

Civil Liability of Doctors for the Use of Dermal Fillers Without a Marketing Authorization in Medical Aesthetic Services

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Abstract. *The use of dermal fillers in medical aesthetic services is growing rapidly because this procedure is considered to provide fast results, is minimally invasive, and is increasingly popular with the public. Dermal fillers are essentially non-surgical procedures to improve facial contours, reduce wrinkles, or increase soft tissue volume. However, this procedure still carries medical and legal risks and must be performed with safe, legal products that meet the doctor's competence. Legal issues arise when doctors use dermal fillers without a marketing authorization, because this action has the potential to violate medical device safety regulations, cause patient harm, and open up opportunities for civil liability. This study aims to analyze the civil liability of doctors in the use of dermal fillers without a marketing authorization using the Civil Code, consumer protection, and health law approaches. The results of the study indicate that doctors can be held liable based on unlawful acts, breach of contract, and breach of professional obligations and the obligation to ensure the legality of the products used. From a consumer protection perspective, patients are considered consumers of health services who have the right to security, correct information, and compensation for any losses incurred. The use of dermal fillers without a marketing authorization is not only an administrative violation but can also result in serious civil liability for doctors.*

Keywords: *Civil Liability; Consumer Protection; Dermal Filler; Doctor; Health Law; Marketing Authorization.*

1. Introduction

The development of medical aesthetic services in Indonesia demonstrates growing public interest in non-surgical procedures that offer rapid results, short

recovery times, and relatively immediate visible changes in appearance. One of the most widely used procedures is dermal fillers, an injection procedure to improve facial contours, reduce fine lines, and add volume to specific soft tissues. However, this procedure is not simple, as its success is determined by an understanding of facial anatomy, the choice of filler type, injection technique, mastery of indications and contraindications, and the doctor's readiness to handle potential complications (R. Mawu, 2018). Therefore, dermal fillers must be understood as a medical procedure that has both clinical and legal consequences.

In clinical practice, the use of dermal fillers should ideally be preceded by adequate informed consent. Medical literature confirms that filler complications are relatively rare, but they are still possible and can have medical, economic, and even legal consequences if patients do not receive adequate information before the procedure. Explanation of the benefits, limitations, risks, and alternatives is crucial for patient protection, as without proper informed consent, medical procedures can be questioned from both professional ethics and legal perspectives. In medical aesthetics, informed consent is even more crucial because many patients seek treatment not for curative purposes but rather for a desire to improve their appearance, leading to high patient expectations for the results of the procedure.

Legal issues become even more serious when the dermal filler used is found to lack a marketing authorization. A marketing authorization is a state oversight mechanism to ensure that medical devices meet safety, quality, and efficacy standards before use on humans. Applicable health regulations place product legality as a key component of patient safety and healthcare governance, so the use of fillers without a marketing authorization indicates a deviation from the legal compliance standards that doctors and healthcare facilities should adhere to (Ministry of Health of the Republic of Indonesia, 2024). In such circumstances, the doctor's actions not only risk medical harm to the patient but also open up the possibility of legal liability for using a product that is not legally authorized.

The urgency of this research is heightened by the continued discovery of illegal aesthetic products circulating in beauty services in Indonesia. In recent years, the Food and Drug Authority (BPOM) and the Ministry of Health have regularly discovered medical devices and aesthetic injection products without marketing authorizations circulating through unauthorized distribution channels and used in beauty practices. Several national news reports have also revealed cases of complications following filler procedures allegedly involving products without marketing authorization, resulting in physical and psychological harm to patients. This situation demonstrates that the use of illegal dermal fillers is no longer merely an administrative issue but has evolved into an issue of consumer

protection, patient safety, and healthcare professional liability, requiring more serious legal attention.

Table 1. Findings and Cases of Illegal Aesthetic Products in Indonesia

Year	Source	Findings	Relevance
2023	BPOM	Action against illegal aesthetic products	Shows that fillers are still circulating without distribution permits
2024	Ministry of Health & BPOM	Aesthetic clinic supervision	Shows weak distribution supervision
2024–2025	National News	Cases of filler complications	Demonstrates real patient harm

From a civil law perspective, the doctor-patient relationship creates rights and obligations that can lead to liability if harm occurs. The literature on health law and malpractice shows that legal consequences for doctors do not always depend on intent but can also arise from negligence, carelessness, or deviation from professional standards and applicable medical procedures (S. Machmud, 2008). When a doctor uses dermal fillers without a marketing authorization and the patient suffers harm, civil grounds such as unlawful acts and breach of contract become relevant as the basis for a claim for compensation (M. Sabri, 2021).

Beauty clinic patients can also be considered service consumers. Research on legal protection for beauty clinic consumers shows that legal relationships in this area arise from a combination of laws, therapeutic agreements, and service agreements, ensuring that patients are entitled to safe, transparent, and non-harmful services (D. Suryani and A. Hidayat, 2024). The use of fillers without a marketing authorization is not only a violation of health standards but also a violation of consumers' rights to adequate services and accurate information. This perspective is important because medical aesthetic services tend to be commercial in nature, making consumer protection a prominent element.

Based on this description, this study places a central question on how doctors' civil liability is constructed when dermal fillers are used without a marketing authorization in medical aesthetic services. This study also examines the extent to which the Civil Code, the Consumer Protection Law, and health law can be used together to provide legal protection to patients. Ultimately, this article aims to formulate the most appropriate liability model so that medical aesthetic practices operate within legal, safe, and accountable corridors. Based on this background, the problem formulations in this article are: 1) How are doctors' civil liability for the use of dermal fillers without a marketing authorization in medical aesthetic services? 2) How do the Civil Code, consumer protection, and health law form the basis for legal protection for patients? 3) What is the ideal

construction of civil liability for doctors for the use of illegal dermal fillers in medical aesthetic services?

2. Research Methods

This study aims to comprehensively analyze the civil liability of physicians in the use of dermal fillers without a marketing authorization in medical aesthetic services based on the perspectives of the Civil Code, consumer protection, and health law in Indonesia. This study is directed at examining how the legal relationship between doctors and patients in medical aesthetic practices can give rise to legal liability when medical procedures are performed using products that do not have an official marketing authorization. This study aims to examine the forms of civil liability that can be imposed on doctors, both based on the concept of unlawful acts and breach of contract, if the use of illegal dermal fillers causes harm to patients.

This study also aims to analyze the status of patients as consumers of healthcare services who have the right to safety, comfort, and accurate information regarding the medical procedures they receive. This study seeks to examine the relevance of the Consumer Protection Law as a legal instrument that can provide additional protection for patients in medical aesthetic services. This study aims to examine the relationship between product legality, physicians' professional obligations, healthcare standards, and patient safety principles in the practice of dermal filler use. Ultimately, this study aims to formulate the most appropriate and proportional legal accountability model so that medical aesthetic practices can operate safely, legally, and accountably and provide optimal legal protection for patients as consumers of healthcare services.

This research is a normative juridical legal research, namely research that places law as the norms, rules, principles, and doctrines that apply in the legal system. In normative juridical research, the analysis is conducted by examining legislation, legal theory, legal concepts, and relevant scientific literature to answer the legal issues studied. This approach was chosen because the problem studied focuses on the civil liability of doctors in the use of dermal fillers without a marketing authorization, so what is needed is a normative interpretation of the legal rules governing the relationship between doctors, patients, and the legality of health products.

In terms of its nature, this research is descriptive-analytical. Descriptive means that this research aims to systematically describe the legal provisions related to the use of dermal fillers, medical device distribution permits, physician responsibility, and legal protection for patients. Analytical means that this research not only describes legal norms but also analyzes the interrelationships between these norms to find the most appropriate legal construction in assessing physicians' civil liability. This research does not stop at an inventory of

regulations but also provides legal arguments for the application of these regulations to the case under study.

The approaches used in this research include:

- a. Statute approach,
- b. Conceptual approach, and
- c. Literature approach.

A statutory approach was used to examine the provisions of the Civil Code, the Consumer Protection Law, the Health Law, and technical regulations regarding medical devices and distribution permits. A conceptual approach was used to understand the concepts of civil liability, unlawful acts, breach of contract, informed consent, patient safety, and consumer protection in medical aesthetic services. Meanwhile, a literature approach was used to review health law books, scientific journal articles, and previous research relevant to the topic of dermal fillers and medical malpractice.

The legal materials used in this research consist of primary legal materials, secondary legal materials, and tertiary legal materials.

1. Primary legal materials include:

- a. The laws and regulations that form the basis of the analysis, especially the Civil Code,
- b. Law Number 8 of 1999 concerning Consumer Protection,
- c. Law Number 17 of 2023 concerning Health, as well as
- d. Government Regulation Number 28 of 2024 concerning the Implementation of the Health Law.

2. Secondary legal materials include:

- a. Health law books,
- b. Books on medical malpractice,
- c. Journal articles about dermal fillers,
- d. Articles about consumer protection for beauty clinics, and
- e. Other scientific writings that provide explanations, comments, or analysis of primary legal materials.

3. Tertiary legal materials include:

- a. Legal dictionary,
- b. Encyclopedia, and
- c. Other supporting sources that help clarify the legal terms or concepts used.

The legal data collection technique was conducted through literature review. Literature review is conducted by searching, reading, sorting, and recording legal materials related to the research issue. This stage is crucial to ensure that all arguments are based on valid, relevant, and up-to-date sources. In this research, the literature review focused on literature discussing the legality of medical devices, physicians' responsibilities in medical practice, patient protection as consumers, and the complications and medical risks of dermal filler procedures.

The legal material analysis was conducted qualitatively using deductive legal reasoning. This means that the researcher began with general norms contained in legislation and legal doctrine, then connected them to the specific issue of the use of dermal fillers without a marketing authorization in medical aesthetic services. Qualitative analysis was used to interpret the content of the norms, connect the provisions, and assess the relevance of legal doctrine to the case under discussion. The results of the analysis were then systematically compiled to explain how doctors' civil liability can be established based on Indonesian positive law.

This method is expected to provide a clear picture of the legal basis for physician liability, the limits of civil liability, and the legal protections available to patients. This method also allows researchers to formulate the most appropriate liability model for cases involving the use of dermal fillers without a marketing authorization, ensuring that the research is not only theoretical but also has practical relevance for the development of health law and consumer protection in Indonesia.

3. Results and Discussion

3.1. The Position of Dermal Fillers in Medical Aesthetic Practice

Dermal fillers cannot be positioned simply as a regular cosmetic procedure, but rather must be understood as a medical procedure that touches the patient's body and has the potential for legal consequences if performed improperly. This characteristic emphasizes that fillers have not only an aesthetic dimension, but also a legal one, as their implementation requires adherence to professional standards, patient safety, and product legality (Sampoerno, 2011). Dermal fillers fall within a healthcare system that prioritizes patient protection.

The popularity of dermal fillers in medical aesthetics services stems from the procedure's relative speed, minimal invasiveness, and immediate visible results. However, its apparent simplicity often leads to underestimated legal risks. In

practice, this procedure can lead to serious complications if the product used is of unclear quality and legality, the injection technique is incorrect, or the doctor fails to understand facial anatomy and patient contraindications (Widjaja, G, 2008). The aesthetic appeal of fillers cannot override the fact that this procedure carries the potential for real harm to patients.

From a health law perspective, dermal fillers must be treated as part of standardized healthcare services. Law Number 17 of 2023 stipulates that healthcare services must be implemented in accordance with healthcare service standards (Ministry of Health of the Republic of Indonesia, 2023). Consequently, doctors must not only possess the technical skills to administer injections but also ensure that the products used are legal, safe, and medically indicated. The absence of a distribution permit is not merely an administrative issue but also indicates that the product has not received state recognition for its safety, quality, and benefits (Food and Drug Monitoring Agency of the Republic of Indonesia, 2023).

This situation also has a direct impact on the civil liability of doctors. In civil law, the use of illegal or unverified products can be viewed as negligence or a breach of the duty of care. Therefore, when complications arise, the question goes beyond whether the procedure was successful or unsuccessful, but also whether the doctor acted in accordance with the law, professional standards, and the principles of due care from the outset (Sutrisno and Hartono, 2011). In other words, the crux of the matter is not simply the final outcome of the procedure, but rather the doctor's adherence to legal and professional standards from the outset.

The role of dermal fillers also needs to be considered within the therapeutic relationship, which is now blended with commercial relationships. Patients come not solely for healing, but also for changes in appearance based on personal preferences. This situation tends to create high patient expectations and a low tolerance for failure. Therefore, transparency of information is crucial. Doctors are required to explain the product's legal status, the risks of complications, the possibility of unsatisfactory results, and the limits of success of the procedure to prevent the doctor-patient relationship from devolving into one prone to disputes.

Dermal fillers ultimately have a dual status in medical aesthetic practice: as a medical procedure subject to health standards, and as a service product subject to the principle of legal precaution. This dual status makes the use of fillers without a marketing authorization a serious issue, as violations on one side will immediately impact the other. Therefore, within the framework of physician civil liability, dermal fillers should not be viewed as a minor procedure, but rather as a high-risk medical procedure that requires product legality, physician competence, and full patient protection.

Table 2. Articles on the Use of Dermal Fillers Without a Marketing Authorization

Regulation	Chapter	Relevance
Law No. 17 of 2023 concerning Health	Article 24 paragraph (1)	Health services must be carried out according to health service standards.
Law No. 17 of 2023 concerning Health	Article 77 paragraph (1)	Health care actions require patient consent
Law No. 29 of 2004 concerning Medical Practice	Article 45 paragraphs (1) and (2)	Informed consent after full explanation.
Civil Code	Article 1365	Basis for unlawful acts and compensation.

3.2. The Concept of Product Legality and the Legal Obligations of Doctors

The legality of medical devices is a fundamental requirement in medical aesthetic services, as any product inserted into a patient's body must first meet safety, quality, and efficacy standards. For dermal fillers, a marketing authorization is not merely an administrative formality but a form of state recognition that the product is suitable for human use. Therefore, when a doctor uses fillers without a marketing authorization, the action is no longer merely a technical choice but a violation of the doctor's legal obligation to act carefully, professionally, and in accordance with medical standards (Machmud, S, 2008).

The legality and product information requirements for consumers are also related to the Food and Drug Monitoring Agency Regulation Number 30 of 2020 concerning Technical Requirements for Cosmetic Labeling, which emphasizes the importance of providing complete, clear, and non-misleading product information as a form of consumer protection. This regulation requires information regarding product identity, composition, notification number, and other information necessary to ensure safe product use. Although dermal fillers are essentially classified as medical devices, the principle of transparency regarding product identity and legality remains relevant in ensuring patients' right to obtain accurate information before undergoing medical aesthetic procedures.

A doctor's legal obligations in medical aesthetic practice extend beyond the ability to perform injections, but also include ensuring that the products used are sourced legally and are guaranteed safe. In services that involve direct contact with the patient's body, product legality is an integral part of patient protection, as patients have the right to receive safe procedures that do not pose preventable risks. The use of illegal fillers means that doctors face not only potential ethical or professional criticism but also legal liability for disregarding the principle of due care inherent in medical practice.

From a civil law perspective, a breach of legal obligations can be the basis for proving a doctor's fault if a patient suffers harm. This is important because a doctor's responsibility is not judged solely by good intentions or the outcome of their actions, but rather by adherence to professional standards, procedures, and reasonable care. If illegal fillers cause injury, necrosis, infection, tissue dysfunction, or other harm to a patient, this circumstance can strengthen the element of fault in a civil dispute. The legal question is not simply whether the doctor intended to help the patient, but rather whether the doctor acted in accordance with the legal obligations that should have been fulfilled before the procedure was performed (Sabri, M, 2021).

Studies on medical malpractice show that the legal consequences of medical errors generally operate within a civil legal framework when the patient suffers harm. This harm can include physical suffering, impaired bodily function, material losses, or immaterial losses. Therefore, if a doctor uses illegal fillers and causes complications in a patient, the causal relationship between the action that violates legal standards and the patient's harm can be used as a basis for a civil suit. In other words, product legality is not merely an administrative compliance issue but a crucial factor in proving a doctor's fault and legal liability (Wibowo, A., 2023).

Violations of product legality are also closely related to professional disciplinary mechanisms. Disciplinary sanctions primarily focus on whether the doctor has practiced in accordance with professional standards, standard operating procedures, and medical ethics. Meanwhile, civil liability is more focused on recovering patient losses. The use of dermal fillers without a marketing authorization can raise two layers of issues simultaneously: professional disciplinary issues and civil issues. In practice, if a doctor uses an illegal product, the assessment goes beyond simply whether the patient recovers, but must also extend to whether the doctor has fulfilled the legal obligations that constitute the validity of the medical procedure.

Product legality is also crucial because patients seeking aesthetic services typically seek treatment based on personal preference, rather than an urgent need for treatment. This makes the doctor-patient relationship more sensitive to failure and more vulnerable to disputes. In such situations, transparency regarding the product's legal status is crucial so that patients can provide informed and rational consent. If the doctor fails to explain that the product being used lacks a marketing authorization, the patient is not fully protected. This lack of information can strengthen the suspicion of a breach of legal obligations, especially if the procedure subsequently results in complications or harm to the patient.

Product legality in medical aesthetic practice is not merely an additional element, but rather a requirement that determines whether a doctor's actions

are legally appropriate. Doctors who continue to use fillers without a marketing authorization have essentially ignored their duty of care and placed patients at undue risk. If harm subsequently occurs, civil liability may be directed against the doctor due to the link between the unlawful action and the patient's harm. Within this framework, product legality, physician competence, and patient protection are inseparable.

Table 3. Summary of Legal Aspects of Using Dermal Fillers Without a Marketing Authorization

Aspect	Description
Product legality	Must have a distribution permit and meet safety standards
Doctor's obligations	Ensuring products are legal, safe, and meet professional standards
Violation	The use of illegal fillers is a deviation from due care.
Legal consequences	Can be the basis for civil liability if the patient suffers a loss
Focus on proof	The presence or absence of errors, omissions, and causal relationships

3.3. Civil Liability According to the Civil Code

A doctor's civil liability for using dermal fillers without a marketing authorization can be established based on two main grounds: unlawful acts (*onrechtmatige daad*) and breach of contract. As professionals, doctors are obligated to practice medicine in accordance with professional standards, standard operating procedures, and the principle of prudence. If a doctor deviates from these standards and causes harm to a patient, they may be held civilly liable. A similar opinion states that a doctor's negligence in carrying out medical practice can give rise to an obligation to compensate if there is an element of error, loss, and a causal relationship between the doctor's actions and the patient's harm.

The most relevant basis for liability in the use of dermal fillers without a marketing authorization is an unlawful act as regulated in Article 1365 of the Civil Code (KUHPerdata). This article states that any unlawful act that causes harm to another person requires the perpetrator to compensate for the resulting loss. An act can be categorized as an unlawful act if it meets the elements of an act, unlawfulness, fault, loss, and a causal relationship (Munir Fuady, 2013). The use of dermal filler products without a marketing authorization clearly violates health and consumer protection laws, so the element of unlawfulness has been met from the outset of the act.

Besides being against the law, using products without a marketing authorization also indicates a doctor's negligence in fulfilling their professional obligations.

Doctors should ensure that any medical products they use have obtained a marketing authorization from the competent authority, namely the Food and Drug Monitoring Agency (BPOM). Doctors have an ethical and legal obligation to prioritize patient safety by using safe and standardized medical devices and materials (M. Jusuf Hanafiah and Amri, 2017). If a doctor continues to use illegal products despite knowing the potential risks, this action can be categorized as gross negligence.

The legal relationship between a doctor and a patient also includes the aspect of breach of contract. The therapeutic relationship between a doctor and a patient is essentially a contract that gives rise to rights and obligations for both parties (Bahder Johan Nasution, 2013). Doctors are obligated to provide medical services in accordance with professional standards and to use safe and legal products. If a doctor uses dermal fillers without a marketing authorization, resulting in harm to the patient, the doctor is deemed to have failed to fulfill the obligations agreed upon in the therapeutic relationship. This breach of contract can take the form of failure to fulfill obligations properly or carrying out obligations in a manner inconsistent with legal and professional standards.

The losses experienced by patients due to the use of illegal dermal fillers can be both material and immaterial. Material losses include the costs of further treatment, health recovery costs, lost income, and the costs of corrective action for the physical damage that occurs. Meanwhile, immaterial losses can include psychological suffering, embarrassment, trauma, and even decreased self-confidence due to the damage to facial appearance. Compensation in civil law aims to restore the victim's condition to the state it was in before the harmful act occurred. Patients have the right to demand compensation commensurate with the losses they suffered (Subekti, 2005).

Furthermore, a doctor's liability arises not only from actual harm but also from a violation of the principle of due care in medical services. Professionals are held to a higher standard of care than ordinary people because their profession directly relates to the safety and rights of others (Shidarta, 2006). The use of dermal fillers without a marketing authorization demonstrates a disregard for the principle of professional due care, which should be upheld in the practice of aesthetic medicine.

3.4. Consumer Protection in Beauty Clinics

Patients in beauty clinic services are not only recipients of medical treatment, but also consumers of services as referred to in Law Number 8 of 1999 concerning Consumer Protection. The legal relationship between patients and beauty clinics is born through several bases, namely contractual relationships, therapeutic agreements, and legal relationships arising from the law. Beauty clinics, as business actors, have legal responsibility for product safety and the

quality of services provided to patients (Napitupulu, R., 2020). If the clinic or doctor uses dermal fillers without a distribution permit, then this action can be seen as a violation of the consumer's right to obtain a sense of security, comfort, and correct information about the services used.

Consumers' right to safety and security is a key principle in consumer protection law. Businesses are required to ensure that the goods or services they sell do not cause harm to consumers (Ahmadi Miru and Sutarman Yodo, 2015). In beauty clinics, the use of illegal products indicates that the business has failed to fulfill its legal obligation to provide safe and standardized services. Consumers also have the right to receive honest and complete information about the products used in medical aesthetic procedures, including their legality, ingredients, benefits, and the risk of potential side effects.

The use of dermal fillers without a marketing authorization can also be categorized as a violation of business actors' obligations as stipulated in Article 7 of the Consumer Protection Law. Business actors are required to act in good faith in carrying out their business activities and provide correct, clear, and honest information regarding the condition of the goods or services offered (Ahmadi Miru and Sutarman Yodo, 2015). When doctors or clinics use products without a marketing authorization without informing patients of the condition, this constitutes a violation of the principles of information transparency and good faith in consumer service.

Legal protection for consumers in beauty clinics is becoming increasingly important as medical aesthetic practices expand rapidly, while oversight of products and services remains suboptimal. Weak oversight of beauty clinics can increase the risk of using illegal products and services that do not meet health standards (D. Suryani and A. Hidayat, 2024). In such circumstances, patients often find themselves in a vulnerable position due to a lack of understanding of the medical and legal aspects of the procedures they receive. Consumer protection laws exist to balance the roles of patients as consumers and beauty clinics as business actors.

From a consumer protection law perspective, patients harmed by the use of illegal dermal fillers can seek both material and immaterial compensation. Compensation in consumer protection law aims to restore consumer rights violated by the use of goods or services that do not meet safety standards (Janus Sidabalok, 2018). This compensation can take the form of reimbursement of treatment costs, follow-up medical expenses, compensation for physical damage, and compensation for psychological suffering experienced by the patient. Consumer protection law provides an additional basis that strengthens the legal standing of patients in holding clinics and doctors accountable.

Table 4. Consumer Protection in Beauty Clinics

Protection Aspects	Forms of Violations in the Use of Illegal Dermal Fillers	Legal basis	Legal Consequences
The right to security and safety	Use of dermal fillers without a marketing authorization	Article 4 letter a of the Consumer Protection Law	Consumers have the right to demand compensation
The right to correct information	The doctor did not explain the legality of the product.	Article 4 letter c of the Consumer Protection Law	Patient consent may be considered flawed
Obligations of business actors	Clinics continue to use illegal products	Article 7 of the Consumer Protection Law	Business actors are responsible for patient losses
Javanese service standards	Actions not in accordance with professional standards	Health Law and medical professional standards	May give rise to civil liability
Consumer compensation	Patients experience physical and psychological damage	Article 19 of the Consumer Protection Law	Reimbursement of costs and immaterial compensation

Beauty clinic patients are considered consumers of healthcare services and have the right to receive safety, comfort, and accurate information regarding the medical procedures they receive. The relationship between consumers and providers in providing services creates a legal obligation for providers to ensure the quality and safety of the services provided. The use of dermal fillers without a marketing authorization violates basic consumer rights because the products fail to meet legal and safety standards.

In beauty clinics, doctors and clinics act not only as healthcare professionals but also as service providers. Businesses are required to provide honest, clear, and responsible information regarding the products or services used by consumers. When a doctor fails to explain that the filler product being used does not have a distribution permit, this constitutes a violation of the principle of transparency, which is the basis for consumer protection.

The development of the medical aesthetics industry increases the risk of consumer harm if medical products are not properly monitored. Many beauty clinic consumers lack understanding of the legality of the aesthetic products they use due to a lack of education from medical personnel and clinics. This situation places patients in a vulnerable position, requiring stronger legal protection.

In terms of liability, consumer protection law gives patients the right to seek compensation for both material and immaterial losses. Compensation in consumer protection law aims not only to compensate for economic losses but also to provide redress for the suffering experienced by consumers due to the use of unsafe services (Gunawan Widjaja and Ahmad Yani, 2003).

3.5. Health Law and Service Standards

Health law's primary function is to ensure that medical services are carried out in accordance with professional standards, standard operating procedures, and patient safety principles. In medical aesthetic practice, the use of dermal fillers without a marketing authorization contradicts the objectives of health law because it ignores product legality and patient safety. Health law is fundamentally designed to protect patient rights while ensuring that medical personnel carry out their profession responsibly and in accordance with applicable laws (J. Guwandi, 2010).

The use of medical products without a marketing authorization constitutes a violation of the precautionary principle in healthcare. Healthcare standards are a measure used to ensure the quality of medical services and avoid risks to patients (Soekidjo Notoatmodjo, 2010). When administering dermal fillers, physicians should ensure that the products meet the safety, quality, and efficacy standards set by health authorities. If a physician uses a product without a marketing authorization, this action could be considered a violation of the established medical standards.

Modern health regulations also prioritize patient safety as a key principle in healthcare. Every medical device and medical preparation used in healthcare must meet safety and legal requirements before being distributed to the public. These provisions aim to prevent health risks from the use of untested or non-compliant products (Ministry of Health of the Republic of Indonesia, 2024). The use of illegal dermal fillers not only violates administrative regulations but also contradicts the fundamental principles of patient protection in health law.

In addition to product legality, health law also emphasizes the importance of informed consent in medical procedures. Consent to medical procedures can only be considered valid if the patient receives complete information regarding the diagnosis, purpose of the procedure, risks, benefits, alternative treatments, and potential complications. In the case of the use of dermal fillers without a marketing authorization, the information provided to the patient is incomplete if the doctor fails to disclose the legal status of the product being used. The patient's consent can be considered legally flawed because it is given without adequate information.

Violations of healthcare standards can have legal consequences for both doctors and beauty clinics. Medical personnel can be held accountable if they are proven to have acted inconsistently with professional standards and caused harm to patients (Hermien Hadiati Koeswadji, 2002). Compliance with healthcare standards is not only a matter of professional ethics but also an important part of legal protection for patients in aesthetic medical practice.

Table 5. Health Law and Medical Service Standards

Principles of Health Law	Implementation in Beauty Clinics	Form of Violation	Consequence
Patient safety	Use of products that have been registered with BPOM	Use of illegal fillers	Risk of complications and lawsuits
Professional standards	Doctors act according to SOP	Actions without safety standards	Medical negligence
Informed consent	Patients are given complete information	Product legality is hidden	Consent to the action becomes invalid
Precautionary principle	Product safety inspection	Doctor neglected to check distribution permit	Civil liability
Legality of medical devices	Products must have a distribution permit	Product does not meet regulatory requirements	Violation of health laws

Health law regulates the delivery of medical services in accordance with professional standards and patient safety principles. Good health care must meet the requirements of safety, quality, and professional responsibility. In medical aesthetics practice, physicians are required to ensure that every product used meets legal and safety requirements before administering it to patients.

The use of dermal fillers without a marketing authorization constitutes a violation of the principle of due care in medical care. Medical personnel are required to act cautiously because every medical procedure carries risks to patient safety. If a doctor uses an illegal product without verifying its legality and safety, such actions could constitute professional negligence.

Another important aspect of health law is informed consent. Consent for medical procedures must be given based on complete and accurate information regarding the procedure. In the case of illegal filler use, patients do not receive complete information regarding the product's legal status, potentially rendering their consent legally invalid (A. Isfandyarie, 2006).

Indonesian health regulations place oversight of medical devices as a crucial component of patient protection. Weak oversight of the distribution of illegal aesthetic products remains a major factor in the increasing number of complications in cosmetic procedures (M. Arifin and D. Rahmawati, 2023). Compliance with healthcare standards should be viewed as both a legal and ethical obligation for medical personnel.

3.6. Ideal Construction of Civil Liability against Doctors for the Use of Illegal Dermal Fillers

The most appropriate liability model for the use of dermal fillers without a marketing authorization is liability based on fault. This model places the element of fault as the primary basis for determining the responsibility of doctors and

beauty clinics. Fault-based liability arises when someone commits an unlawful act, violates a legal obligation, or fails to observe proper standards of care, resulting in harm to another party.

In cases of illegal dermal filler use, the element of fault can be seen in the doctor's continued use of an unlicensed product despite knowing or reasonably ought to have known that it did not comply with health law. Fault in civil liability can be either intentional or negligent. The doctor's failure to ensure the product's legality represents a violation of the principle of professional due care, which is mandatory in medical practice.

The primary basis for this liability is found in Article 1365 of the Civil Code concerning unlawful acts. Unlawful acts include any action that violates the rights of others, violates the perpetrator's legal obligations, violates morality, or violates social propriety (Rosa Agustina, 2003). The use of illegal products in medical aesthetic procedures fulfills these elements because it directly violates the patient's right to safety and proper medical care.

Liability in cases of illegal dermal filler use cannot be solely assigned to the doctor without considering the clinic's role as a healthcare provider. A distinction must be made between the doctor's personal liability and the clinic's corporate liability.

Doctors are personally liable if they are proven to have used dermal fillers without a marketing authorization, failed to verify the product's legality, failed to provide adequate information to patients, or engaged in actions that violate professional standards and standard operating procedures. The basis for their liability stems from unlawful acts under Article 1365 of the Civil Code, breach of contract in the therapeutic relationship, and breach of professional obligations of medical personnel.

Meanwhile, beauty clinics can be held liable under the principle of vicarious liability because they are obligated to supervise medical personnel, ensure the legality of the products used, and provide a safe service system. If the use of illegal dermal fillers occurs due to weak supervision, unauthorized product procurement, or management policies that violate legal provisions, the clinic can be held civilly liable, along with the doctor.

Table 6. Comparison of Doctors' and Clinics' Liability for Illegal Dermal Filler Use

Aspect	Doctor	Beauty Clinic
Legal basis	Article 1365 of the Civil Code	Article 1367 of the Civil Code
Form of Responsibility	Personal Liability (Fault Liability)	Vicarious Liability
Basic Error	Professional negligence, use of illegal fillers, breach of professional standards	Negligence of supervision, procurement of illegal products,

Legal Relationship with Patients	Therapeutic relationship	failure of service systems
Object of Accountability	Medical actions performed by doctors	Healthcare provider relationships
Form of Compensation	Material and immaterial	Clinical service and supervision system
		Material and immaterial

In addition to the Civil Code, the liability model is also reinforced by the Consumer Protection Act and health law provisions. Business actors are responsible for losses suffered by consumers due to the use of goods or services that do not meet safety standards. In beauty clinics, doctors and clinics can be viewed as healthcare providers and therefore obligated to guarantee the safety of the products and services provided to patients (Az. Nasution, 2011).

For more effective legal construction, physician liability should be viewed cumulatively. This means that violations of marketing authorizations, violations of professional standards, and violations of consumer rights can be assessed simultaneously in determining fault. This cumulative approach allows judges to assess all aspects of the physician's actions, from the perspective of civil law, consumer protection, and health law. An approach that combines multiple bases of liability can strengthen legal protection for injured parties by providing a broader scope for proof.

A fault-based liability model combined with a cumulative approach is the most appropriate model to apply in cases of unauthorized use of dermal fillers. This approach not only provides legal certainty for injured patients but also encourages medical aesthetic practices to operate in accordance with professional standards, ethics, and applicable legal provisions.

Table 7. Model of Doctors' Liability in the Use of Illegal Dermal Fillers

Accountability Model	Legal basis	Error Form	Legal Consequences
Act against the law	Article 1365 of the Civil Code	Using illegal products	Compensation to patients
Default	Therapeutic agreement	Service is not up to standard	Demands for fulfillment of performance and compensation
Consumer protection	Consumer Protection Act	Violation of consumer rights	Compensation
Violation of professional standards	Code of ethics and health law	Medical negligence	Professional accountability
Cumulative liability	Combination of the Civil Code, UUPK, and health law	Violations of legality and patient safety	Stronger legal protection

The most appropriate liability model for the use of dermal fillers without a marketing authorization is fault liability. A person can be held liable if there is an element of fault, loss, and a causal relationship between the act and the

resulting loss. In the case of illegal fillers, the doctor's fault is evident in the use of products that do not comply with health law (CST Kansil, 2006).

The strengthening of the civil liability framework can also be seen in judicial practices that use the unlawful act approach to assess losses resulting from violations of legal obligations. In the Central Jakarta District Court Decision Number 734/Pdt.G/2023/PN.Jkt.Pst, issued on July 11, 2024, the court emphasized the importance of proving the elements of unlawful act, fault, loss, and causality in determining civil liability. This approach is relevant in cases of illegal dermal filler use because the use of products without a marketing authorization is essentially a violation of legal obligations, the precautionary principle, and patients' rights to safe healthcare.

In addition to unlawful acts, the therapeutic relationship between doctor and patient also gives rise to contractual responsibilities. Breach of contract occurs when one party fails to fulfill its agreed obligations (Setiawan, 1999). Doctors who use illegal products are deemed to have failed to fulfill their obligation to provide safe and standardized medical services.

The consumer protection approach further strengthens the patient's position as the injured party. Businesses are responsible for consumer losses resulting from services that fail to meet safety standards. In beauty clinics, doctors and clinics can be viewed as healthcare providers and therefore held accountable for the use of illegal products.

A cumulative approach between the Civil Code, health law, and consumer protection law provides more comprehensive legal protection for patients. A multidimensional approach to medical liability is more effective because it allows judges to simultaneously assess all aspects of the violation, including contractual, professional, and consumer protection (F. Lestari and R. Firmansyah, 2021).

In judicial practice, judges tend to assess the liability of healthcare workers and healthcare facilities simultaneously when patient harm arises from a breach of service standards. This approach is evident in a number of court decisions that place patient protection obligations, professional standards, and the obligation to provide information as key elements in determining civil liability. The use of dermal fillers without a marketing authorization can be viewed as a violation of health care standards, strengthening the basis for a patient's lawsuit against the doctor or clinic.

4. Conclusion

The ideal structure for civil liability against doctors for the use of illegal dermal fillers must be built cumulatively through Article 1365 of the Civil Code, provisions on breach of contract in therapeutic relationships, the Consumer Protection Law, and the Health Law. Doctors are personally liable for the use of

products without marketing authorization and for violations of professional standards and the duty of care. On the other hand, beauty clinics can be held liable under the principle of vicarious liability if the use of illegal products occurs within the scope of services under their supervision. This study recommends harmonizing Article 1365 of the Civil Code, Articles 4 and 7 of the Consumer Protection Law, and Article 24 of Law Number 17 of 2023 concerning Health in assessing physician liability for the use of illegal dermal fillers. Specific informed consent standards for medical aesthetic procedures should be established, requiring the inclusion of product identification and distribution permit numbers. Supervision of dermal filler distribution by the Food and Drug Authority (BPOM) and the Ministry of Health should also be strengthened through a digital traceability system to prevent the use of illegal products and improve patient protection.

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