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**Application of the Criminal Law for Distribution of Illegal Drugs by Business Actors Without a License**

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**ABSTRACT**

Access to these drugs is an important part of a drug control system aimed at protecting people from the risks of unsafe or inferior use of drugs. Still, there are serious concerns regarding the illegal transmission of drugs or without approval in many countries. The circulation of arms and the issues associated with illegal drugs has significantly negative effects on people's health and economies. Illegal drugs are often involved in illegal trade and organized crime, which contributes to increased crime and social instability. The methods used in this study are a type of normative that focuses on laws and rules that already exist in legislation. To ensure that people can easily obtain safe, qualified and effective drugs. To achieve this, it requires cooperation and coordination between government, drug enforcement agencies, law enforcement, and other related sectors. The goal is to tackle the challenges associated with illicit drugs and provide society with optimal health protection.

Keywords : Drugs, Criminal Sanctions, Without Permission

**INTRODUCTION**

Business has a crucial role in a country's economy. The main goal of a business is to generate financial profits for the owner or other stakeholders. However, business goals can also include developing innovation, providing social benefits, and achieving environmental sustainability. In the activities of running a business, there is no fraud committed by business actors as producers to generate greater profits. Like the case of illegal drug distribution that occurred in Indonesia.

The distribution of illegal drugs is an activity that violates the law, such as the distribution of sales of drugs that do not have an official permit or contain dangerous ingredients. In Indonesia, the distribution of illegal drugs is a criminal act that is prohibited by law. Medicines sold must meet marketing authorization requirements and must be produced by manufacturers who have safety and quality standards regulated by the competent health authority.

Medicines that will be distributed or marketed must go through several testing processes carried out and supervised by the Food and Drug Supervisory Agency (BPOM) in order to obtain permission to distribute the medicines made to the public. Medicines that obtain distribution permits from BPOM must meet the requirements set by BPOM.

There are cases found in Indonesia regarding drugs distributed in the community that do not have a distribution permit from BPOM. Hard drugs, which have addictive effects similar to narcotics, must be subject to strict supervision by the government from the stage of manufacture to use. These medicines can only be given by pharmacies with a doctor's prescription. Pharmacies are also required to report the purchase and use of these medicines to the government every month.

The use of medicines must be done with a doctor's prescription and according to the instructions for proper use. The selection and use of drugs must be based on an accurate medical diagnosis and with appropriate supervision by qualified medical personnel (Rokhman, et al. 2017). It is important to always follow the rules and dosage given by the doctor or responsible health worker in order to minimize the risk of side effects and ensure the effectiveness of treatment. Examples of hard drugs include Trihexyphenidyl HCL, Loratadine, Pseudoephedrine, Bromhexin HCL, Alprazolam, Clobazam, Chlodiazepokside,

Amitriptyline, Lorazepam, Nitrazepam, Midazolam, Estrazolam, Fluoxetine, Sertraline HCL, Carbamazepine, Haloperidol, Phenytoin, Levodopa, Benzeraside, Ibuprofen, Ketoprofen, Charnopen, and others.

Circulation of medicines without a distribution permit has a serious negative impact on public health, because the medicines may contain unknown ingredients, unmeasured doses, or dangerous ingredients. Use of drugs without marketing authorization can cause adverse side effects, allergic reactions, poisoning, or even death.

The government and health authorities are working hard to combat the distribution of drugs without a distribution permit by intensifying supervision, law enforcement and educating the public about the dangers of using drugs without a distribution permit. It is important for people to be smart consumers by ensuring that the medicines they use have official distribution permits and are prescribed by competent medical personnel.

## RESEARCH METHODS

This research uses Normative legal research methods, which focus on analyzing and solving internal problems in positive law. This research method also includes library research, where relevant theories are collected from various sources to describe the problem being studied. The data used in this research is secondary data, including primary and secondary legal materials. Qualitative data analysis methods are used to interpret and relate the information obtained in order to clarify the truth in the context of this research (Ishaq, 2017).

## RESULTS AND DISCUSSION

### **Criminal Sanctions Against Perpetrators Who Distribute Cosmetics That Do Not Have a Marketing Permit**

Drugs are chemical substances that have the ability to influence biological tissue in the human body (Batubara, 2008). Medicine is a type of substance that is used for diagnosis, treatment, healing, repair and prevention of health problems in the human body. As the main therapy, drugs have a significant role in the healing process of a disease and are closely related to healing efforts (Potter and Perry, 2009). The function of medicine itself is to help all types of diseases or certain conditions. Medication can help reduce symptoms, slow disease progression, and eliminate the disease completely.

LPND (Non-Departmental Government Institution) is a central government institution established to carry out certain tasks assigned by the President, and has direct responsibility to the President. One example of LPND is BPOM (Food and Drug Supervisory Agency), which is responsible for supervising drugs and food (Panji, 2022).

Drugs that are bought and sold by the public must have a distribution permit issued by BPOM through several predetermined stages, through several testing processes. The Food and Drug Monitoring Agency (BPOM) was established based on Presidential Regulation Number 80 of 2017 as a non-ministerial government agency tasked with supervising medicine and food. BPOM is directly responsible to the president and has an important role in maintaining the safety, quality and efficacy of medicines and food in Indonesia.

The process of obtaining a distribution permit for drugs that are traded must go through several testing processes by BPOM such as preclinical testing, clinical trials, review and evaluation, and granting a marketing permit. After passing the testing process and obtaining a distribution permit, the aim is to ensure that drugs circulating on the market are safe, effective and meet the quality standards set by health authorities. Thus, consumers can have greater confidence in using the drug. However, there are still many drugs found that do not have distribution permits being bought and sold in the Surakarta city area.

Drugs that do not have a distribution permit or are illegal drugs often do not undergo strict testing and regulations like drugs that are legal or fit for distribution. Consuming illegal drugs can cause serious side effects on health, including organ damage, neurological disorders, mental damage, and can even result in death. Dependence and abuse are also consequences of the ingredients contained in illegal drugs. Illegal drugs have strong addictive properties, continuous use of drugs results in physical and psychological dependence which can lead to drug abuse and mental health problems.

The use of illegal drugs not only harms individual health, but beyond the use there are crimes and illegal trade. It is often involved in illicit trafficking networks and organized crime. Illegal drug trafficking and organized crime often coexist. Illegal drugs are produced, smuggled, and traded illegally, creating a black market that benefits criminal groups. The existence of this illegal market contributes to increasing crime rates and social instability in society.

Thus, illegal drug abuse has detrimental impacts both individually and socially and economically. Law enforcement, prevention and rehabilitation efforts are important in dealing with this problem in order to reduce the illicit trade in illegal drugs and reduce the negative impacts it causes.

Illegal drug use places a burden on the health system, including the costs of medical care, rehabilitation, and recovery programs needed to help individuals negatively impacted by illegal drug use. The illegal drug trade often operates outside the tax system and can cause revenue losses for governments. Apart from that, this illegal economic activity can also reduce the income generated from the distribution of legitimate and officially licensed drugs.

The activity of distributing drugs without a permit is a criminal offense. Crime is a legal term that has a special meaning as a translation of the Dutch word "straf", which means "punishment". In the legal context, a criminal act is a juridical definition that refers to behavior that violates the law and can be subject to sanctions or punishment in accordance with applicable legal provisions. The term "criminal" is used to indicate that the perpetrator of a criminal act will face legal consequences in the form of punishment or criminal sanctions (Moeljatno, 1987).

Sentencing is a process in which sanctions or punishments are determined in a court hearing. In the legal system, the term "criminal" generally refers to the law governing criminal acts, while "sentencing" refers to the process of imposing punishment. In criminal law theory. Material criminal law includes defined criminal acts, the regulations that apply to these criminal acts, and the sanctions threatened for these criminal acts.

Regulations regarding the availability of pharmaceuticals and/or medical devices are regulated in Article 196, Article 197 and Article 198 of Law no. 36 of 2009 concerning Health. These three articles form the legal basis for dealing with violations related to the distribution of drugs and medical devices.

In Article 196, it is regulated that anyone who deliberately produces or distributes pharmaceutical preparations and/or medical devices that do not meet the standards and requirements for safety, efficacy, usefulness and quality as described in Article 98 paragraph (2) and paragraph (3), will be subject to criminal penalties. The punishment is in the form of imprisonment with a maximum term of 10 years and a fine of up to Rp. 1,000,000,000.00 (one billion rupiah).

After that, Article 197 stipulates that anyone who deliberately produces or distributes pharmaceutical preparations and/or medical devices without having a distribution permit will be subject to imprisonment with a maximum limit of 15 years and a fine of up to Rp. 1,500,000,000.00 (one billion five hundred million rupiah).

And finally, Article 198 states that every person who does not have the expertise and authority to carry out pharmaceutical practice as described in Article 108, will be subject to criminal penalties in the form of a maximum fine of Rp. 100,000,000.00 (one hundred million rupiah).

Therefore, according to the author, law enforcement against criminals who distribute drugs without a distribution permit is less effective, because with the presence of illegal drugs without local BPOM supervision, fatalities can occur.

**Factors that Inhibit Law Enforcement Efforts for the Distribution of Drugs That Do Not Have a**

### Marketing Permit

Circulation activities are a process of distributing, marketing and distributing trade, non-trade and transfer products and/or services (Nasution, et al. 2020). The most frequent criminal acts in the health sector are in the pharmaceutical sector.

Pharmacy is a profession that is involved in the process of providing sources of natural materials and synthetic materials that are suitable for distribution and use in the treatment of a disease (Barda Nawani Arief, 2008). Pharmacies have an important role in providing medicines for sale to the public. All types of goods produced for health purposes must obtain permits in accordance with the regulations in article 106 paragraph (1) of Law no. 36 of 2009 concerning Health "pharmaceutical preparations and medical devices can only be distributed after obtaining a distribution permit". However, in reality, there are still many pharmaceutical preparations in circulation, such as drugs in circulation, that do not have a distribution permit.

This criminal act occurred because of the background factors, namely:

A. Lack of understanding of the law

Human daily life will certainly not be free from rules such as legal norms. The legal norm itself is that every human interaction is regulated and is binding or coercive in nature, so human behavior is regulated in legal norms. If it is violated, sanctions will be imposed in the form of threats of punishment. The purpose of these legal norms is so that humans live their lives safely and comfortably.

B. Economic factors

This factor is one of the triggers for someone to dare to commit a criminal act, there is someone who commits a criminal act to gain greater profits without having to care about the safety and security of the goods produced. A person commits a crime because he is in a low economic position so he dares to take the risk of committing the crime.

C. Factors of weak supervision

The next factor is that the supervision of drug distribution is still considered to be poor, so the perpetrators can easily carry out production activities and sell and sell them freely to the public.

The factors above can also become obstacles for the government in dealing with criminal acts of drug distribution without permits. And also the involvement of a third person or better known person who knows what action the government will take regarding the distribution of drugs without a permit. Then there are also rogue pharmacists or clever business actors who falsify documents and doctor's prescriptions that are recommendations (Mia Amelia and Anggraini, 2020).

However, the government still needs to take more serious action on this case, because if this case is not handled immediately, it could be dangerous for the public as consumers and also for state income which will suffer because of drugs that do not undergo a licensing process.

The first thing the government must do is provide education to the public regarding medicines so that people can be more careful in buying and consuming medicines. This is so that consumer safety and security can be guaranteed and does not cause side effects that endanger consumers.

Then the government must also check with each distributor providing medicines whether the medicines to be marketed are suitable for sale in the public. And also take action against drugs that are already circulating in the community so that the drugs are immediately withdrawn from business actors and then destroyed so that they do not cause undesirable things.

### CONCLUSION

The importance of maintaining the integrity of safe and quality drug distribution is illustrated by imposing criminal sanctions on business actors who violate these regulations. This can create a deterrent effect and provide a warning to other actors to comply with regulations. Strict law enforcement also has an important role in protecting public health and safety from the risks of using drugs that do not meet standards. In addition, criminal law enforcement provides legal certainty in the pharmaceutical industry,

creates a fair business climate, and increases public trust in pharmaceutical products circulating on the market.

Law no. 36 of 2009 concerning Health states provisions regarding criminal acts related to the production and distribution of medicines that do not meet standards. Article 196 regulates criminal acts for those who produce or distribute drugs that do not comply with established standards. Furthermore, Article 197 regulates criminal acts for those who produce or distribute drugs without the distribution permits required according to applicable regulations. Article 198 also regulates criminal acts for those who produce or distribute drugs without having the expertise and authority stipulated in the applicable regulations. These three articles form the legal basis that regulates criminal sanctions against business actors who violate regulations in the production and distribution of drugs in Indonesia.

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