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Legal Responsibility for Misuse of Limited Over-The-Counter Drugs Sold by Small Traders

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Abstract

This research is useful to know about the legal responsibility for the misuse of limited free drugs sold by small traders, in order to achieve legal responsibility in health services. The type of normative law used in this research as research with the use of statutory approach (statue approach) and conceptual approach (conceptual approach). Based on this study, it can be concluded that the *BPOM* Regulation Number and Online Food and Permenkes Number 3 of 2021 concerning Changes in the Classification, Restrictions and Categories of Drugs have regulated the mechanism for the Limited Free Distribution of Pharmaceutical Drugs, but have not fully regulated the legal responsibilities of small traders who produce pharmaceutical preparations at retail for 16 years 2022 related to the supervision of the circulation of drugs circulated in Indonesian regions, PP 8 of 2020 by the Ministerial Regulation of the Food and Drug Supervisory Agency regarding supervision. Drugs and food sold online and Decree of the Minister of Health Number 3 of 2021 concerning Changes in Classification, Restrictions and Classes of Drugs have regulated the mechanism for the circulation of restricted over-the-counter drugs, but have not fully regulated the legal responsibility of drugs. Small traders who produce medicines in retail trade. As a complement to the existing regulations, preventive and repressive efforts require holistic arrangements and revitalization of the supervisory guidance system for the circulation of limited over-the-counter drugs in the community. Legal liability should be provided through a special law that contains authorities so that there is legal certainty over the legal liability for misuse of limited over-the-counter drugs sold by small traders.

Keywords: Legal Liability, Limited Free Medicines, Small Traders

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Introduction

The Indonesian state is a state of law (rule of law). The law is accepted as the view of the Indonesian state to produce, security, order, justice and welfare for Indonesian citizens. As a result, the law binds all the behavior of Indonesian citizens. The way the science of law works is by issuing directives (actions, behaviors) and therefore also includes legal norms, which are called legal norms. Law is associated with the position of society as the enactment of law (ibi ius ibi societas) (Sari, 2014). Therefore, law can be seen as a weapon used by society to bring security and order to the lives of its citizens. As stated in the introduction of the Constitution of the Republic of Indonesia, it is stated that the purpose of the state is to maintain Indonesia's natural wealth and all unity in Indonesia. The specific purpose of making law is to facilitate services to the community to achieve welfare, security, justice and prosperity.

Health is part of the human rights of every individual. In the absence of health, almost everyone cannot carry out their activities normally. Instead, the element of health is also part of the welfare that must be implemented in accordance with the goals of the Indonesian

nation. Based on Law No. 36/2009 on Health, everyone is obliged to be healthy to live, maintain, and even safeguard the health of each individual and others in order to support the development of Indonesian society as a potential resource. Only the government can exceed this obligation.

Due to the mandatory nature of the law, any illegal or prohibited act is punishable by penalty. Laws that regulate crimes and other transitions against the interests of the state are known as criminal laws that regulate society, and individuals, who can be punished by punishment (Purbacaraka, 2010). With the help of sustainable national expansion according to Pancasila and the 1945 Constitution, health must be realized as part of the general welfare in accordance with the goals of the Indonesian nation mentioned in the introduction of the document.

Medicine is an important component as it is required for most health interventions. People now tend to request more professional healthcare services, including drug treatment, as a result of increased public health awareness and knowledge. When it comes to medicines, as in pharmaceutical availability. Based on Government Regulation No. 72 of 1998 concerning the Safety of Pharmaceutical Supplies and Medical Devices, it means that the distribution of drugs is regulated so that the general public or as the case may be, patients can receive the correct medicinal materials and that it complies with all standards of safety and expediency. (Dhadang Wahyu Kurniawan, 2009). Medicine is a material intended to anticipate and recover from disease and to restore and elevate the health of the wearer. all drugs have benefits and purposes, but also side effects that can be detrimental. Therefore, Decree of the Minister of Health Number 3 of 2021 regulates changes in classifications, restrictions and classes to ensure public safety from the circulation of drugs that pose a risk.

The importance of medicine in the world of health and its unique place in society is because products are needed to maintain and promote public health and cure health problems or diseases. If drugs are misused or used illegally without a standard license from the Food and Drug Administration, it will harm the public as consumers and will further cause problems if it affects the health of those who consume it (G. Eka Putra Pratama Arnawa & Ni Ketus, 2018). Even the use of dangerous illegal drugs can have adverse effects resulting in death, as well as complications of disease or organ damage, which increases medical costs. The types of drugs are classified into limited free drugs, free drugs, compulsive drugs, hard drugs, psychotropic drugs and safety, speed and security drugs. These categories are stipulated in the Decree of the Minister of Health of the Republic of Indonesia 949/Menkes/Per/VI/2000.

However, there are still cases of drug dependence and pharmaceutical errors in Indonesia. Drug abuse can take the form of misuse in the sale of drugs. For example, hard drugs that cannot be sold over the counter are sold over the counter in stalls or small drug stores. The rampant circulation of drugs so that restrictions on the circulation of drugs without a distribution permit in Indonesia, especially on limited over-the-counter drugs, has proven Indonesia's weak defense against the disturbance of some dangerous things in society. Restricted over-the-counter drugs are drugs that are available and sold by small traders or authorized pharmacies without a doctor's prescription. Only some over-the-counter drugs are used to treat easy conditions that can be identified by the affected person. Drugs sold over-the-counter are basically hard drugs with restrictions on the dosage of active ingredients. Some others serve as examples of restricted over-the-counter drugs: CTM drugs, Decolgen, Tremenza syrup, Betadine, and others. Many of these class W drugs are sold over-the-counter by small traders and many people consume these restricted over-the-counter drugs in large quantities without a doctor's prescription.

Drug distribution is regulated by Government Regulation No. 72 of 1998 concerning the Safety of Pharmaceutical Supplies and Medical Devices, so that the general public or general consumers in this case the patient can designate the correct drug that carries out all quality requirements and is safe and effective for use. However, there are still drug and medication errors in Indonesia.

Article 3 of Government Regulation No 72/1998 concerning the Safety of Pharmaceutical Supplies and Medical Devices states that only companies that have an appropriate industrial license with existing laws and regulations can produce pharmaceutical products and medical devices. Article 9 of Government Regulation No 72/1998 on the Safeguarding of Pharmaceutical Supplies and Medical Devices states that

1. Distribution licenses for drugs and medical devices are granted based on a written request to the Minister.
2. The written request referred to in paragraph 1 shall include a description and/or purpose of the drugs and medical devices for which distribution authorization is sought as well as examples of such drugs and medical devices.
3. More detailed rules on the procedure for applying for a distribution license based on Articles 1 and 2 by the Minister.

In public law, government action is unilateral (Adami Chawawi I, 2002) saying that the government wins in this case rather than issuing a decision (beschikking). Vergunning, or permit, is one type of decision. A permit (vergunning) is a government agreement that in certain situations departs from the provisions of statutory restrictions. It is based on a law or government regulation.

According to Minister of Health Decree No. 1331/Menkes/SK/X/2002 on the Amendment of Minister of Health Decree No. 167/KAB/B.VIII/1972 on Drug Retailers, drug retailers are only allowed to market more over-the-counter drugs and limited over-the-counter drugs that are still in their original packaging and in limited quantities from the manufacturer that produces them. The decree further stipulates that the Head of the District or City Health Office is responsible for granting licenses to drug retailers. The head of the provincial health office, the local *Balai POM*, and the minister of health must receive a copy of each license request put forward by the head of the district/municipal health office.

Materials and Methods

This research uses normative legal research with a legal approach in the health sector, especially related to drug distribution issues. And using a conceptual approach. A conceptual approach is an approach method that is not the same as the theory and learning of other legal sciences, which is also a field of legal studies that provides a fundamental point of view to overcome problems in legal research from a jurisprudential perspective. The terms used have a relationship with the laws drafted as well as with the principles contained in the standardization of the rules. The legislative concept of legal liability rules for the misuse of restricted over-the-counter drugs sold by small traders is the main subject of this study..

Result and Discussion

A. Liability of Small Merchants for the Sale of Restricted Free Drugs

A healthy human being is one of the goals of the Indonesian state. All individuals have the right to a life of physical and spiritual success, as well as the ability to live with dignity, to have a pleasant and healthy environment, and to receive health services, according to Article 28 H paragraph (1) of the 1945 Constitution of the Republic of Indonesia. Utilizing pharmacological formulations, the government works to support public health. Pharmaceutical preparations are defined in Article 1 Point 4 of Law Number 36 Year 2009 on

Health. Medicines, drug components, conventional drugs, and cosmetics are examples of pharmaceutical preparations. There are drug stores and pharmacies where you can get pharmaceutical preparations (Nurhayati, 2009a). Drug Retailers and Drug Stores are also synonyms. Drug stores and drug retailers are defined as "facilities licensed to store limited over-the-counter drugs for retail sale" in Article 1 of the Minister of Health Regulation No. 167/KAB/B.VII/1972 on Drug Retailers which has been replaced by Kepmenkes No. 1331/MENKES/SK/X2002. A pharmacy is a location where products are sold to customers for consumption. Drug stores sell pharmaceutical products that fall into the category of over-the-counter drugs as well as prescription drugs (Janus Sidabalok, 2014).

Over-the-counter drugs obtained without the use of a prescription from a doctor include those on the W-list, also called the Waarschuwing list or Waarschuwing which means dangerous. However, when using such drugs, users should pay attention to the drug information on the container. The restricted over-the-counter drug label is a blue circle with a blue border. These drugs are sold in limited quantities, and the content of any effective ingredient must be accompanied by a warning sign, P1-P6 warning, and a unique sign on the container. Restricted use can only be purchased at licensed pharmacies or drug stores. Class W or Waarschuwing drugs must be prescribed by a doctor if consumed in quantities that exceed the rules. In the drug trade, the container / box / bottle is marked with a special marker. This is because limited over-the-counter drugs include drugs that are relatively safe to use, but if consumed in excess of the dosage amount must use a doctor's prescription. Before using the drug, there are properties and dosage instructions on the label, pamphlet, or drug container to ensure safe and proper use (Happy Susanto, 2008).

There is usually a list in every pamphlet or medicine package: Name of the drug, Composition or raw materials, Indications and factors, how the drug works, Rules of use, Warnings (especially for limited over-the-counter drugs), description, Name of the manufacturer, Batch/lot number, registration number, valid distribution license issued by the government indicated by the registration number listed in each package of the drug expiration date.

Restrictions on over-the-counter drugs for self-medication must be in accordance with general guidelines for drug use, including the responsible and safe use of drugs in accordance with Minister of Health Regulation No. 3 of 2021 concerning Changes in Classification, Restrictions, and Drug Categories. To self-medicate responsibly, one should choose drugs that have been proven safe, effective, and of high quality. In addition, one should choose suitable drugs based on the symptoms of the disease and the patient's condition. Every medicine has side effects in its use, especially hard drugs whose use must be based on a prescription from a doctor. One example is the injection drug with the brand name Norages. This medicine is a medicine to treat pain. The packaging contains instructions on the packaging and the doctor's instructions must be followed. The side effects of using this drug are causing severe allergies to reactions that occur suddenly and can cause bleeding in the digestive tract, itching, increased heart rate, can cause side effects in the form of increased blood pressure. Another example of the side effects of hard drugs is the drug commonly consumed by the public, Amoxicillin. Amoxicillin is an antibiotic to treat diseases caused by bacterial infections. The mild and common side effects of Amoxicillin include diarrhea, abdominal pain, nausea, headache and dizziness, insomnia, and tongue swelling. While Amoxicillin side effects that are classified as quite serious include causing allergic reactions, respiratory problems, bloody stools, jaundice, and even kidney failure.

Rules for the Sale of Restricted Over-the-Counter Drugs in Health Law Number 36 Year 2009

Established by Law No. 36/2009 on Health Article 1, health is a state of enabling all people to live productive social and economic lives. This includes being in good physical, mental, spiritual, and emotional health. One of the nation's development initiatives is health efforts that are directed at achieving awareness, willingness, and leading a healthy life to achieve optimal public health. The goal of health development is to increase public awareness of health problems as an investment in the creation of economically and socially viable human resources. Medicines are substances or instructions prepared for use to affect or treat physiological systems or pathological situations for the purpose of diagnosis, prevention, cure, recovery, health promotion, and protection. Drugs can be defined as objects or substances that can be used to cure diseases, relieve symptoms, or replace the body's chemical mechanisms. So far, medicine has served as a substance that is intended to be used to diagnose, prevent, eliminate, and treat as a therapeutic effect. To reduce medical costs, most people often treat diseases that are considered mild with drugs obtained without a doctor's prescription and not consulted with a doctor first.

The use of restricted over-the-counter drugs such as antibiotics without a prescription is commonplace in standard practice in our society. The use of restricted over-the-counter drugs when consumed in excess of the dosage without a doctor's prescription poses a problem. This is because some retail drug dealers sell restricted over-the-counter drugs without a prescription. Restricted over-the-counter drugs can be freely distributed in limited quantities with warning labels. There are six types of warning signs printed on black paper:

1. Warning 1 : watch out! potent drug. read the terms of use
2. Warning 2: watch out! potent drug. For gargling only, do not swallow
3. Warning 3: watch out! potent drug. only for the outside of the body.
4. Warning 4: watch out! potent drug. only to be burned (for asthma cigarettes)
5. Warning 5 : watch out! potent drug. Not to be taken internally
6. Warning 6: watch out! potent drug. hemorrhoid medicine. do not swallow

Liability of Small Merchants for the Sale of Restricted OTC Medicines

Small trader liability is a requirement that restrains their commercial operations. product liability, also known as product responsibility (Nova Yanti M et al., 2021). A person or organization that produces a product (manufacturer, manufacturer), receives the product from another person or organization (processor, assembler), or distributes the product (seller, distributor) is said to be legally responsible for the product. In legal relations the Government is in a unique position as it is the only entity that has the responsibility to carry out and take care of the public interest, and as such is given the power to make rules and regulations, use coercion, and impose penalties to fulfill this responsibility (Yovita Arie Mangesti, 2017). In public law, government action is unilateral. In this case, a decree (beschikking) is issued by the government. Statute Vergunning is one type of law. The government is authorized to interfere (staatsbemoeinis) in people's lives as necessary to advance the public interest (social welfare), as long as it remains within the limits of the law. As a result, the government has the power to make and implement laws and regulations.

The pharmaceutical industry is a responsibility with the government as well as the public because it is a component of the health industry. To establish expertise in the pharmaceutical industry and provide direction, regulation, control, and supervision to achieve the desired expertise and programs, the government has duties and responsibilities based on BPOM Regulation No. 16 of 2022 concerning the Supervision of the Distribution of Donated Medicines in the Indonesian region (Nurhayati, 2009). In order for drugs to be produced efficiently and drugs to be distributed correctly and equally to all levels of society, drug procurement is accompanied by an appropriate and efficient distribution system. Law No. 36 of 2009 concerning Health and Decree of the Minister of Health No. 1331/Menkes/SK/X/2002 amending Decree of the Minister of Health No.

167/KAB/B.VIII/1972 concerning drug dealers is licensing. drug dealer criteria. Based on Minister of Health Decree No. 1331/Menkes/SK/X/2002 amending Minister of Health Decree 167/KAB/B.VIII/1972 on the retail sale of drugs, over-the-counter drugs as well as limited over-the-counter drugs, over-the-counter drugs in factory packaging are sold in units of small dealers sold.

Medicine cannot be directly dispensed to the public; instead, it must be distributed to health facilities starting from the point of manufacture by a trader who obtains a business license to distribute medicines to the public followed by health services. Health care facilities in this situation are clinics, pharmacies with pharmacists in charge, and hospitals with pharmaceutical installations (I Kadek Sukadana Putra & Ayu Putu Nia Priyantini, 2021). In this situation, Health Care Facilities offer a wide range of drug services, including the distribution of drugs to the general public with a doctor's prescription. However, only certain over-the-counter drugs and over-the-counter drugs that do not require a doctor's prescription are dispensed to Drug Retailers under the supervision of a Pharmacist (Imam Cayono et al., 2019).

In reality, the application for a license to open a pharmacy is considered to meet the requirements of a drug retailer license. The term "Drug Retailer" is used because it refers to the Kepmekes, which regulates the granting of licenses to Drug Retailers. This is because Drug Retailers are only allowed to market over-the-counter drugs and drugs with certain restrictions, which in this case are still in their original packaging from the manufacturer. This is as stated in the Decree of the Minister of Health. This means that Drug Retailers are not allowed to manufacture or repackage medicines as part of their commercial operations. Small traders are obliged by the legal relationship established between consumers and them to bear responsibility for consumer losses if the losses are actually caused by a mistake made by the small trader (Anis Rifai, 2022).

According to legal responsibility, the principles are differentiated as follows (Khairunnisa, 2008) :

1. Principles of Liability Based on the Element of Fault

In criminal as well as civil law, the concept of fault-based liability (also known as fault liability or fault-based liability) is a rather common concept. According to this rule, there must be an element of fault for a person to be held legally responsible.

There are 4 main elements which include:

- The existence of an act, is to understand what it is to act (active) or not act (passive) in such a way as to violate the law, whether in the form of a violation of the rights of another individual, one's own obligations against acts, acts against decency, or acts against decency.
- There is an element of fault, which is either intentional or negligent. Deliberation indicates the motivation or desire of the commercial actor to produce a certain effect. The act may be done intentionally even when one knows or anticipates the consequences.
- Lack of care in dealing with the issue of delay and carelessness in acting appropriately, resulting in unintended effects. Loss is carelessness in the form of the elements of loss, costs, and interest mentioned regarding defaults with agreements, as well as losses related to unlawful acts.
- There is a causal relationship between loss and fault, which means that the loss incurred by the victim of unlawful conduct is the loss that only results or arises from the unlawful conduct committed by the perpetrator. There is a direct causal relationship between fault and loss. This means that it must be proven that the

business actor's involvement in the unlawful act and the existence of a causal relationship between the loss.

2. Presumption of Responsibility
   According to this rule, the defendant is often said to be guilty until he can prove otherwise (the concept of presumption of responsibility). Thus, the plaintiff is obliged to prove his case.
3. Principle of Presumption of Liability
   The rule is reversed from the order of the second principle. The principle of liability is only recognized in a very specific part of consumer behavior and the limitation is usually justified by common sense.
4. Principle of Absolute Liability
   The concept of strict liability is sometimes confused with the idea of absolute liability. However, strict liability is essentially liability that prohibits the use of the principle of fault as a criterion for judgment. However, there are certain exceptions that permit immunity from fault, such as situations involving force majeure. Absolute liability, on the other hand, refers to the idea of liability without fault and imperfection. According to the various provisions above, it can be concluded that :
   a. Small business owners have an obligation to compensate customers who suffer losses as a result of using the goods they produce or sell. Compensation may take the form of replacement, exchange of products or health or compensation.
   b. Replacement of compensation within 7 days or a week.
   c. Reverse proof, or the business providing evidence of consumer fault, is used to defend the small business owner.

Conclusion

Small traders are basically not allowed to sell restricted over-the-counter drugs, as stipulated in the Minister of Health of the Republic of Indonesia No. 167/Kab/B.VII/72. In this regard, it is recommended that customers be careful when choosing and taking some of the free drugs available for themselves and animals or livestock. The government is expected to get strong assistance in regulating the circulation of drugs carried out by these unauthorized parties. The government should also impose harsh penalties to have a deterrent effect on traders and consumers who continue to abuse these over-the-counter drugs. Agencies responsible for restricting over-the-counter drugs need to perform supervisory functions to minimize the risk of their existence. The government and *BPOM* also need to conduct supervision through regulation and standardization, safety, efficacy and quality assessment.

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