Clinics as Business Actors

The Consumer Protection Law was formed with several considerations, including because the legal provisions to protect the interests of consumers in Indonesia at that time were still inadequate, so there was a

need for legislative regulations to create a balance between protecting the interests of consumers and business actors in order to create a healthy economy. Considering that consumers are in a weaker position than business actors in all aspects, starting from the number of consumers being greater than business actors, to the use of economic principles by business actors, namely as little capital as possible to obtain maximum profits, it is feared that this could lead to unfair competition. healthy to the detriment of consumers. Therefore, the Consumer Protection Law does not only regulate consumers, but also regulates business actors, especially in terms of the rights and obligations between consumers and business actors in order to provide balance between the two. This is in line with the fact that products in the form of goods or services will not be absorbed without consumers and consumers will always need goods or services that come from business actors. Regulations regarding the rights owned by business actors are regulated in Article 6 of the Consumer Protection Law. Specifically, the rights owned by clinics are regulated in Article 36 of Minister of Health Regulation Number 9 of 2014 concerning Clinics. Meanwhile, in general, the obligations of business actors are regulated in Article 7 of the Consumer Protection Law. Thus, the main obligations of business actors are:

- a. have good faith;
- b. giving information;
- c. serve in the same way;
- d. provide guarantees;
- e. give it a chance to try, and
- f. compensate

Clinics have obligations as regulated in Article 35 of Minister of Health Regulation no. 9 of 2014 concerning Clinics. In addition, Clinic Organizers are required to:

- a. post the name and classification of the Clinic;
- b. create and report to the health service a list of medical personnel and other health personnel working at the Clinic including:
 - 1) Registration Certificate (STR) number and Practice Permit (SIP) number for medical personnel;
 - 2) permit number as a sign of registration or Registration Certificate (STR), and Practice Permit (SIP) or Work Permit (SIK) for other health workers;
- c. carry out records for certain diseases and report them to the district/city health office in the context of implementing government programs in accordance with statutory provisions. One of the obligations of business actors in Article 7 of the Consumer Protection Law is to have good faith in carrying out their business activities, this is one of the principles known in contract law. Provisions regarding good faith are regulated in Article 1338 paragraph (3) Burgerlijk Wetboek (BW) which states that agreements must be made in good faith, which means that the business actor's obligation to act in good faith starts from the time the goods are produced until the sales stage. This is of course caused by the possibility of losses for consumers starting from the moment the goods are produced by the producer or business actor.

Based on Article 7 letter b of the Consumer Protection Law regarding the obligations of both business actors, namely providing correct, clear and honest information regarding the condition and guarantee of goods and/or services as well as providing explanations of use, repair and maintenance, this is an obligation for business actors because information is a right. consumers and the absence of inadequate information from business actors will be very detrimental to consumers. 17 This is also the clinic's obligation as stated in Article 53 letter i of Minister of Health Regulation No. 9 of 2014 concerning Clinics. If this is related to cosmetic consumer protection, then the information contained in a cosmetic packaging must be information that provides correct and clear information. This information can contain ingredient composition, recommended use, side effects, expiration date and other important information that consumers must know about the cosmetic product. If there is no information on the product, then the business actor is obliged to provide this information to consumers verbally.

4. CONCLUSION

The absence of regulations that give authority to mix cosmetics shows that the doctor is exceeding his authority as a doctor. Consumers who suffer losses can sue business actors on the basis of claims of unlawful acts based on the rules contained in the Consumer Protection Law. This is because on the basis of unlawful acts, consumers who are harmed can obtain maximum compensation, both material and immaterial.

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