




Criminal Law Policy in Efforts to Combat the Illegal Distribution of Hard Drugs Without a Doctor's Prescription

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Abstract

Introduction: Nowadays, there are many irregularities related to the Health Act. The urgency of problem solving arising from medication errors is very great because one type of medication error, namely administration error, ranks first compared to other types of medication errors. With the percentage of administration errors amounting to 81.32% of errors related to medical administration that occur in Indonesia.

Purposes of the Research: To understand and explain the juridical responsibility that must be imposed on the perpetrators of selling prescription drugs without a doctor's prescription through online buying and selling sites.

Methods of the Research: Research methods are used to find and process data in accordance with the research objectives and solve the problems posed by researchers.

Results of the Research: The results showed that: (1). In Law Number 17 of 2023 concerning Health (hereinafter referred to as the Health Law) there are offenses that can be imposed on the perpetrator, these offenses are listed in Article 435 & Article 436. Article 435 states that every violation of medication error will be sentenced to imprisonment for a maximum of 12 (twelve) years or a maximum fine of Rp. 5,000,000,000.00 (five billion rupiah). Meanwhile, a person who does not have the expertise in the field of pharmacy in accordance with the provisions of the Law but continues to distribute pharmaceutical preparations will be subject to the offense in article 436 with a maximum imprisonment of 5 (five) years or a maximum fine of Rp. 500,000,000.00 (five hundred million rupiah)." Countermeasures against prescription drugs without a doctor's prescription can basically be dealt with by article 435 and article 436 of the Health Law, and there is a lot of evidence of the existence of these two articles that apply to offline prescriptions drug dealers. (2). Countermeasures against the distribution of prescription drugs through online buying and selling sites are still somewhat ambiguous because there is no law that specifically regulates the countermeasures of prescription drugs online, which causes a legal vacuum in countermeasures against the distribution of prescription drugs online. Therefore, elaboration, and hard work from every law enforcement officer is needed to tackle the problem.

Keywords: Criminal Law Policy; Countermeasures; Illegal Distribution of Prescription Drugs.

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INTRODUCTION

Law in its concept must follow the development of the times through legal reform, with the existence of legal reform, there are also retroactive laws but still apply in certain criminal acts (retroactive principle). A legal reform must include three main aspects of values contained in society. The three aspects are general socio-political values, socio-philosophical values, and cultural values in society. Without these values in the discipline of legal reform, it can be concluded that the legal reform cannot be applied efficiently to society because these values are not applied in the formation or a legal reform, the implementation of the

three values is stated in a legislation formed by the government.¹ The formation of legislation must be formed by the government itself or through representatives who represent the people because it is hoped that such legislation can force a person's will to follow the legal spirit of the legislation that is formed. Based on Law Number 17 of 2023 (hereinafter referred to as the Health Law/Health Law), there is a legal spirit based on the principles of humanity, benefits, protection, respect for rights and obligations, gender justice, non-discrimination, and religious norms. These principles are the foundation of the formation of the Health Law. Therefore, any deviation from these principles is indirectly the same as a deviation from the outline of the Health Law.

Nowadays, there are many irregularities related to the Health Law. One of them is irregularities in the field of pharmacy. Violations in the health sector are generally referred to as medication errors which are divided into four stages, namely, prescribing error or the process of formulating a prescription for a patient by an authorized party, transcription error is an error that occurs when a pharmacist makes a mistake in reading the medicine, dispensing error is an error that occurs when the medicine is mixed by an authorized party which results in a defect in the substance of the drug material, and administration error which is an error by the authorized party in providing the medicine. A concrete example of an administration error is when a pharmacist makes a mistake in giving the medicine prescribed by a doctor so that the medicine that has been given by the pharmacist to the patient is different from the medicine prescribed by the doctor to the patient.

The urgency of problem solving arising from medication errors is very large because one type of medication error, namely administration error, ranks first compared to other types of medication errors, with a percentage of administration error occurrence of 81.32% of errors related to medical administration that occur in Indonesia. Concrete forms of administration errors are the provision of hard drugs without a doctor's prescription (illegal distribution of hard drugs) and the exchange of drugs in patients with the same name.

Illegal drug distribution often occurs in Indonesia. Although the frequency of this type of violation is relatively high, the public is not aware that the actions taken by drug dealers are administrative errors that can result in criminal penalties for the perpetrators, even people who are not familiar with positive laws related to the Health Law can indirectly be caught in criminal offenses contained in the laws and regulations related to drug distribution. In general, the main motive of the perpetrators in carrying out illegal drug distribution is to reap the greatest possible profit from the sale of the drugs. The legal stuttering that occurs in Indonesian society creates a conducive situation for perpetrators of illegal drug distribution.

Misuse of hard drugs can cause serious problems, one of which is antibiotic resistance. Antibiotic resistance occurs due to incomplete consumption of antibiotics, causing bacteria to adapt to the antibiotics. Many people do not yet know how dangerous it is to consume antibiotics that are not in accordance with Standard Operating Procedures (SOP). This is not in accordance with the legal spirit of the Health Law, where it violates two main principles of the Health Law, namely the principle of humanity and the principle of benefit.

Following the development of the times, international integration that occurs globally cannot be stopped. Indonesia is one of the countries affected by globalization that occurs

¹ Margie Gladies Sopacua, Submission of Electronic Evidence in General Crimes and Special Crimes, *Scholars International Journal of Law, Crime and Justice*, 3 (4), 2020, p. 117. DOI :10.36348/sijlcj.2020.v03i04.006

due to dynamic technological developments and its increasingly rapid development. The rapid development of technology in Indonesia can be identified through innovations found through digital footprints, the most prominent example is the development of digital-based social media such as Facebook, Twitter, Instagram, Snapchat, and many more. The development of digital-based social media also affects the development of the world of trade and buying and selling.

Before the rapid impact of technological developments in the world of trade, people carried out buying and selling transactions face to face or what the author calls conventional trade. There are several pros and cons in conducting conventional trade. The disadvantages of conventional trade for consumers include limited market reach, and relatively expensive prices due to market monopoly so that the price is very far from the actual price of the product. The advantages of conventional trade for consumers are greater credibility compared to online trade because sellers can see and directly assess the products to be purchased, the next advantage is easier consumer service and the existence of physical stores that allow consumers to directly see the products offered. This also facilitates bargaining between producers and consumers.

Due to the weaknesses that occur when carrying out conventional trading activities, modern trade was developed through online trading sites (online marketing) or what is commonly referred to as e-commerce. The formation of online trading is in line with developments in the fields of information and technology. These developments do not only occur in the fields of stock exchanges, trade, and buying and selling, but technological developments also greatly assist trials in the overmacht that occurred due to the COVID-19 pandemic with the implementation of teleconference trials.²

Pharmaceutical work is basically carried out by authorized parties as regulated by statutory provisions. The authorized party in question is a party who has expertise in carrying out pharmaceutical work. Whether or not someone is an expert is based on the standards of a profession. The professional standards of pharmacists are regulated in the Decree of the Minister of Health of the Republic of Indonesia Number: 573/Menkes/SK/VI/2008 Concerning the Professional Standards of Pharmacist Assistants, in the regulation, it is stated that a pharmacist is someone who has completed education related to pharmaceutical work whose provisions apply to laws and regulations in the field of education. The provisions of the laws and regulations relating to the offenses of the laws and regulations are regulated in Article 435, and Article 436 of Law Number 17 of 2023 Concerning Health.

The difference between Article 435 and Article 436 of the Health Law lies in the elements of the subject of the crime of the two articles. The application of the offense in Article 435 can ensnare a person who distributes or produces pharmaceutical preparations and/or medical devices that do not meet the standards and/or requirements for safety, efficacy or benefits, and quality in accordance with the provisions of the Health Law, even though the subject of the crime has sufficient certification and adequate credibility as a pharmaceutical worker. While the requirements for a person to be ensnared using Article 436 only apply to

² J.M. Saimima, R.G.I. Matrutty, Tinjauan Yuridis Pelaksanaan Persidangan Perkara Pidana Daring Pada Pandemi Covid-19 Dikaitkan Dengan Asas Pengadilan Terbuka Untuk Umum, *Jurnal Belo*, 7(1), 2021, p. 98. DOI : <https://doi.org/10.30598/belovol7issue1page96-112>

people who do not meet the requirements as pharmaceutical workers but the person continues to practice pharmacy.

Further information related to the distribution of prescription drugs without a doctor's prescription is regulated in Letter C of Government Regulation Number 51 of 2009 concerning Pharmaceutical Work, which requires the use of a doctor's prescription in the distribution of prescription drugs to the public. In accordance with the postulate of no punist without representative, it is not possible to include a criminal sanction in Government Regulation Number 51 of 2009 concerning Pharmaceutical Work because the Government Regulation is a derivative regulation of the Law whose formulation did not go through a representative body or a high representative body. However, it does not rule out the possibility that violations of Letter C of Government Regulation Number 51 of 2009 concerning Pharmaceutical Work can be subject to sanctions in Article 435 or Article 436 of the Health Law.

There is a dilemma associated with Article 24C of Law Number 17 of 2023 concerning Health & Government Regulation Number 51 of 2009 concerning Pharmaceutical Work and Paragraph 1 and Paragraph 2 of Article 8 of the Regulation of the Food and Drug Supervisory Agency Number 8 of 2020 concerning Supervision and Food Distributed Online. The implementation of the application of the rules that have been previously listed on online buying and selling sites can be observed directly on the Tokopedia site which is an electronic system. Article 1 Number 5 of Law Number 19 of 2016 concerning Amendments to Law Number 11 of 2008 concerning Electronic Information and Transactions states that an Electronic System is a series of electronic devices and procedures that function to prepare, collect, process, analyze, store, display, announce, send, and/or distribute Electronic Information.

Tokopedia site requires someone to upload a photo of a doctor's prescription on its server when purchasing a prescription drug of the amoxicillin type. However, in its application, there are several types of prescription drugs that are not required to upload a photo of a doctor's prescription on the Tokopedia site, one of which is the prescription drug of the metformin type. In fact, metformin type drugs have a red circle with the letter "K" on the diameter of the drug circle, so metformin drugs can be classified as prescription drugs. In relation to information and technology in the distribution of prescription drugs, Article 9 of Law Number 11 of 2008 concerning Information and Electronic Transactions states that Business Actors who offer products through Electronic Systems must provide complete and correct information relating to the terms of the manufacturer's contract, and the products offered.

In line with Article 9 of Law Number 11 of 2008 concerning Information and Electronic Transactions, in the sale of hard drugs on e-commerce sites, a business actor must describe the product accurately. In some cases, there are business actors who sell hard drugs on e-commerce sites but the business actor tries to trick their products into being easily accessible by not describing that the drug is classified as a hard drug, so that the system on the site detects that the buyer is not required to upload a photo of a doctor's prescription on the site because the product purchased from the business actor is detected by the system that the product is not included in the hard drug category. In relation to the sale of illegal hard drugs, Article 4 of Law Number 8 of 1999 concerning Consumer Protection (hereinafter referred to as the Consumer Protection Law) states several rights that must be given by the seller to the

consumer, namely: a) the right to comfort, security, and safety when using goods and services; b) the right to choose and receive goods and services according to the exchange rate, conditions, and guarantees promised; c) the right to obtain correct, straightforward, and honest information about the conditions and guarantees of goods and services; d) the right to be heard of their opinions and complaints about the goods and services they use; e) the right to receive fair protection, protection, and efforts to resolve consumer disputes; f) the right to receive consumer guidance and education; g) the right to be treated or served properly, honestly, and without discrimination; h) the right to receive compensation, damages, or replacement if the goods and services received do not comply with the agreement or are not as they should be; i) other rights regulated in other laws and regulations.

It is stated in the Consumer Protection Law that a consumer has the right to obtain correct, clear, and honest information related to the products sold by business actors. The harmony between Article 9 of Law Number 11 of 2008 concerning Information and Electronic Transactions and Article 4 of the Consumer Protection Law requires a business actor to describe the product with actual information. Violations of consumer rights as stated in the Consumer Protection Law activate Article 19 paragraph (1) of the Consumer Protection Law which states that business actors are responsible for providing compensation for damage, pollution, and/or consumer losses due to consuming goods and/or services produced or traded.

Legal studies on the previously mentioned laws and regulations are also grammatically unwritten that only certain hard drugs require the use of a doctor's prescription for the distribution of hard drugs from pharmacies to the public, but every hard drug requires a doctor's prescription as the main requirement for the distribution of hard drugs from the pharmacy to the public. The distribution of hard drugs without a doctor's prescription is considered illegal based on laws and regulations.

Due to the existence of misappropriation and loopholes in the distribution of prescription drugs, there should be legal research (legal findings) to be used as a guideline for application to a case related to the title of this thesis. In addition, a law must follow the development of the times. There are twists and turns in the application of sanctions for perpetrators of cases of distributing prescription drugs, so scientific studies are needed to solve legal problems whose misappropriation goes hand in hand with technological developments.

METHODS OF THE RESEARCH

The type of research that will be used in this writing is legal research by applying the concept of normative legal research by carrying out the concept of approach: statute approach, conceptual approach, and analytical approach. The legal material search technique uses document study techniques, and the analysis of the study uses qualitative analysis.

RESULTS AND DISCUSSION

A. Elements of a Criminal Act

Criminal law is a branch of law that regulates acts that are considered criminal acts (delicts) and determines the punishment or sanctions for the perpetrators. The purpose of

criminal law is to maintain public order, protect society, and provide a deterrent effect for perpetrators of crimes. There are many opinions related to criminal law in terms of terminology according to experts. WPJ Pompe said that criminal law is all legal rules that determine what actions should be punished and what kind of punishment it is, in the classical theory of the application of criminal law according to Cessare Beccaria not through acts of violence committed by one person or many people against citizens. The punishment should be public, immediate, as efficient as possible in certain situations, proportional to the crime, and stipulated by law. Meanwhile, the opinion of modern criminal law theory was put forward by Immanuel Kant who said that there are two objectives of the application of criminal law, namely "crime control" and "crime rehabilitation".

Crime control is the purpose of the existence of criminal law that utilizes the psychological effect of human fear to commit a crime. This fear is caused by the deterrent effect caused by the crime in criminal law, whether it is physical responsibility or fine (luat in aere solvere in corpore). While crime rehabilitation is the purpose of the formation of criminal law so that perpetrators of criminal law personally become better people with rehabilitation in correctional institutions and it is hoped that perpetrators of criminal acts in the future will no longer commit the crimes they have committed. Components of Criminal Law: 1) Criminal Act (Delict): An act that is prohibited by law and is threatened with punishment. For example, theft, murder, fraud, and corruption; 2) Criminal Act Perpetrator: A person who commits an act that is categorized as a crime. Criminal law distinguishes between the main perpetrator, assistant, and accomplice; 3) Criminal Responsibility: The requirements that must be met so that a person can be held accountable for the crime he has committed, including the elements of error (*mens rea*) and action (*actus reus*); 4) Criminal Sanctions: Punishments imposed on perpetrators of criminal acts. Sanctions can be in the form of the death penalty, imprisonment, fines or other actions that have been regulated by law.

There are three objectives of criminal law, namely preventive objectives, repressive objectives, and rehabilitative objectives. Preventive objectives are preventive measures to prevent violations of applicable norms, and to ensure that the security and public order situation is maintained and remains safe and under control, especially by ensuring the intentional factor.³ Repressive objectives (or repressive actions) are actions taken in the form of criminal prosecution by giving punishment if a crime or crime is committed. Repressive efforts can also be interpreted as a conceptual aspect faced after a crime is committed. Countermeasures with repressive actions provide treatment or actions in accordance with the actions committed by the perpetrator of the crime, show how to correct their criminal actions, and show that the actions they do are against the law and detrimental to society. Therefore, considering the sanctions given are very severe, they will not repeat the same thing and so will others.

The rehabilitative goal was born from the theses of experts related to modern criminal law. As previously explained, Immanuel Kant not only leaned criminal law based on the prevention of criminal acts but Immanuel Kant also classified rehabilitative efforts as an important substance. From these theses, a product was born called restorative justice, in Article 97 paragraph (1) of Law Number 8 of 1981 concerning Criminal Procedure Law stating that a person has the right to receive rehabilitation if the court has declared him free or has decided to be free from all legal charges whose decision has permanent legal force.

³ Tafik Yanuar Chandra, Yasmon Putra, *Hukum Pidana, Sanging Multi Usaha*, Jakarta, 2022, p. 18.

In addition, in a case of theft, criminal law will identify: 1) Criminal Act: Theft, which is defined as taking someone else's property without permission with the intention of possessing it unlawfully; 2) Criminal Act Perpetrator: A person who is caught red-handed taking someone else's property; 3) Criminal Responsibility: Evidence that the perpetrator had the intention (*mens rea*) to steal and carried out the act (*actus reus*) of stealing the item; 4) Criminal Sanctions: Prison sentences or fines in accordance with the provisions set out in the Criminal Code.

Meanwhile, the elements of a crime are elements that must be met so that an act can be categorized as a crime. These elements are usually divided into objective elements and subjective elements. Objective elements consist of acts (*actus reus*) and causal relationships. While subjective elements consist of intent, negligence, and malicious intent of the perpetrator of the crime. Elements of acts (*actus reus*), *Actus reus* refers to actions or omissions that consist of physical elements of a crime as required by law. *Actus reus* only includes actions that force the victim or perpetrator to make a decision, or negligence (failure to act) that causes criminally prohibited consequences. For example, if a thief points a gun at the victim's side and says "Your money or your life" the thrust of the gun is an *actus reus* that forces the victim to be in a psychological condition called "fight or flight condition" so that there is the potential for a crime to occur and the victim turns into a perpetrator. This condition is also a problem in the application of a crime in a criminal procedure because sometimes if we look at the jurisprudence of judges, there is a dilemma in punishing the perpetrator for a similar crime that can cause *actus reus*. While the element of physical action is an action or negligence carried out by a person. For example, in the case of theft, the physical act is taking someone else's property, in the *actus reus* state certain conditions or situations attached to the act are also considered. For example, in the case of murder, the condition of the person who is the victim must be alive before the act of murder is carried out. In addition, judges also usually look at certain consequences or results of the act committed. For example, in the case of fraud, the result is a loss suffered by the victim.

While the subjective elements of a crime are divided into intention, negligence, and malicious intent (*mens rea*). Intention has the root word intentionally. Based on KBBI, intentionally has the meaning: intended (planned); indeed intended so; not by chance, in a criminal procedure, in fact the authorities always pay attention to whether a crime is committed intentionally. Generally, crimes committed based on intent will get a heavier punishment when compared to crimes committed based on unintentionation. In addition, criminal procedures also pay attention to the intention or intent of the perpetrator in committing the crime. Actions that are carried out intentionally and planned in advance, such as in cases of premeditated murder.

Negligence is an unintentional mistake. Simply put, the explanation of negligence can be explained in an example of a case where forgetfulness can occur, and psychologically when committing a crime, the person never wants the consequences of the act to occur. Criminal law itself does not contain the definition of negligence, therefore the definition of negligence must be traced from doctrine and legal science (definitions according to experts). Both doctrine and the definition of experts basically define negligence as a lack of caution in doing something that leads to a crime, there are five elements of negligence. These elements are responsibility, violation, actual cause, alleged cause of the incident, loss. The implementation of these five elements can be seen in an example of a case where the perpetrator of the crime works as an air traffic controller. However, an incident occurred

where an accident occurred between two planes due to the perpetrator's negligence. There, the five elements are considered. The first element pays attention to the duties and responsibilities of the perpetrator, where in the job application of the air traffic controller it is stated that the person working in the occupation must concentrate, but there is a possibility that the perpetrator is not concentrating while doing his job, causing an accident. The second element is the element of violation when doing the job. The element of violation pays attention to what actions were taken by the perpetrator that violated the standard operating procedures of the air traffic controller's job. The third element is the actual cause, where the authorities pay attention to what actually happened to the perpetrator and ensure that the perpetrator is the guilty subject. The fourth element is the element of the alleged cause of the incident (*proxima causa*), where the authorities make a series of analogies related to what actions caused the perpetrator to commit the crime, whether the perpetrator consumed illegal drugs or there were personal problems that occurred with the perpetrator that caused the perpetrator to not concentrate when doing his job. The last element is the element of loss where later in the case, attention will be paid to the losses caused by the perpetrator, for example how many victims were caused by the crime, how much damage was incurred between the two airlines. *Mens rea* is an objective element of criminal law that must be analyzed in a trial. The integration of the *mens rea* element into the criminal element comes from statements by experts. Wilson describes that "an act isn't criminal in the absence of a vicious mind". Paulsen also said that "an unwarrantable act without a vicious will is not a crime at all". Meanwhile, Oliver Wendell Holmes Jr. said that "even a dog knows the difference between being stumbled over and being kicked." In essence, *mens rea* refers to a person's intention to commit a crime. The literal translation of *mens rea* is evil intent, in Latin, the plural of *mens rea* is *mentes reae*. The implications of *mens rea* can also be seen in the principle of "actus non facit reum nisi men sit rea".

In a judicial system, law enforcement officers pay attention to the existence of *mens rea* of the perpetrator of the crime. Usually, judges decide crimes accompanied by malicious intent with a more serious offense than crimes caused by negligence. The punishment for a crime committed by a person based on *mens rea* is not explicitly stated in the law to punish certain defendants for certain crimes accompanied by malicious intent. However, there are legal elements that clearly distinguish crimes committed based on malicious intent and negligence, in Law Number 1 of 2023 concerning the Criminal Code (hereinafter referred to as the new Criminal Code) Article 55 states that anyone who commits a crime is not exempt from criminal liability based on the reason for the elimination of the criminal penalty if the person has intentionally caused a situation that can be a reason for the elimination of the criminal penalty. In addition, determining a perpetrator's *mens rea* is the same as determining *actus reus* in a criminal procedure. It is usually necessary to prove his guilt in court. The prosecutor usually has to prove beyond a doubt that the defendant committed the crime with malicious intent.⁴

B. Distribution of Hard Drugs

The distribution of hard drugs can involve various stages from production to reaching consumers. Each stage is strictly regulated by regulations to ensure the safety and legality of the use of the drug. The following are details of the distribution process of hard drugs: 1) Production: In the Research and Development (R&D) Development Stage, hard drugs are

⁴ Romli Atmasasmita, *Rekonstruksi Asas Tiada Pidana Tanpa Kesalahan*, Gramedia, Jakarta, 2017, p. 79.

first developed through scientific research to ensure effectiveness and safety. After initial development, the drug is tested through several phases of clinical trials to ensure its safety for humans. Then the drug is produced in large quantities in a pharmaceutical factory that has a permit and production standards in accordance with Good Manufacturing Practices. Good Manufacturing Practice (hereinafter referred to as GMP) itself is a complex standard in drug manufacturing procedures. In the scope of drug production, the purpose of GMP is to create a product that is affordable for the public and has good quality.⁵ 2) Supervision and Permits: In Indonesia, the Food and Drug Supervisory Agency (BPOM) must issue a distribution permit after assessing the safety, quality, and efficacy of the drug. Then Food and Drug Supervisory Agency conducts regular inspections to the factory to ensure that production meets standards. Details of the granting of permits from Food and Drug Supervisory Agency in the first stage, the company must prepare various required documents, such as administrative data, quality data, efficacy data, and safety data of the drug to be registered. Other documents that may be required include evidence of clinical trials, Good Manufacturing Practice (GMP) certificates, and other supporting documents. Furthermore, the manufacturer submits a registration application submitted through the Food and Drug Supervisory Agency e-Registration system. The company must fill out the registration form and upload all required documents.⁶

Then Food and Drug Supervisory Agency will check the completeness and validity of the administrative documents submitted. If there are any documents missing or incomplete, the company will be asked to complete them. After that, the Food and Drug Supervisory Agency evaluation team will conduct a technical evaluation of the quality, efficacy, and safety data of the drug. This process involves a detailed assessment of the submitted data to ensure that the drug meets the established standards, in some cases, Food and Drug Supervisory Agency may require additional laboratory tests to ensure the quality of the drug. This may include testing drug samples submitted by the company. Then Food and Drug Supervisory Agency will assess the risk of using the drug based on the data that has been evaluated, including the potential side effects and benefits of the drug.⁷ If the drug is declared to meet all the requirements, Food and Drug Supervisory Agency will issue a distribution permit for the drug. The company can then market the drug in Indonesia. After obtaining a distribution permit, the drug remains under the supervision of Food and Drug Supervisory Agency. The company must report any unwanted side effects and renew the permit periodically. A drug distribution permit is usually valid for a certain period of time. Before the expiration date, the company must apply for an extension of the permit by attaching updated documents and data.⁸ 3) Distribution: After obtaining permission from Food and Drug Supervisory Agency, hard drugs are distributed through official distributors who have special permission to distribute hard drugs. After that, hard drugs must be sent using methods that ensure safety and quality are maintained, such as refrigerated vehicles for drugs that require a certain temperature.

Guidelines for the distribution of prescription drugs are regulated in the Regulation of the Food and Drug Supervisory Agency Number 6 of 2020 concerning Amendments to the Regulation of the Food and Drug Supervisory Agency Number 9 of 2019 concerning

⁵ Nil Maitimu, Mercy Pattiapon, Penerapan Good Manufacturing Practise Pada UD. XYZ Di Kota Tual. *Arika*, Vol. 15, No. 20, ISSN: 19781105, 2021, p. 116-117.

⁶ *Ibid.*,

⁷ Tim Penulis BPOM, *Buku Saku Standar Pelayanan Publik*, BPOM, Palembang, 2021, p. 1-2.

⁸ *Ibid.*

Technical Guidelines for Good Drug Distribution Methods (hereinafter referred to as Regulation of the Food and Drug Supervisory Agency Number 6 of 2020). In general, there are five applications of general principles listed in Chapter I of the Regulation of the Food and Drug Supervisory Agency Number 6 of 2020. In the Regulation of the Food and Drug Supervisory Agency Number 6 of 2020, there is a crucial principle called the principle of Good Drug Distribution Methods (hereinafter referred to as CDOB). The CDOB principle is a principle that is applied with the aim that the distributed drugs are still intact and still suitable for use. Usually there are several topical drugs that cannot be exposed to direct sunlight, for example drugs clobetasol propionate. Typically this type of drug must be stored in the refrigerator to ensure that the function of the drug is not disturbed by external factors. The CDOB principle is a very complex principle, because there are more than a hundred drug variants so that the procedures for caring for these drugs are also different. 4) Sales: At the stage of distribution to pharmacies and hospitals, only pharmacies that have special permits are allowed to sell hard drugs. These pharmacies must have pharmacists who have credibility. In addition, hospitals and clinics must also have permits and special storage standards for hard drugs. 5) Post-Market Supervision: At the supervision stage, there are two types of supervision systems, namely through pharmacovigilance and periodic audits. Pharmacovigilance is a system for reporting and monitoring the side effects of hard drugs to assess the safety of use after the drug is on the market. Meanwhile, audits are carried out by Food and Drug Supervisory Agency and related agencies on pharmacies, distributors, and factories to ensure compliance with regulations.⁹

C. Policy Law Criminal Law in Combating the Circulation of Hard Drugs Without a Doctor's Prescription Online

To combat the illegal distribution of hard drugs online (without a doctor's prescription), Food and Drug Supervisory Agency has established Regulation of the Food and Drug Supervisory Agency Number 8 of 2020 concerning Supervision of Drugs and Food Distributed Online. Basically, Regulation of the Food and Drug Supervisory Agency Number 8 of 2020 cannot apply criminal sanctions to business actors. This is due to the principle of no punist without representative, where criminal offenses can only be found in regulations made by legislative officials elected through Election. Basically, these sanctions are applied by the head of the Food and Drug Supervisory agency (Article 33). If the perpetrator does not heed the administrative sanctions given, then the relevant party can submit the case or case to law enforcement officers. If the case is taken over by law enforcement officers, then criminal offenses can be applied to the perpetrator.

The criminal offense of distributing hard drugs without a doctor's prescription is stated in the Health Law, in the Health Law there are crimes that can be imposed on the perpetrator. The crime is stated in Article 435 & Article 436 of the Health Law. It has been previously analyzed that the difference between the two articles is not only in the subject, where Article 435 can apply to parties who do not have expertise in the field of pharmacy and parties who have expertise in the field of pharmacy. While Article 436 only applies to parties who do not have expertise in that field. The difference in objects in these two articles is also found in the scope of the objects contained in Article 76 paragraph 2 and Article 145 paragraph 1. It is possible that someone can be charged with alternative charges of crimes under Article 435 and Article 436 of the Health Law.

⁹ Baharuddin Yusuf, Christina Avanti, (2020), Cara Distribusi Obat yang Baik (CDOB) dan Implementasinya oleh Pedagang Besar Farmasi (PBF) di Kota Banjarmasin Banjarbaru Tahun 2019, *Jurnal Pharmascience*, Vol. 07, No. 02, p. 58-74.

CONCLUSION

Criminal sanctions circulation Prescription drugs without a doctor's prescription are illegally regulated in Law Number 17 of 2023 concerning Health, Article 435, and Article 436. Both articles can bind manufacturers (Article 435) and Distributors (Article 436). So far, there has been no specific criminal sanctions related to perpetrators of illegal online distribution of prescription drugs in Law Number 17 of 2023 concerning Health. However, the regulation of illegal online distribution of prescription drugs is regulated in Regulation of the Food and Drug Supervisory Agency Number 8 of 2020 concerning Supervision of Drugs and Food Circulated Online.

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