JURNAL JURISPRUDENCE
Vol. 14, No. 1, 2024, pp.152-136
p-ISSN: 1829-5045 ; e-ISSN : 2549-5615
Website: https://journals2.ums.ac.id/index.php/jurisprudence/issue/view/172

Juridical Reasoning for the Distribution of Pharmaceutical Preparations that Failed the Efficacy Test in Court Decisions

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DOI: 10.23917/jurisprudence.v14i1.4094

Submission Track:

Received:

January 22, 2024

Final Revision:

June 25, 2024

Available online:

June 30, 2024

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ABSTRACT

Purpose: The purpose of this research is to determine the judge's considerations in imposing sanctions on pharmaceutical distributors who do not meet the efficacy and quality standards by the Ponorogo District Court Decision 115/Pid.Sus/2023/PN Png using ratio decidendi. **Methodology:** The methodology used is normative or library research. This research is qualitative in nature and describes data regularly. This research employed a jurisprudential and legal approach. The data were then analyzed using interpretation. **Results:** The results of this research revealed several cases of drug distribution that did not match the efficacy and quality, violating the protection rights of consumers. The government and BPOM are expected to pay more attention to the pharmaceutical production process and provide education to the general public regarding the pharmaceutical sector so that they **obtain** safe and quality pharmaceutical products. In Ponorogo District Court Decision 115/Pid, Sus/2023/PN Png, the panel of judges considered evidence, legal interpretation, and ethics during the trial. This case violates Act Number 36 of 2009 Article 196 concerning Health. Considering this, mitigating and aggravating circumstances arose for the defendant, and the theory of will and the theory of knowledge were used so that he was charged with imprisonment for 1 (one) year and a fine of IDR 5,000,000.00 (five million rupiah) provided that if the fine was not payment, it was replaced

by imprisonment for one month. The decision at the Ponorogo District Court provides a solid foundation for future courts in handling similar cases.
Applications of this study: This research can be used to provide an in-depth understanding of the ratio decidendi in Ponorogo District Court decisions for perpetrators, legal practitioners, academics, and policymakers for future directions.
Novelty/Originality of this study: This research differs from previous studies in terms of research focus, including research location, type of drug used, and District Court Decisions.
Keywords: Juridical, Pharmaceutical, Decision

ABSTRAK

Tujuan*: Tujuan penelitian ini adalah untuk mengetahui pertimbangan hakim dalam menjatuhkan sanksi kepada distributor farmasi yang tidak memenuhi baku mutu khasiat dan mutu berdasarkan Putusan Pengadilan Negeri Ponorogo 115/Pid.Sus/2023/PN Png menggunakan rasio keputusan (ration decidendi).*
Metodologi*: Metodologi yang digunakan adalah penelitian normatif atau kepustakaan. Penelitian ini bersifat kualitatif dan mendeskripsikan data secara berkala. Penelitian ini menggunakan pendekatan yurisprudensi dan hukum. Data kemudian dianalisis menggunakan interpretasi.*
Temuan: *Hasil penelitian mengungkapkan beberapa kasus peredaran obat yang tidak sesuai khasiat dan mutunya sehingga melanggar hak perlindungan konsumen. Pemerintah dan BPOM diharapkan lebih memperhatikan proses produksi farmasi dan memberikan edukasi kepada masyarakat umum mengenai sektor farmasi sehingga memperoleh produk farmasi yang aman dan berkualitas. Dalam Putusan PN Ponorogo 115/Pid, Sus/2023/PN Png, majelis hakim mempertimbangkan alat bukti, penafsiran hukum, dan etika selama persidangan. Perkara ini melanggar Undang-Undang Nomor 36 Tahun 2009 Pasal 196 tentang Kesehatan. Menimbang hal tersebut, maka timbul keadaan yang meringankan dan memberatkan bagi terdakwa, dan digunakan teori kemauan dan teori pengetahuan sehingga didakwa dengan pidana penjara 1 (satu) tahun dan denda Rp5.000.000,00 (lima juta rupiah) dengan ketentuan: jika denda tidak dibayar, diganti dengan pidana penjara selama satu bulan. Putusan Pengadilan Negeri Ponorogo memberikan landasan yang kuat bagi pengadilan selanjutnya dalam menangani kasus serupa.*
Kegunaan: *Penelitian ini dapat digunakan untuk memberikan pemahaman mendalam mengenai ratio decidendi dalam putusan Pengadilan Negeri Ponorogo bagi pelaku, praktisi hukum, akademisi, dan pengambil kebijakan untuk arah ke depan.*
Kebaruan/Orisinalitas: *Penelitian ini berbeda dengan penelitian-penelitian sebelumnya dalam hal fokus penelitian, meliputi lokasi penelitian, jenis obat yang digunakan, dan Putusan Pengadilan Negeri.*

Kata Kunci: Yuridis, Kefarmasian, Keputusan

INTRODUCTION

The human body requires health as a critical component. All humans, including nations worldwide, aspire to good health, and all nations are striving to enhance their health systems. Indonesia is one of them. This aligns with the international definition of health, which defines it as *"a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"* (Saragih et al., 2021)**.**

Health is a state in which humans are physically, mentally, and even socially well. A person can be considered healthy if he/she can do productive activities in his/her life economically and socially (Sidoretno & Oktaviani Rz, 2018). As such, maintaining health is an obligation for all humans. Health can be maintained by consuming nutritious foods, exercising, and even taking vitamins. Maintaining health is also a form of gratitude from humans to God, who created them. Moreover, one of the human rights is the right to health. Every human being has the right to have a decent life. These rights include the right to obtain adequate health (Miharso, 2021). Consequently, medicine is a crucial component of human health. Medicines are used to maintain health, restore health, and even save lives. Most health efforts in society and health services require a drug (Pambudi & Raharjo, 2020).

In Indonesia, Article 34, section 3 of the 1945 Constitution states that the state has the responsibility to provide adequate health service facilities and public facilities. The government is obliged to guarantee the health of its people by providing and distributing essential medicines. To meet the public's need for medicines, some obtain a distribution permit freely, and there are those whose distributors must obtain permission from a competent party (Nachrawi & Dewi, 2021). Most of the community, when experiencing symptoms of illness in their bodies but with mild symptoms, prefer to use self-medication or buy medicine without a doctor's prescription, including herbal and traditional medicine. These medications are intended for minor illnesses that can be self-diagnosed.

Self-medication is better used with adequate knowledge to avoid drug abuse or inappropriate use of drugs. BPOM (The Indonesian Food and Drug Authority) created the slogan "Cek KLIK," which stands for Checking Packaging, Label, Marketing Permit, and Expiry, so that people feel safe when using self-medication (Suena et al., 2022). Nevertheless, nowadays, there are many inappropriate sales of drugs. Pharmacies are a means of selling

medicines. The pharmacy itself has a pharmacist who knows about the medicines being sold. The large number of cases of drug distribution without a distribution permit has caused an increase in crime cases in Indonesia. In Ponorogo City, there are several cases of illegal drug distribution. This proves that in Ponorogo Regency, this case has not been handled properly.

The government has stipulated the regulation as a form of health protection for Indonesian citizens, Act Number 17 of 2023 concerning Health. This law establishes the government as a supervisor in the implementation of health. The regulation aims to ensure equal health services for consumers or citizens and protect consumer rights in the form of discrimination or negligence that can endanger their health (Wirasto et al., 2024). The regulation on health, which was originally Act No. 36 of 2009, was abolished and amended with Act No. 17 of 2023. The new regulation discusses health in a more general and non-specific manner. However, overall, it discusses the technical aspects of drug distribution in a single space, namely a pharmaceutical management facility or non-individual institution, to close the gap in individual drug distribution (Pratama & Herlina, 2023).

The rules above were created to avoid the sale of drugs that do not match the efficacy and quality. Nevertheless, most perpetrators of distributing inappropriate drugs do not feel afraid and are deterred by only caring about their gain (Amelia & Anggraini, 2020). The distribution of drugs without efficacy and quality or illegal, apart from being for the personal interests of the perpetrators, is because illegal drugs are easier to obtain than legal drugs, and illegal drugs are more economical than drugs that have obtained a distribution permit from the Indonesian Food and Drug Authority. The profits from selling illegal drugs are more significant than those selling legal drugs (Putra & Priyanti, 2021). Frequently, the people who become victims of illegal drug distribution are those from the lower classes. These people are forced to consume illegal drugs, as they are cheap, without looking at future losses. Lack of information and education for consumers about the dangers of using drugs that are not effective and quality has resulted in high losses and risks; it is due to the distribution of these illegal drugs.

Lack of supervision from the Indonesian Food and Drug Authority will further bring about the spread of medicinal or food products that violate regulations. It will not create a healthy business climate in Indonesia. The increasing number of illegal drug trafficking cases in Indonesia also indicates that the government does not pay enough attention to crime in society. With so many illegal drugs circulating, people face many bad risks. If the distribution

of illegal drugs is allowed to develop, it will cause the lowering of the nation's dignity in the eyes of the world (Saragih et al., 2021).

Based on the explanation above, it is drawn to raise the research title of "Ratio Decidendi for the Distribution of Pharmaceutical Preparations that Failed to Comply with the Efficacy Standards in Ponorogo District Court Decision Number 115/Pid.Sus/2023/PN Png." This research will discuss law enforcement for drug dealers who do not comply with the standards of efficacy or usefulness and quality of Ponorogo District Court Decision Number 115/Pid.Sus/2023/PN Png. Therefore, this research aims to determine the ratio decidendi of perpetrators distributing pharmaceutical preparations that do not meet the standards of efficacy or usefulness and quality, focusing on Ponorogo District Court Decision Number 115/Pid.Sus/2023/PN Png. The existence of this research will ascertain whether the judge has administered the appropriate punishment to drug distributors who fail to meet the standards of efficacy, usefulness, and quality while considering the current regulations. This penalty will serve as a deterrent to individuals, thereby preventing them from engaging in behaviors that cause injury to others.

RESEARCH METHOD

Data research of literature associated with research problems was implemented in this investigation. Legal norms that are established in judicial regulations and rulings are the subject of literature studies. The normative technique is another name for this approach. The research is qualitative in nature, and the data is consistently described logically, without any overlap or intersection. This approach is effective in facilitating comprehension of data analysis and interpretation (Askin & Masdin, 2023).

The structure of norms in the form of rules or regulations that need to be considered was applied in this research approach, which was based on jurisprudence and legislation (Santini, 2017). The data content analysis used interpretation based on data collected from the primary, secondary, and debt-based legal material of Ponorogo District Court Decision Number 115/Pid.Sus/2023/PN Png, Act No 17 of 2023 concerning Health, as well as analyzing library materials associated with this research.

RESULTS AND DISCUSSION

Legal enforcement for criminal acts of distribution of pharmaceutical preparations that do not meet efficacy or usefulness and quality standards

In Act No. 17 of 2023, the state clearly guarantees each citizen's right to have a good, healthy, and prosperous life from the inside. Therefore, to avoid harming countries, a transformation of health would be required to achieve a rise in public health. Additionally, Act No. 17 of 2023 concerning Health explains that good public health development creates self-reliance, encourages national health industries at regional and global levels, and promotes improved safety, quality, and affordable service to communities in improving quality of life.

Apart from that, the government's efforts to advance the level of public health care include providing facilities to buy medicine, namely pharmacies (Sholehah et al., 2020). Each pharmacy is run by pharmacy graduates who already have a license and have undertaken professional education. In addition, the medicines being traded are medicines that have obtained a distribution permit. Several hard drugs are sold if the buyer has received a prescription from a doctor. Medicine is defined as a substance used to reduce the pain experienced by humans, animals, and plants. Medicine is one of the efforts to improve health status. If there is no medicine, humans will continue to experience pain, resulting in humans not living their lives productively.

According to the Republic of Indonesia Minister of Health Regulation Number 949/Menkes/Per/III/2020 concerning Drug Registration, drugs are classified into several groups. First, over-the-counter drugs are drugs that can be consumed without a doctor's prescription. This drug is usually used to treat mild symptoms of the disease. The drug has a sign, namely a green circle with a black border, meaning that it is the safest drug that can be purchased freely. Examples of them are vitamins or multivitamins (Nachrawi & Dewi, 2021). Second is limited drugs, namely drugs that can be purchased in certain quantities at pharmacies without a doctor's prescription. The markings on the drug are limited to a blue circle with a black border. Examples of these drugs are hangover medicine (Antimo) and anti-flu (noza). Limited medicines can be consumed without a doctor's prescription if the illness is mild, but if the illness is serious, it is recommended to see a doctor (Riyanti & Emelia, 2021).

The third is hard drugs, which are drugs with great medicinal properties. To get hard medicine, buyers have to get a doctor's prescription (Irawansyah et al., 2022). The sign of hard drugs is a red circle with a black border with the letter K written inside. Drugs included in hard

drugs are antibiotics (penicillin, tetracycline, and others). Aside from that, they include drugs containing hormones (tranquilizers, diabetes meds, and others). Hard drugs cannot be consumed carelessly, as they can cause harm, poison the body, and even worsen disease and result in death (Nachrawi & Dewi, 2021). The fourth is psychotropic or narcotic, and this drug causes addiction (Dwi, 2023). Therefore, the use of this drug is strictly monitored by the government and can only be dispensed by pharmacies with a doctor's prescription. Pharmacies are required to report usage and sales to the government (Nachrawi & Dewi, 2021).

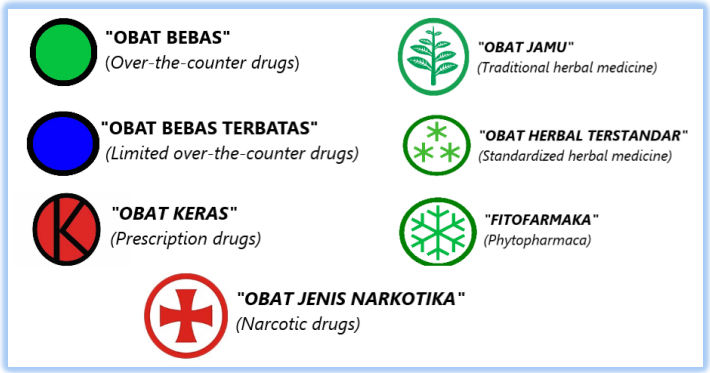

Figure 1.0 (Drug Symbols in Indonesia)

Furthermore, drug distribution is required to obtain a distribution permit. Marketing authorization means obtaining approval by registering a drug so that it can be distributed throughout Indonesia. Therefore, if a drug is distributed without a distribution permit, the perpetrator will receive sanctions or punishment by the provisions set by the government, namely criminal law (Samosir, 2020). Additionally, if a drug has received a distribution permit but is bought and sold without complying with procedures, the dealer will also be subject to criminal penalties. Some of these behaviors harm other people by distributing drugs without efficacy and quality, which will result in nerve damage and even death.

The legal substance of the criminal act of distributing pharmaceutical preparations that do not meet the efficacy standards or efficacy and quality standards is present in several laws, namely (Marianti et al., 2020):

a. Act No. 1 of 2023 concerning the Criminal Code
b. Act No. 8 of 1981 concerning the 2009 Criminal Procedure Code
c. Act No. 17 of 2023 concerning Health

d. Government regulation No. 30 of 2017 concerning the Supervision of Drugs and Food in the Indonesian Territory

Based on the explanation of Act No. 17 of 2023 Article 142, section 1, "Pharmaceutical preparations in the form of drugs and drug ingredients must meet the standards and requirements of the Indonesian pharmacopeia and/or other recognized standards." According to the explanation of Act No. 17 of 2023 concerning Health, Article 143, section (2), "Any person who produces and/or distributes Pharmaceutical Preparations, Medical Devices, and Household Health Supplies (PKRT) products that have obtained a business license, which is proven not to meet the requirements for safety, efficacy/benefit, and quality shall be subject to administrative sanctions in accordance with the provisions of laws and regulations in the field of business licensing". Moreover, according to the Regulation of the Minister of Health of the Republic of Indonesia Number 10101menkes/Per/Xi/2008, Article 18 section 4, the granting of a distribution permit for medicines requires the head of the agency to approve or reject the distribution permit based on recommendations provided by the National Committee for Drug Evaluation, the Committee for Evaluation of Efficacy and Safety, and the Committee for Evaluation of Quality, Technology, Labeling and Rationale for Medicines, which reports marketing permits to the Minister once a year. The distribution permit is valid for five years and can be extended as long as the applicable provisions are met (Kementrian Kesehatan, 2008).

The Indonesian Food and Drug Authority is an institution that monitors or supervises the circulation of medicines and food in Indonesia (Hartanto & Wilda Meutia Syafiina, 2021). The supervision carried out by the Indonesian Food and Drug Authority on food and medicine should be very effective and efficient because this agency can detect, monitor, and prevent a product by protecting the health of consumers both abroad and domestically (Yusuf Dm et al., 2023). However, today's drug distribution cannot be controlled. Many drugs that do not have distribution permits are distributed freely, with the risk of endangering users (Gondokusuma & Amir, 2021). Medicines in circulation must have a distribution permit, and business actors or pharmacies are required to obtain a distribution permit and business permit. If there is a drug that does not have a distribution permit but is consumed or misused without a doctor's prescription at an unclear dosage, it will result in the risk of disability and even death. Apart from medicines that must have a distribution permit, every pharmacy or drug distribution business must also obtain a permit according to the laws and regulations in Indonesia (Marianti et al., 2020).

The enactment of Act No. 17 of 2023 concerning Health is a consideration in the imposition of criminal sanctions for the distribution of drugs without a distribution permit by the judge. Sanctions have been regulated in Article 435 of the Health Law, which states that "Any person who produces or distributes pharmaceutical preparations and/or medical devices that do not meet the standards and/or requirements for safety, efficacy/benefit, and quality as referred to in Article 138 sections (2) and (3) shall be punished with imprisonment for a maximum of 12 (twelve) years or a maximum fine of IDR 5,000,000,000.00 (five billion rupiah) (Peraturan Pemerintah, 2023). In addition to the regulations above, every community has the right to be protected, which is regulated in Act Number 8 of 1999 (Nugroho, 2020). Article 8, section 1 point a of Act Number 8 of 1999 concerning Consumer Protection states that business actors are prohibited from producing or distributing drugs that do not meet the applicable standards in statutory regulations. Inappropriate medicines include counterfeit medicines. With the above regulations, consumers have the right to obtain protection from the distribution of drugs that do not comply with the provisions.

The above legal materials are taken into consideration by judges when imposing sanctions on drug dealers without distribution permits or drug dealers who do not comply with the efficacy and quality standards. With these legal materials, people will be deterred and not do these dangerous things. If the distribution of medicines is carried out based on their efficacy and quality, health in Indonesia will improve and have a good impact on national development.

Judge Ratio Decidendi at Ponorogo District Court Decision No 115/Pid.Sus/2023/PN Png

Ratio decidendi for distributors of pharmaceutical preparations who do not meet the standards of efficacy, usefulness, and quality, as revealed in the Ponorogo District Court Decision Case Study Number 115/Pid.Sus/2023/PN Png illustrates the complexity of the legal aspects involved in responding to violations in the pharmaceutical sector.

Pharmaceutical law is a legal framework that regulates all aspects related to the production, distribution, and sale of pharmaceutical preparations. This legal basis has the main aim of protecting the public from the risks of using pharmaceutical products that do not meet established health standards. Thus, pharmaceutical regulations form a crucial basis for maintaining the integrity and safety of health products consumed by the public (Novita et al., 2023). Pharmaceutical regulations also play an important role in ensuring that innovation in the pharmaceutical industry can occur safely. By setting clear standards and monitoring industry

compliance, pharmaceutical law helps create an environment that supports the development of innovative and effective new drugs.

Violations of efficacy standards can take many forms, ranging from significant discrepancies between efficacy claims and research results to a lack of sufficient scientific evidence to support the declared therapeutic effect. In some cases, these violations can have a serious impact on public health, especially if the product is used to treat a serious medical condition. Additionally, the evaluation of violations of efficacy standards involves an examination of recommended dosages and product safety. Efficacy standards also include dosage parameters that ensure that the use of pharmaceutical preparations does not produce undesirable or even harmful side effects. Violation of the recommended dosage may result in the risk of overdose or lack of therapeutic effect, both of which may endanger the patient's health.

The importance of evaluating violations of efficacy standards is also related to understanding drug interactions. This standard includes an assessment of whether a pharmaceutical preparation can be used safely in conjunction with other medicines that the patient may be taking. Violation of this aspect can trigger adverse reactions or affect the effectiveness of other drugs used by the patient (Afianto & Qona'ah, 2020). Furthermore, analysis of violations of efficacy standards requires an in-depth understanding of the clinical research process and methodology used to prove a product's therapeutic effects. A discrepancy between efficacy claims and research design or insufficient research results can raise doubts about the accuracy of the information provided to the public. Maintaining efficacy standards is vital, not only for manufacturers' compliance with regulations but also for consumer protection. By guaranteeing that pharmaceutical preparations meet established efficacy standards, it can be ensured that people consume the product with confidence in the therapeutic benefits that the manufacturer claims.

Assessment of violations of efficacy standards is an essential step in maintaining the integrity and safety of pharmaceutical products. By involving aspects such as the consistency of efficacy claims, recommended dosages, product safety, drug interactions, and the quality of clinical research, this analysis helps safeguard public health. It ensures that the use of pharmaceutical preparations provides the expected therapeutic benefits. Analysis of violations of the benefits and quality of pharmaceutical products requires a thorough understanding of several critical aspects, including the sustainability of the product and the quality of the raw

materials used. Evaluation of this aspect aims not only to ensure that pharmaceutical products meet established quality standards but also to identify potential negative impacts that they can cause.

The sustainability of pharmaceutical products is also an important aspect to consider in the analysis of benefits and quality violations. This involves assessing the product's durability and stability throughout its expected lifetime. Violations of sustainability may include a decline in product quality over time, changes in formulation without adequate notification to consumers, or even the inability of the product to maintain its therapeutic effects. In the case of these violations, the risks facing society include uncertainty about the effectiveness of treatment and the potential for unexpected side effects. Furthermore, violations of the usefulness and quality aspects of pharmaceutical products may be related to counterfeiting or illegal duplication. These practices may include the use of unauthorized raw materials, production in facilities that do not meet standards, or distribution of counterfeit products. The impact of counterfeiting is not only detrimental to consumers by providing products that do not match their efficacy claims but can also endanger public health as a whole. (Hot et al., 2023)

The importance of preventing violations of the benefits and quality of pharmaceutical products is not only regulatory but also humanitarian by ensuring that pharmaceutical products provide the expected therapeutic benefits and meet established quality standards, unnecessary health risks can be avoided, and consumer confidence in the pharmaceutical industry is maintained.(Nurrohmah & Hufron, 2023)

In the era of globalization, international cooperation in monitoring and preventing these violations is becoming increasingly critical. Collaboration between countries can strengthen the global monitoring system and ensure that pharmaceutical products circulating on the international market meet universally recognized standards of efficacy and quality. Analysis of violations of the benefits and quality of pharmaceutical products requires a holistic approach that includes evaluation of product sustainability, quality of raw materials, production processes, and efforts to prevent counterfeiting. By paying attention to all these aspects, it can be guaranteed that pharmaceutical products on the market truly provide the desired therapeutic benefits, meet strict quality standards, and protect public health as a whole.

Specifically, Ponorogo District Court (PN) decisions have a crucial role in the legal system, and understanding the ratio decidendi when analyzing this case is essential. The ratio decidendi, or the basis of the court's considerations in making a decision, forms the legal basis,

which can then become a guide for similar cases in the future. In detailing the ratio decidendi of the Ponorogo District Court decision, it is important to pay attention to the reasons explained by the court when making the decision. Factors such as the evidence presented, legal interpretation, and ethical considerations often form an integral part of the ratio decidendi.

First, the court will usually evaluate the evidence presented by both parties at trial. Analysis of the validity and relevance of this evidence is a crucial part of the ratio decidendi. The court will consider whether the evidence is sufficient to support the claims or defenses put forward by the parties to the dispute. Mistakes in assessing evidence can be the basis for overturning a decision or appealing it. Furthermore, legal interpretation becomes a key element in the ratio decidendi (Sumawan & Saravistha, 2023). The court will evaluate the legal arguments submitted by the parties to the dispute and align them with applicable law. Careful interpretation of legal regulations and norms is the basis for forming court decisions. The ratio decidendi will detail how existing law is applied to the facts presented in a particular case.

Ethical considerations can also be an element that influences the ratio decidendi. Courts often have to consider the moral and ethical values involved in the case. This may include consideration of the justice, truth, and social impact of decisions taken. The court will explain how these ethical considerations played a role in shaping the decision and how the decision can reflect the value of justice. Jurisprudence or legal policies that develop from previous decisions are also an important part of the ratio decidendi. The Ponorogo District Court's decision can create a legal precedent that will serve as a guide or reference for similar cases in the future. The court will detail how this ruling aligns with or may provide guidance for the decision in the broader legal context.

It should be remembered that the Ponorogo District Court's decision not only affects the disputing parties in the case but also has a potential impact on the legal system as a whole. Therefore, the ratio decidendi will reflect the court's efforts to achieve balanced justice and ensure legal certainty. In preparing the ratio decidendi, the court may also consider other aspects, such as public interests, principles of procedural law, and norms developing in society. A careful and detailed ratio decidendi will provide a solid foundation for future courts in handling similar cases. Thus, an in-depth understanding of the ratio decidendi in the Ponorogo District Court decision is important not only for the parties to the dispute but also for legal practitioners, academics, and policymakers to understand the evolution of jurisprudence and

provide direction for future legal developments. This decision not only reflects law enforcement at the local level but can also shape the direction of legal policy more broadly in society.

Consumer protection in the context of pharmaceutical law receives special emphasis, recognizing consumers' rights to obtain safe and quality pharmaceutical products. Analysis in this framework includes an in-depth understanding of how the law protects consumers in the pharmaceutical industry, as well as the policies and practices that support consumer rights. Consumer rights in pharmaceutical law further include access to clear and accurate information about products, the right to receive pharmaceutical products that meet health standards, and the right to be protected from the risks of using products that do not match their claimed efficacy. As such, analysis of consumer protection must take into account the effectiveness of regulation in ensuring that these rights are respected and applied consistently.

In addition, research on legal sanctions imposed to perpetrators of violations is essential for determining the extent to which the pharmaceutical legal system can provide a deterrence effect (Asshiddiqie, 2021). The type of sanction, whether criminal or administrative, reflects the seriousness of the violation and signals the potential consequences for the perpetrator. An in-depth analysis of these sanctions allows an assessment of the extent to which they can deter future violations and provide justice for affected consumers. In terms of consumer protection, information transparency is key. Effective regulation must ensure that consumers have access to accurate and comprehensive information about the pharmaceutical products they consume. Clear labels, easy-to-understand directions for use, and information about potential risks or side effects are integral to consumers' right to make informed and wise decisions regarding their health (Tutik Nurul Janah, 2020).

Improving the pharmaceutical regulatory system is also a pivotal aspect of this analysis. Evaluation of the ineffectiveness of existing regulations allows the identification of areas where improvements are required. This could include increased oversight of the production, distribution, and marketing processes of pharmaceutical products, as well as increased transparency in responding to detected violations (Gowasa et al., 2023). Recommendations for improving the pharmaceutical regulatory system could include strengthening cooperation between health regulatory agencies and the pharmaceutical industry, introducing more sophisticated technology for product tracking and verification, and improving consumer education about their rights and how to report violations (Sihotang et al., 2024). Additionally, it is important to consider the role of consumer education in the context of protection (Daeng et

al., 2023). Increasing consumer awareness about their rights, potential risks in using pharmaceutical products, and how to report non-compliance can improve the safety and security of pharmaceutical products on the market.

A holistic analysis of consumer protection under pharmaceutical law must also involve dialogue between the government, health regulatory agencies, the pharmaceutical industry, and consumer groups. Involving all these parties in the process of improving and developing regulations can create a system that is more responsive, effective, and proactive in protecting consumer rights. To maintain the integrity of the pharmaceutical industry and protect the public, a comprehensive analysis of consumer protection, legal sanctions, and improving the regulatory system is a crucial step. This can create a solid legal foundation, support consumer confidence, and encourage the pharmaceutical industry to adhere to the highest standards in producing and distributing health products.

The Ponorogo District Court issued a decision in the case of a distributor of pharmaceutical preparations that did not meet the standards of efficacy or usefulness and quality with Decision Number 115/Pid.Sus/2023/PN Png. The defendant, in the name of BA, was proven to have sold medicines that did not meet the efficacy and quality standards to one of his neighbors. With the available evidence and witnesses, the judge stated that BA had committed a criminal offense under Article 196 of Act No. 36 of 2009 concerning Health (Direktori Putusan Mahkamah Agung Republik Indonesia, 2023). The judge's decision on the sentence is based on the existing evidence, the legal interpretation used, and the ethical considerations of the accuser. By considering the three things above, the judge will decide on the charges or sanctions to be received by the defendant. The Ponorogo District Court judge’s considerations will become a reference for similar cases or even for researchers or students as material for consideration or research material.

From the evidence in Decision Number 115/Pid.Sus/2023/PN Png, it has been proven that the defendant committed an unlawful act by carrying out drug sales transactions without looking at the efficacy and quality. The defendant bought the drug on the TikTok application. The defendant never received education in the pharmaceutical field. The medicines sold did not have expiration labels, the name of the medicine, **and** the composition of the ingredients. The drugs sold were those containing the active ingredient of trihexyphenidyl or tramadol. This kind of drug is useful for relieving moderate to severe pain, for example, in pain after surgery. If an individual takes the trihexyphenidyl drug inappropriately, it will cause him to feel more excited.

Meanwhile, if he consumes too much tramadol, he will feel tired and sleepy easily, affecting his overall body condition. The above matters were taken into consideration by the judge when deciding the charges by looking at the evidence.

In addition to the evidence, the panel of judges considered the legal interpretation regulated in Article 196 of the Act of the Republic of Indonesia Number 17 of 2023 concerning Health by considering the elements of each person, intentionally and produced. After considering these three things, the defendant was proven to have intentionally distributed pharmaceuticals that did not comply with efficacy and quality. This was used as material for the judge to give a decision because the defendant was proven to have violated government regulations. The judge's next consideration was the defendant's ethical considerations. During the trial, the panel of judges will consider the attitude and behavior of the defendant. The panel of judges considered that the defendant admitted that he was guilty of his behavior; the defendant asked for leniency in his sentence, which he obtained with a guarantee that the defendant promised not to repeat the act and that the defendant had never committed a crime.

As seen from the analysis above, the panel of judges considered the charges in two circumstances. The aggravating circumstance is that the defendant did not support the government's program to eradicate the young generation's use and distribution of hard drugs, which are destroying the nation's future. Meanwhile, mitigating circumstances are that the defendant admitted guilt, regretted his actions, and promised not to repeat his actions, and the defendant had never been convicted (Direktori Putusan Mahkamah Agung Republik Indonesia, 2023). By considering the mitigating and aggravating factors, the judge gave a verdict that the defendant BA deliberately distributed pharmaceutical preparations that did not meet the standards, safety requirements, efficacy, usefulness, and quality as stated in the single indictment. The judge sentenced the defendant to imprisonment for 1 (one) year and a fine of IDR 5,000,000.00 (five million rupiah) with the provision that if the fine were not paid, it would be replaced by imprisonment for one month (Direktori Putusan Mahkamah Agung Republik Indonesia, 2023).

Hopefully, the above court decision will have a deterrent effect on perpetrators, and the public will be more careful. With cases of pharmaceutical distribution that do not match the efficacy and quality, it is expected that the government will review products, quality, raw materials, production processes, and efforts to prevent counterfeiting. In addition, with the existence of online transactions, people prefer to buy online without looking at the efficacy and

quality of the drug. Therefore, the government should pay more attention to pharmaceutical distribution in Indonesia.

Fundamentally, cases where pharmaceutical distribution does not match the efficacy and quality violate consumer rights, resulting in more serious illnesses, organ damage, and even death. The government, thus, should pay more attention to consumer rights, which must be fulfilled. People should be more careful when purchasing medicines, and the Indonesian Food and Drug Authority should educate the public about pharmaceuticals, especially for people in rural areas or underprivileged people.

CONCLUSION

This study discusses law enforcement for drug dealers who do not have the standards of efficacy or benefits and quality of the Ponorogo District Court Decision Number 115/Pid.Sus/2023/PN Png. Legal analysis of the Ponorogo District Court Decision Number 115/Pid.Sus/2023/PN Png, in the case of distribution of pharmaceutical preparations that do not meet requirements and quality, considers the charges by taking into account the evidence, legal materials, and ethics. The panel of judges considered two things when making their decision. First is the aggravating factor because the defendant violated the government's program to eradicate the use and distribution of hard drugs among the younger generation, which damages the future of the nation. Meanwhile, the mitigating factor is because of the defendant's ethics in admitting his mistakes and regretting his actions. Regarding the case of drug distribution that does not meet the standards of efficacy and quality, it is expected that the government will pay more attention to raw materials, quality, and production processes. The government or the Food and Drug Supervisory Agency is also expected to provide re-education to the general public regarding pharmaceutical supplies or medicines so that the public does not buy drugs inappropriately.

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