JOURNAL OF INTERNATIONAL ISLAMIC LAW, HUMAN RIGHT AND PUBLIC POLICY

E-ISSN: 3031-2280| https://jishup.org/ojs

Volumes 2 No. 2 (2024)

CRIMINAL LIABILITY FOR CRIMINAL OFFENDERS WHO DISTRIBUTE PHARMACEUTICAL PREPARATIONS THAT DO NOT MEET STANDARDS

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Abstract

One of the implementation of health efforts as intended in Article 48 of Law Number 36 of 2009 concerning Health is carried out through security service activities, pharmaceutical preparations and medical devices. Pharmaceutical preparations in the form of drugs and medicinal ingredients must meet the requirements of the Indonesian pharmacopoeia or other standards. The aim of this research is to find out and analyze legal provisions regarding the quality and safety standards of pharmaceutical preparations in Indonesia, the factors that cause criminal acts of distributing pharmaceutical preparations that do not meet standards, and criminal liability for perpetrators of criminal acts of distributing pharmaceutical preparations that do not meet standards. standards. This type of research is normative juridical with library data collection methods (library research). The data sources used in this research are secondary data in the form of primary legal materials, secondary legal materials and tertiary legal materials. The results of this research are: 1) Legal provisions for quality and safety standards for pharmaceutical preparations in Indonesia have been stated in Law Number 17 of 2023 concerning health. The legal provisions regulated in this Law include: a) Provisions for Distribution of Pharmaceutical Preparations (Drugs), b) Regulatory provisions regarding pharmaceutical preparations, and c) Sanctions for Criminal Actions for Distribution of Pharmaceutical Preparations (Drugs). 2) Factors that cause criminal acts of distributing pharmaceutical preparations that do not meet standards include: a) Financial gain, b) Lack of supervision and law enforcement, c) Economic Factors, d) Community Environmental Factors, and e) Business Actor Factors, 3) Criminal liability for criminals who distribute pharmaceutical preparations that do not meet standards emphasizes the principles of legality in criminal law, where a person can only be punished if they are proven to have made a mistake.

*Keywords:**Crime, Pharmaceutical Preparations, Circulating Pharmaceutical Preparations That Do Not Meet Standards***

1. INTRODUCTION

Health is a Human Right (HAM) which must be realized by implementing health efforts in Indonesia, as stated in the opening mandate of the 1945 Constitution of the Republic of Indonesia. The right of every human being to obtain health is stated in Article 4 of Law Number 36 2009 concerning Health which states "Everyone has the right to health". Apart from that, the right to receive welfare and health services is also stated in the 1945 Constitution of the Republic of Indonesia in Article 28 H Paragraph (1) which reads "Every person has the right to live in physical and spiritual prosperity, to live in and have a good and healthy living environment, and has the right to health services". Based on this article, it can be interpreted that the position of each person in question is the same and has the right to live in prosperity and receive health services regardless of status, age, etc. One of the implementation of health efforts as intended in Article 48 of Law Number 36 of 2009 concerning Health is carried out through security service activities, pharmaceutical preparations and medical devices. Pharmaceutical preparations in the form of drugs and medicinal ingredients must meet the requirements of the Indonesian pharmacopoeia or other standards.

Medicines are substances or combinations of substances, including biological products, which are used to influence or investigate physiological systems or pathological conditions in the

context of diagnosis, prevention, healing, recovery, health improvement and contraception for humans. Among the public, medicine is known to be an important element in health services. However, on the other hand, drugs can also be detrimental to health if they do not meet the requirements, if they are used inappropriately or if they are misused. Therefore, unlike other trade commodities, the distribution of medicines is regulated in such a way as to ensure safety, quality and correct use. The most frequent problem in health law that is currently widespread is crime in the pharmaceutical sector. This form of crime can occur such as the large number of drugs being distributed or traded without having a distribution permit from the authorized party, namely the Food and Drug Supervisory Agency (BPOM), which is regulated in Article 2 Paragraph 1 of the Food and Drug Supervisory Agency Regulation Number 23 of 2022 concerning Standards and /Or Quality Requirements for Medicines and Medicinal Ingredients, namely Medicines and Medicinal Ingredients manufactured and/or distributed by the permit holder must meet standards and/or requirements for safety, efficacy and quality as well as product information.

Based on the Regulation of the Minister of Health of the Republic of Indonesia regarding Number 34 of 2021 concerning Pharmaceutical Service Standards in Clinics, it states that Pharmaceutical Preparations that do not meet the standards/provisions of statutory regulations are carried out by the distribution permit holder based on a withdrawal order by BPOM (mandatory recall) or based on voluntary initiation by the owner of the distribution permit (voluntary recall) while continuing to provide reports to the Head of BPOM. This requires the government to protect consumers from pharmaceutical preparations that do not meet applicable standards. Article 1 paragraph 2 of the Regulation of the Minister of Health of the Republic of Indonesia Number 72 of 2016 concerning Pharmaceutical Service Standards in Hospitals explains that Pharmaceutical Service Standards are benchmarks used as guidelines for pharmaceutical personnel in providing pharmaceutical services. Meanwhile, criminal provisions for people who violate the provisions of Article 138 paragraph 2 are regulated in Article 435 of the Health Law Number 17 of 2023 concerning Health which reads "Every person who produces or distributes Pharmaceutical Preparations and/or Medical Devices that do not meet standards and/or safety, efficacy/benefit and quality requirements as referred to in Article 138 paragraph (2) and paragraph (3) shall be punished by a maximum imprisonment of 12 (twelve) years or a maximum fine of IDR 5,000,000,000.00 (five billion rupiah)."

Based on the case of illegal drug and food distribution revealed by BPOM through the "apotik_official" account on Shopee, this is a serious violation of the applicable laws and regulations regarding pharmaceutical preparations. Based on the Regulation of the Minister of Health of the Republic of Indonesia Number 34 of 2021 concerning Pharmaceutical Service Standards, every pharmaceutical preparation that does not meet the standards or provisions must be withdrawn from circulation by the distribution permit holder through a BPOM order (mandatory recall) or voluntary initiative (voluntary recall). However, in this case, the trafficker did not have a distribution permit and had sold products that did not meet the established quality and safety standards, and contained unknown dosages of medicinal chemicals (BKO). These actions not only violate provisions on pharmaceutical service standards but also place consumers' health at grave risk, demonstrating flagrant non-compliance with public health and safety regulations.

2. METHOD

This research specification uses a descriptive analytical type, namely research that provides detailed data about a situation or other symptoms. This research specification is descriptive analytical in nature, that is, it describes the legal facts and/or applicable laws and regulations in a comprehensive manner regarding the object of research to then be linked to legal theories in the practice of implementation concerning the problem under study. Apart from providing a description, writing and reporting of an object or event, research will also draw general conclusions from the issues discussed regarding criminal liability for perpetrators of criminal acts who distribute pharmaceutical preparations that do not meet standards.

3. RESULTS AND DISCUSSION

3.1 Proving the Crime of Distributing Pharmaceutical Preparations That Do Not Meet Standards

Proof in criminal cases is different from evidence in civil cases, because in criminal case evidence (criminal procedural law) the aim is to find material truth, namely the true or real truth. In this context, the evidentiary process in the legal system is very important to generate confidence in judges in making decisions in accordance with the provisions regulated in Article 183 of the Criminal Procedure Code. This article states that a judge can only impose a crime on a person if there are at least two valid pieces of evidence that make him believe that a criminal act has occurred and that the defendant is guilty of committing that act.

The meaning of proof can be viewed from the perspective of criminal procedural law, including:

1. Provisions that limit the court's efforts to seek and maintain the truth. Whether judges, public prosecutors, defendants or legal advisors are all bound by the provisions of procedures and evaluation of evidence as determined by law. You must not be free to act in your own way in assessing evidence. When using evidence, it must not conflict with the law. The defendant cannot freely defend something he considers to be true outside of the provisions outlined in the law. Especially for the Panel of Judges, they must be truly aware and carefully assess and consider the strength of the evidence found during the trial examination. If the panel of judges wishes to place the truth found in the decision to be handed down, that truth must be tested with evidence, in a manner and with the strength of proof inherent in each piece of evidence found. If this is not the case, bad people could get away with it and innocent people would be punished.
2. In connection with the above definition, the panel of judges in seeking and placing the truth to be handed down in a decision must be based on evidence that has been determined by law in a "limitiative" manner as referred to in Article 184 of the Criminal Procedure Code.

The negative system of evidence according to law is a theory between the positive system of evidence according to law and the system of evidence according to belief or conviction in time. In several countries around the world there are several legal systems adopted, including the following:

1. Proof is based solely on the judge's belief (conviction in time), namely an evidentiary system for determining whether a defendant is guilty or not based solely on belief alone, it does not matter where the belief comes from. The judge only follows his conscience and everything depends on the judge's discretion. The judge's impression is very subjective in determining whether a defendant is guilty or not. So, the judge's decision is possible without being based on evidence regulated by law. Even though the judge himself is just an ordinary human being. Of course, you can be wrong in determining this belief
2. The evidentiary system is based on positive law (possitieg wetteliejke bewijstheorie), namely an evidentiary system aimed at determining whether the defendant is guilty or not must be guided by the principles of proof using evidence determined by law. This system is the opposite of the conviction in time system. Beliefs are sidelined in this system. According to this system, the law determines the limitations of the evidence which may be used by the judge, the ways in which the judge uses the evidence and the evidentiary strength of the evidence in such a way. If the evidence has been used legally as stipulated by law, then the judge must determine the condition of being legally proven, even though he may believe that what must be proven is not true.
3. The Evidence System is based on the judge's belief for logical reasons (La conviction raisonnee), namely the role of the judge's belief is very important. However, a judge can only sentence a defendant if he believes that the act in question has been proven to be true. This belief must be accompanied by reasons based on a series of thoughts (logic). The

judge is obliged to describe and explain the reasons underlying his belief in the defendant's guilt. The reason must be truly acceptable to reason. This evidentiary system recognizes the existence of certain things that are not stipulated by law. The amount of evidence used to determine whether a defendant is guilty or not is the sole authority of the judge. Of course, the judge must be able to explain the reasons for the decision he made.

4. The system of evidence according to the law is negative (negatief wettelijk Bewijstheorie), which is a combination of the system of evidence according to the law positively and the system of evidence based solely on the judge's belief. The system of evidence according to the law in a negative way is a system of balance between systems that are in extreme opposition to each other. This system accommodates a positive system of evidence according to law and a system of evidence based solely on the judge's belief.

The evidence system adopted by Indonesia is a negative evidence system based on law (negatief wettelijk), this can be concluded from article 183 of the Criminal Procedure Code.
Article 183 of the Criminal Procedure Code reads:

"The judge may not sentence a person to a crime unless, with at least two valid pieces of evidence, he is convinced that a criminal act actually occurred and that the defendant is guilty of committing it."

From this sentence it is clear that evidence must be based on the law (KUHAP), namely the valid evidence as stated in article 184 of the Criminal Procedure Code, accompanied by the judge's confidence obtained from the evidence. In this system or theory of evidence which is based on negative law, punishment is based on multiple pieces of evidence, namely on statutory regulations and on the judge's belief, and according to the law, the basis of the judge's belief is based on statutory regulations.

To be considered valid as evidence that has evidentiary value, witness testimony must be met with the following provisions:

1. Must take an oath or promise. According to the provisions of Article 160 paragraph (3), before a witness gives a statement, he or she is "must take" an oath or promise. As for oaths or promises:
   a. Done according to the way of each religion
   b. The oath or promise states that the witness will provide truthful information and nothing other than the truth
2. Witness statements that have value as evidence. Not all witness statements have value as evidence. Witness testimony that has value is information that is in accordance with what is explained in Article 1 point 27 of the Criminal Procedure Code:
   a. What the witness saw for himself
   b. The witness heard it himself
   c. Experience it yourself
   d. And mention the reasons for his knowledge.
3. Witness statements must be given in court. In order for witness statements to be considered as evidence, the statements must be stated in court. This is in accordance with the confirmation of Article 185 paragraph (1). If so, a witness's statement, which contains an explanation of what he himself heard, saw or experienced regarding a criminal incident, can only be valuable as evidence if the witness declares this information in court.
4. The testimony of one witness alone is considered insufficient. In order for a witness's testimony to be considered sufficient to prove the guilt of a defendant, it must be accompanied by at least two pieces of evidence, so the testimony of one witness alone is only valuable as one piece of evidence which must be supplemented and sufficed with other pieces of evidence. . So, starting from the provisions of Article 185 paragraph (2), the testimony of a witness alone cannot be considered sufficient evidence to prove the defendant's guilt. It can be concluded that the requirements required by Article 185 paragraph (2) are:

a. To be able to prove the defendant's guilt, it must be supported by at least two witnesses.
b. Or if there is only one witness, then that single testimony must be supplemented or supplemented by one other piece of evidence

5. The testimony of several witnesses who stand alone. Often there are errors in opinion, while people think that the presence of several witnesses is considered to be that the testimony of many witnesses is sufficient to prove the defendant's guilt. This opinion is wrong because even if the witnesses who are presented and whose statements are heard at the court hearing "quantitatively" have exceeded the minimum threshold of proof, it is not certain that their "qualitative" statements are sufficient as valid evidence to prove the defendant's guilt. There is no point in presenting a large number of witnesses if qualitatively their statements stand alone without any relationship between one another that can establish a truth about the existence of a particular event or situation.

Proving the criminal act of distributing pharmaceutical preparations that do not meet standards involves a series of legal processes that require strong and clear evidence. First of all, in this process, it needs to be proven that the perpetrator deliberately carried out the act of distributing pharmaceutical preparations that do not meet the standards set by health law. This includes understanding and implementing standards for safety, efficacy, usefulness and quality of medicines in accordance with applicable regulations. Relevant evidence such as laboratory test results, certifications, or expert pharmacist reports may be needed to substantiate the charges. In addition, in this proof, it is important to show that the perpetrator does not have the expertise and authority required to carry out pharmaceutical distribution activities, in accordance with the provisions of the law. This evidentiary process will ensure that justice is served by investigating and enforcing the law against perpetrators responsible for violating actions that have a negative impact on public health.

Analysis of the evidence for criminal acts of distributing pharmaceutical preparations that do not meet standards also reflects the importance of law enforcement in maintaining the quality and safety of health products. A thorough evidentiary process will provide a strong signal that the government is serious about fighting illegal practices that can endanger society. Apart from that, law enforcement against perpetrators who violate drug standards can also have a preventive effect, by warning other parties to comply with applicable health regulations. This has the effect of increasing awareness of the importance of drug quality and compliance with the rules set by health regulatory bodies. Therefore, the process of proving this criminal act is not only a step to uphold justice, but also an effort to protect public health and safety from health products that do not meet established standards. Proving the criminal act of distributing pharmaceutical preparations that do not meet standards involves a legal process that requires strong and clear evidence to find material truth. This requires evidence showing that the perpetrator deliberately violated the safety, efficacy, usefulness and quality standards of medicines set by health law. Evidence such as laboratory test results, certifications, and pharmacist expert reports are used to strengthen the charges. This process is important to uphold justice, prevent illegal practices, increase awareness of drug quality, and ensure compliance with applicable health regulations, thereby protecting public health and safety from health products that do not meet standards.

3.2 Criminal Sanctions Against Criminal Perpetrators Who Distribute Pharmaceutical Preparations That Do Not Meet Standards

Criminal sanctions are a type of cause and effect punishment, the cause is the case that was committed and the effect is the punishment received. Someone who is affected will be sentenced to prison or other punishment from the authorities. One type of sanction of a sad nature given to perpetrators of criminal acts that can endanger and damage legal interests is called criminal sanctions. Basically, criminal sanctions are a guarantor for changing the behavior and mindset of perpetrators of these crimes, but for some people these criminal sanctions are created as a threat to

human freedom. Criminal sanctions imposed on perpetrators of crimes can be divided into two types, namely basic penalties and additional penalties. Based on its objective, criminal sanctions aim to provide special suffering (Bijzonder leed) to the offender so that he feels the consequences of his actions. Apart from being aimed at imposing suffering on the perpetrator, criminal sanctions are also a form of expressing condemnation of the perpetrator's actions.

Thus, the difference between principles and action sanctions lies in whether there is an element of blame, not in whether there is an element of suffering. Determining the type and form of sanctions is actually part of criminal policy which requires the use or application of rational methods. It is clear that the policy of determining a sanction is a means, method and/or action that is rational and directed towards a predetermined goal. In other words, the first step in determining a type of sanction is to determine the objectives to be achieved by the sanction itself. An important part of the criminal system is determining sanctions. Its existence will provide direction and consideration regarding what should be used as sanctions in a criminal act to enforce the enactment of norms. On the other hand, punishment itself is the most complex process in the criminal justice system because it involves many different people and institutions. If the criminal provisions of Law no. 36 of 2009 concerning Health (Articles 190 to Article 201) is identified, then the final policy formulation pattern will be found as follows:

1. Law no. 36 of 2009 concerning Health adheres to a "single track system" (only criminal sanctions).
2. In terms of using criminal sanctions, the main penalty and additional penalties are used.
3. The main penalties used are imprisonment and fines, while additional penalties include revocation of business permits and revocation of legal entity status {Article 201 paragraph (2)}.
4. The formulation of criminal sanctions in Law no. 36 of 2009 concerning Health is carried out singly and cumulatively.

The imposition of criminal sanctions and administrative sanctions on those who distribute pharmaceutical preparations without a distribution permit also applies to dealers who distribute pharmaceutical preparations without a permit conventionally/directly or digitally/online sales in accordance with Positive Law. The statutory provisions in the field of consumer protection also emphasize that business actors who do not carry out their obligations as stipulated in the Consumer Protection Law will be subject to legal sanctions, both civil, administrative and criminal sanctions. Administrative sanctions in the form of compensation are contained in Article 60 of the Consumer Protection Law, which states that:

(1) "The consumer dispute resolution body has the authority to impose administrative sanctions on business actors who violate Article 19 paragraph (2) and paragraph (3), Article 20, Article 25 and Article 26.
(2) Administrative sanctions in the form of determining compensation of a maximum of Rp. 200,000,000.00 (two hundred million rupiah)."

Criminal sanctions are explained in Article 62 Paragraph (1) of the Consumer Protection Law, which regulates that;

(1) "Business actors who violate the provisions as intended in Article 8, Article 9, Article 10, Article 13 paragraph (2), Article 15, Article 17 paragraph () letters a, letter b, letter c, letter e, paragraph (2), and Article 18 is punishable by a maximum imprisonment of 5 (five) years or a maximum fine of Rp. 2,000,000,000.00 (two billion rupiah)."

In addition to the criminal sanctions above, Article 63 of the Consumer Protection Law also states additional penalties that can be given to business actors for criminal sanctions as intended in Article 62, in the form of;

a. Confiscation of certain goods;
b. Announcement of the judge's decision;
c. Payment of compensation;
d. Orders to stop certain activities that cause consumer losses;

e. Obligation to withdraw goods from circulation; or
f. Revocation of business license.

The application of criminal sanctions to the distribution of pharmaceutical drug preparations without a distribution permit must fulfill aspects of justice, fulfill the parts of the criminal process or the application of sanctions and must be in accordance with the function of the punishment. Provisions regarding the criminal act of distributing pharmaceutical preparations in Government Regulation Number 72 of 1998 are regulated in Article 75 letter (b). The formulation contained in this article is:

> "Distribute pharmaceutical preparations and medical devices without a distribution permit as intended in Article 9; be sentenced to a maximum imprisonment of 7 (seven) years and/or a maximum fine of Rp. 140,000,000.00 (one hundred and forty million rupiah) in accordance with the provisions of Article 81 paragraph (2) of Law Number 23 of 1992 concerning Health. "

Law no. 36 of 2009 concerning Health Article 197 states: every person who deliberately produces or distributes pharmaceutical preparations and/or medical devices which do not have a distribution permit as intended in Article 106 paragraph (1) shall be punished with a maximum imprisonment of 15 (fifteen) years and a maximum fine of IDR 1,500,000,000.00 (one billion five hundred million rupiah). The main condition for allowing a criminal conviction is the existence of a (human) act that meets the definition of an offense in the law, this is a consequence of the principle of legality. The formulation of this offense is important, meaning that as a principle of certainty, criminal law must be definite in nature, it must be able to know with certainty what is prohibited or what is ordered and whether it is worthy of being called a criminal act.

One of the criminal acts in the pharmaceutical sector is the distribution of drugs or pharmaceutical preparations without a distribution permit from the Food and Drug Supervisory Agency (BPOM), which is a violation that often occurs. A distribution permit is an approval for drug registration that allows the drug to circulate in Indonesia. Every pharmaceutical preparation to be distributed must have a distribution permit in accordance with the provisions of the law, as regulated in Article 143 paragraph (1) and paragraph (2) of Law Number 17 of 2023 concerning Health. This violation is punishable by a criminal penalty in the form of imprisonment for a maximum of 12 years or a maximum fine of IDR 5,000,000,000.00 in accordance with Article 435 of Law number 17 of 2023 concerning Health. Legislation that regulates the distribution of drugs that do not have standards or illegal drugs is regulated in a Special Law, namely Law Number 36 of 2009 concerning Health, apart from that it is also regulated in the General Law, namely the Criminal Code. The explanation regarding the regulation of criminal acts of drug counterfeiting contained in Law Number 36 of 2009 concerning Health is as follows:

1. The crime of drug counterfeiting by producing and distributing drugs that do not comply with drug standards.

   Article 196 of Law Number 36 of 2009 concerning Health regulates the criminal act of counterfeiting medicines or selling medicines without a distribution permit. The article states "that every person who deliberately produces or distributes pharmaceutical preparations and medical devices that do not meet the standards and requirements for safety, efficacy, or usefulness and quality as intended in article 98 paragraph (2) and paragraph (3) will be subject to imprisonment a maximum of 10 years or a maximum fine of Rp. 1,000,000,000.00"

   The act of producing or selling drugs without a distribution permit is an unlawful act because the drug does not meet the standards or requirements for safety, efficacy, or usefulness and quality as intended in Article 98 paragraph (2). This article states that every person who does not have the expertise and authority is prohibited from carrying out activities such as procuring, storing, processing, promoting, distributing or selling drugs and medicinal substances. Meanwhile, Article 98 paragraph (3) emphasizes that provisions regarding the procurement, storage, processing, promotion and distribution of

pharmaceutical preparations and medical devices must meet the quality standards for pharmaceutical services stipulated by Government Regulations.

2. The crime of drug counterfeiting is producing and distributing drugs that do not have a distribution permit

   Referring to the definition of counterfeit drugs according to Minister of Health Regulation Number 1010/Menkes/Per/XI/2008 concerning Drug Registration, counterfeit drugs are drugs produced by those who do not have the right under the applicable laws and regulations or the production of drugs with markings that imitate the identity of other drugs. which already has a distribution permit. So drugs that are produced or sold without a distribution permit or imitate drugs that already have a distribution permit are counterfeit drugs and the regulation is contained in Article 197 of Law Number 36 of 2009 concerning Health, which reads: "Everyone who intentionally producing or distributing pharmaceutical preparations or medical devices that do not have a distribution permit as intended in Article 106 paragraph (1) is punishable by a maximum imprisonment of 15 (fifteen) years and a maximum fine of Rp. 1500,000,000.00 (one billion five hundred million rupiah).

3. The crime of drug counterfeiting is producing drugs without expertise and authority
   Article 198 of Law Number 36 of 2009 concerning Health, reads: "Every person who does not have the expertise and authority to carry out pharmaceutical practice as intended in Article 108 shall be punished with a fine of up to Rp. 100,000,000.00 (one hundred million rupiah)".

According to Article 198 of Law Number 36 of 2009 concerning Health relating to the criminal act of drug counterfeiting, it regulates the prohibition of any person who does not have the expertise and authority to carry out pharmaceutical practice, in this case the manufacture and distribution in accordance with the provisions of the Legislative Regulations, because without having the expertise and authority, errors can occur and the manufacture or distribution of drugs can be categorized as counterfeit drugs. Criminal sanctions against criminals who distribute pharmaceutical preparations that do not meet standards are an integral part of the legal system which aims to enforce compliance with health regulations and protect the public from health risks arising from the consumption of drugs that do not meet standards. Article 196 of Law Number 36 of 2009 concerning Health provides the legal basis for imposing strict sanctions against violators.

The aim of providing criminal sanctions is to provide a deterrent effect to perpetrators and prevent similar actions in the future. With a maximum prison sentence of 10 years and a maximum fine of Rp. 1,000,000,000.00, this penalty is not only a form of justice for detrimental actions, but also an affirmation that the safety and quality of medicines is a priority that must be maintained in the health system. Apart from that, the provision of criminal sanctions also has an important preventive function in protecting society. By providing appropriate punishments to perpetrators of criminal acts, the government and law enforcement agencies demonstrate their commitment to take firm action against any violations that harm society. This also provides protection for consumers' rights to gain access to safe and quality medicines. Apart from that, this criminal sanction can also provide a warning to drug business actors to comply with the standards set in health regulations and reduce the possibility of illegal practices in the pharmaceutical industry. Thus, providing criminal sanctions is an important instrument in ensuring the safety and quality of drugs circulating in society. Criminal sanctions against criminals who distribute pharmaceutical preparations that do not meet standards are a form of punishment regulated in Law Number 36 of 2009 concerning Health. The imposition of these sanctions is a result of violating actions carried out by the perpetrator, and aims to enforce compliance with health regulations and protect the public from health risks arising from the consumption of drugs that do not meet standards. With a maximum prison sentence of 10 years and a fine of up to Rp. 1,000,000,000. This sanction is also a form of confirmation that the safety and quality of medicines is a priority that must be maintained in the health system. Apart from that, the provision of criminal sanctions also has an important preventive function in protecting the public, providing protection for consumer rights, and warning drug

business actors to comply with the standards set out in health regulations. Thus, criminal sanctions are an important instrument in ensuring the safety and quality of drugs circulating in society.

3.3 Criminal Responsibility for Criminal Perpetrators of Distributing Pharmaceutical Preparations That Do Not Meet Standards

The basis for a criminal act is the principle of legality, while the basis for a person being punished is error, which means that a person cannot possibly be held responsible and sentenced to a crime if they have no fault. A person who commits a criminal act can be punished if he has made a mistake, and when can someone be said to have made a mistake? This is what will be discussed in the issue of criminal liability. Article 36 of the 2012 Criminal Code Draft Law states that the meaning of criminal responsibility is the passing of objective blame on a criminal act and subjectively to someone who meets the requirements to be sentenced to a crime because of that act. Criminal liability is closely related to the element of error. The element of error in the case of drugs without a distribution permit is the element of intent (dolus). Deliberation which is only directed at prohibited actions is called formal intent, while that which is aimed at the consequences is material intent. As intended in Law no. 4 of 2004 concerning judicial power Article 6 paragraph (2) states:

> "No one can be sentenced to a crime unless the court, through legal means of evidence according to law, is convinced that a person who is deemed to be responsible is guilty of the act for which he is charged."

Criminal liability in the crime of drug counterfeiting as regulated in Law Number 36 of 2009 concerning Health recognizes the classification of perpetrators, including:

1. A person or individual (person) whose single action fulfills the formulation of a criminal act, in this case the crime of drug counterfeiting, and who is called a sole maker (dader).
2. Corporations as the subject of criminal acts are currently relevant, considering that the majority of counterfeit drug production is carried out by business actors with large-scale companies (big business), and there needs to be a legal umbrella that strictly regulates criminal sanctions for corporate actors.

In the previous Health Law, namely Health Law Number 23 of 1992, corporate criminal acts were not explicitly regulated, but currently it is clearly regulated in the current Health Law. The subject of corporate criminal acts can be found in Article 201 of Law Number 36 of 2009 concerning Health. The explanation of this article is as follows:

Article 201 of Law Number 36 of 2009 concerning Health

1. In the event that criminal acts as intended in Article 190 paragraph (1), Article 191, Article 192, Article 196, Article 197, Article 198, Article 199 and Article 200 are committed by a corporation, in addition to imprisonment and fines for its management, the criminal can be imposed on a corporation in the form of a fine with a weighting of 3 (three) times the fine as intended in Article 190 paragraph (1), Article 191, Article 192, Article 196, Article 197, Article 198, Article 199 and Article 200.
2. In addition to the fine as referred to in paragraph (1), corporations may be subject to additional penalties in the form of revocation of their business license, and/or revocation of their legal status.

Basically, civil liability aims to obtain compensation for losses suffered in addition to preventing undesirable things from happening. In criminal law, in order to be criminalized for an error that can be interpreted as liability, it must fulfill 3 (three) elements, namely:

1. The ability to take responsibility for the perpetrator means that the perpetrator's mental state must be normal.
2. There is an inner relationship between the perpetrator and his actions which can be intentional (dolus) or negligence (culpa).
3. There is no reason to erase mistakes or forgive.

With regard to the responsibilities of business actors, it can be seen in Article 19 Paragraph (1) of the Consumer Protection Law, which regulates that;

"Business actors are responsible for providing compensation for damage, pollution and/or consumer losses resulting from consuming goods and/or services produced or traded."

Paying attention to the substance of Article 19 Paragraph (1) of the Consumer Protection Law, that the responsibilities of business actors include;

1. Responsibility for compensation for damage.
2. Responsibility for compensation for pollution.
3. Responsibility for compensation for consumer losses.

The statutory provisions in the field of consumer protection also emphasize that business actors who do not carry out their obligations as stipulated in the Consumer Protection Law will be subject to legal sanctions, both civil, administrative and criminal sanctions. A form of administrative responsibility that can be demanded from producers as business actors if it is proven that the business actor must be given sanctions in the form of compensation sanctions as explained in Article 19 paragraph (2) of the Consumer Protection Law which regulates that;

"Compensation as intended in Paragraph (1) can be in the form of a refund or replacement of goods and/or services of the same type or equivalent value, or health care and/or provision of compensation in accordance with the provisions of the applicable laws and regulations"

Criminal liability for perpetrators of criminal acts of distributing pharmaceutical preparations that do not meet standards involves the application of the law as an effort to uphold justice and ensure protection of public health. In this context, the perpetrator of the criminal act can be subject to criminal sanctions in accordance with the level of error committed, which can be in the form of a fine, prison sentence, or a combination of both. Criminal liability also aims to provide a deterrent effect on perpetrators and other parties to comply with applicable health regulations and not take the risk of violating drug standards. Thus, the criminal accountability process is not only a law enforcement effort, but also a preventive measure to prevent illegal practices that can endanger public health.

Analysis of criminal liability for perpetrators of criminal acts distributing pharmaceutical preparations that do not meet standards shows the importance of law enforcement in ensuring the quality and safety of health products. Through the criminal sanctions imposed, the government confirms its commitment to protecting public health and maintaining the integrity of the health sector. Apart from that, criminal liability is also an instrument for creating a healthy and orderly business environment in the pharmaceutical sector, which in turn can increase public trust in health products. Thus, criminal liability is not only a form of punishment, but also a strategic step in an effort to maintain public health and safety from health products that do not meet established standards. Criminal liability for perpetrators of criminal acts of distributing pharmaceutical preparations that do not meet standards confirms the principle of legality in criminal law, where a person can only be punished if they are proven to have made a mistake. Article 36 of the 2012 Draft Criminal Code explains that criminal responsibility involves objective criticism of criminal acts and subjective condemnation of individuals who meet the requirements to be punished for their actions. This criminal liability also links the element of error to the crime of drug counterfeiting and introduces criminal liability for corporate actors in the context of health violations. These criminal sanctions, such as imprisonment and fines, aim to uphold justice, prevent illegal acts, and protect the public from health products that do not meet standards. Meanwhile, in the context of consumer protection, business actors who violate the rules may also be subject to criminal and administrative sanctions, including compensation, imprisonment and revocation of business permits. Thus, criminal liability becomes an important instrument in maintaining the quality and safety of health products and creating a healthy business environment.

4. CLOSING

4.1 Conclusion

Based on the results of research conducted by researchers, the conclusions in this study are as follows:

1. Legal provisions for quality and safety standards for pharmaceutical preparations in Indonesia are stated in Law Number 17 of 2023 concerning health. The legal provisions regulated in this Law include: a. Provisions for Distribution of Pharmaceutical Preparations (Drugs), b. Regulatory provisions regarding pharmaceutical preparations, and c. Sanctions for the Crime of Distribution of Pharmaceutical Preparations (Drugs). Regulations regarding the safety and use of pharmaceutical preparations are also regulated in Articles 140, 142 and 143 of Law Number 17 of 2023 concerning Health. The safety of medicinal products is the focus in ensuring marketing suitability. The government carries out inspections at production facilities to ensure good production practices and compliance with applicable standards. Effective reporting and monitoring systems are needed to ensure safe use of products, with the ability for consumers and interested parties to report side effects or health problems related to product use.
2. Factors that cause criminal acts of distribution of pharmaceutical preparations that do not meet standards include: a) Financial benefits. Business actors who do not have a distribution permit can obtain greater profits because they do not need to pay registration and supervision fees from the Food and Drug Monitoring Agency (BPOM); b) Lack of supervision and law enforcement. Weak supervision and law enforcement can make it easier for perpetrators to commit criminal acts of distributing pharmaceutical preparations without a distribution permit; c) Economic Factors, because a person is in a very weak economic position and has various life demands to meet their daily needs; d) Community Environmental Factors, a person's personality will be formed following the pattern or flow in a society where a person lives and develops; and e) Business Actor Factors, weak supervision of drug distribution by BPOM, supervision of pharmacies and drug shops and the process of obtaining distribution permits takes a long time and costs a lot of money as a condition for distributing drugs.
3. Criminal liability for perpetrators of criminal acts who distribute pharmaceutical preparations that do not meet standards emphasizes the principles of legality in criminal law, where a person can only be punished if they are proven to have made a mistake. This criminal liability does not only cover individuals, but also corporations involved in health violations. Every pharmaceutical preparation to be distributed must have a distribution permit in accordance with the provisions of the law, as regulated in Article 143 paragraph (1) and paragraph (2) of Law Number 17 of 2023 concerning Health. This violation is punishable by a criminal penalty in the form of imprisonment for a maximum of 12 years or a maximum fine of IDR 5,000,000,000.00 in accordance with Article 435 of Law number 17 of 2023 concerning Health. Therefore, criminal liability is not only a form of punishment, but also a strategic step in maintaining the quality and safety of health products and creating a healthy business environment.

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