Jurnal Wacana Hukum dan Sains Universitas Merdeka Surabaya

This work is licensed under a <u>Creative Commons Attribution-ShareAlike 4.0 International</u>

ISSN print 2086-6852 and ISSN Online 2598-5892

<u>License</u>

Law Enforcement of the Crime of Trafficking of Imported Drugs That Do Not Have a Distribution Permit

Aryzha Fitri Founda Wahyudi, Bastianto Nugroho, Supolo Setyo Wibowo

Faculty of Law, Merdeka University Surabaya, Indonesia

E-mail: aryzhafitrifw03@gmail.com

ABSTRACT

The research aims to find out what efforts can be made to prevent losses and what liability must be borne by business actors for consumers for the use of drugs. The research method using the normative juridical method is to describe based on legal provisions and legal facts that apply in the wider community and the problems discussed are based on the facts that occur in society. The results of research on drug business actors are liable for consumer losses. Lawsuits can be filed based on default or unlawful acts. Lawsuits based on defaults are very weak because they require a contractual relationship between the parties so that only parties bound by a contract can sue each other. Thus, the producer can refuse responsibility on the grounds that there is no contractual relationship between the parties. However, the producer cannot simply escape responsibility because there are still other legal remedies, namely lawsuits for unlawful acts that do not require a contractual relationship between consumers and business actors. The proof system used in this business actor's liability is regulated in Article 28 of Law Number 8 of 1999, namely using a reverse proof system. Consequently, it is the business actor who proves whether there is a mistake in him or not.

Keywords: Drugs, Law, Consumers, Criminal, Constitution

1. INTRODUCTION

Health is a Human Right (HAM) and one of the elements of welfare that must be realized in accordance with the ideals of the Indonesian nation as referred to in Pancasila and the Preamble to the 1945 Constitution of the Republic of Indonesia and has been explained in Law Number 36 2009 concerning Health. So health is one element of basic human needs that must be met. One of the supporting health services is the availability of drugs. Public health has an important role in facilitating the implementation of development in Indonesia. The higher the degree of people's health, the smoother the course of development. This will accelerate the achievement of development goals, namely increasing people's welfare in order to create an advanced, just and prosperous society. Therefore the health of Indonesian people is something important (Susanto, 2008).

The occurrence of competition in the world of trade can also result in negative implications for consumers. They become the target or object of business activity for business actors to get the maximum profit. "As we know that Indonesia's national development is indicated in the 1998 Outlines of State Policy (GBHN) is complete human development, in which all Indonesian people



YURISDIKSI

Jurnal Wacana Hukum dan Sains Universitas Merdeka Surabaya

This work is licensed under a Creative Commons Attribution-ShareAlike 4.0 International ISSN print 2086-6852 and ISSN Online 2598-5892

are entitled to welfare and justice (ZIA, n.d.). We are also faced with progress in trade economic activities that are increasingly open, for which Indonesia is required to face challenges as a result of this openness, so that it is hoped that the Indonesian people will have strong competitiveness in the world of trade. Health is an inseparable part of human life. Health has also become an absolute requirement for society (Prahardika, 2021). This is in line with the rapid pace of development and the increasing level of public awareness of the importance of health. Someone must have felt or suffered from an illness, whether it was just a minor illness such as a headache, cough, dizziness, influenza, or a serious or chronic illness. causing the body to be unable to carry out daily activities as it should (Barkatullah, 2019).

One of the health development efforts is healing diseases which are generally carried out by using drugs (Prahardika, 2021). Consumers can buy drugs from pharmacies and shops or drug stalls. Stores or drug stalls may only sell over-the-counter drugs because over-the-counter drugs have a low level of risk or danger, while pharmacies are permitted to sell various types of drugs, both over-the-counter drugs, limited over-the-counter drugs, hard drugs and other types of narcotics because pharmacy work in pharmacies is handled by pharmacists with the help of undergraduate pharmacists. pharmacist assistant who has expertise in the pharmaceutical field.

Likewise in terms of delivery to buyers, the presence of a pharmacist is required as the person most responsible for ensuring the safety of drug use. Important information about drugs is absolutely understandable by consumers. If necessary, a pharmacist will give a special time to explain in more detail the continuing side effects of the drug.

Business actor is any individual or business entity, whether in the form of a legal entity or not a legal entity, which is established and domiciled or carries out activities within the jurisdiction of the Republic of Indonesia, either individually or jointly through agreements to carry out business activities in various economic fields. In connection with the use of increasingly advanced technology, the government's efforts to protect consumers from harmful products can be carried out by regulating, supervising and controlling the production, distribution and circulation of products so that consumers are not harmed, either in terms of health or finances.

Permits are legal acts of one-sided state administration that apply regulations in concrete terms based on the requirements and procedures as stipulated by the provisions of laws and regulations. Licensing is a form of implementation of the regulatory function and is in the nature of control owned by the Government over activities carried out by the community. Licensing can take the form of registration, recommendation, certification, determination of quotas and permits to carry out a business which usually must be owned or obtained by a corporate organization or person



YURISDIKSI

Jurnal Wacana Hukum dan Sains Universitas Merdeka Surabaya

This work is licensed under a Creative Commons Attribution-ShareAlike 4.0 International ISSN print 2086-6852 and ISSN Online 2598-5892

before the person concerned can carry out an activity or action. Denial of permits occurs when the criteria set by the authorities are not met. For example, the prohibition of constructing a building, unless there is written permission from the competent authority.

Many drugs in the market are sold without clear information on the packaging. While pharmacists often do not provide detailed explanations to buyers. Many examples can be mentioned, what are the consequences if people are not careful in using drugs. A patient with hemorrhoids experienced anal bleeding when using the drug Anusol. The reason? it does not remove the plastic coating on the medication. In another case, a mother with complaints of gastric pain was given Antacid Mylanta tablets by a pharmacist. However, he was not told that the tablet must be chewed before swallowing. It's just random, the tablet came out again with the stool still intact. The disease does not go away (Zuhaid et al., 2016). Even more sad is the experience of Mrs. Siti who suffers from vaginal discharge. Supposedly, the use of vaginal discharge tablets is simply inserted into the vagina. But by Mrs. Siti was even swallowed. As a result he was vomiting followed by stomach pain.

There was another housewife who gave her maid cold medicine with the rule of taking 1 (one) tablet 3 (three) times a day. Because you want to recover quickly, the medicine that should be taken at least one every 6 (six) hours, 3 (three) tablets are consumed in just four hours. As a result, the sufferer feels palpitations all day long. In this case, if the condition of the heart is weak, the consequences can be fatal.

The use of drugs to cure diseases must be carried out carefully and carefully, bearing in mind that on the one hand, drugs can cure diseases, but on the other hand, drugs are deadly poisons if not used rationally and appropriately. In Indonesia, there are still few consumers who have sufficient knowledge about medicines, especially about their properties and side effects (Faesrahman, 2021). As a result, the ignorance of most people about drugs by some irresponsible parties is often used as an opportunity to make the most of profits without regard to the interests of consumers. For example, producing and selling counterfeit drugs, selling drugs that have been withdrawn from circulation, selling drugs that have expired, changing drug formulations so that their efficacy is substandard or even harmful to drug users, selling G-list drugs without a doctor's prescription, drug advertising without regard to advertising rules. applicable.

Drug side effects are the sharp side of the opponent, a double-edged knife. On the other hand there are good properties, namely the effectiveness or efficacy of drugs to heal. This parable is an explanation that needs to be understood and addressed by the medical profession and society



YURISDIKSI

Jurnal Wacana Hukum dan Sains Universitas Merdeka Surabaya

This work is licensed under a Creative Commons Attribution-ShareAlike 4.0 International ISSN print 2086-6852 and ISSN Online 2598-5892

as well. Humans also take lessons from the benefits and are not aware of the losses that are often hidden and can be caused by the opposite side of the knife (Hairunnisa, 2019).

Drug safety is regulated in the eleventh part of Law Number 23 of 1992 concerning Health (State Gazette of the Republic of Indonesia of 1992 Number 100) and further regulated in Government Regulation Number 72 of 1998 concerning Security of Pharmaceutical Preparations and Medical Devices which is stated in Article 1 point 1, namely: "Pharmaceutical preparations are drugs, medicinal ingredients, traditional ingredients and cosmetics". Whereas securing pharmaceutical preparations and medical devices as one of the efforts in health development is carried out to protect the public from harm caused by the inappropriate use of pharmaceutical preparations and medical devices which do not meet the requirements for quality, safety and efficacy. People's behavior in consuming drugs is often influenced by drug advertisements in the mass media. One of the effects of this promotion is to create a tendency for people to become drug minded. If they are sick, they immediately seek medicine and try to self-medicate before seeking other medical assistance.

Advertising in the mass media is a source of information that is heard, seen and read by all levels of society, from those who are unfamiliar with drugs to people who are able to choose the right medicine and treatment. Information is very necessary for consumers to make decisions about which drug to use, given the large number of drug trademarks circulating in Indonesia. However, the available information is usually only information that tempts consumers to buy, not information that provides socio-economic reasons why consumers should buy. Incorrect and misleading information about medicines can cause consumers to make decisions that can endanger the health of consumers (Nurhayati, 2009).

The tendency of people to become addicted to drugs (drug minded) and to self-medicate is very dangerous if not supported by sufficient knowledge about drugs. This is indicated by the large number of consumers who think that taking drugs in excess of the dosage or taking various kinds of drugs at the same time can speed up recovery, even though this assumption is wrong. Excessive drug consumption can reduce the benefits of the drug and can also lead to poisoning because there is a possibility that these drugs have the same active ingredients which can cause double doses (Cahyaningtiyas et al., 2022).

Incorrect and irrational use of drugs usually occurs in the use of over-the-counter drugs and limited over-the-counter drugs. Even though it is called an over-the-counter drug, it still contains chemicals that must be considered in the rules of use. Therefore, consumers must pay attention to the rules for use and drug contents listed on the label on the drug packaging which



YURISDIKSI

Jurnal Wacana Hukum dan Sains Universitas Merdeka Surabaya

This work is licensed under a Creative Commons Attribution-ShareAlike 4.0 International ISSN print 2086-6852 and ISSN Online 2598-5892

provide honest and sufficient information so that consumers get a clear picture of the contents of a drug.

Usually the label gives information about the composition, dosage or rules for use, indications, contraindications, side effects, warnings, warnings or attention, green label (free drug sign), blue (restricted free drug sign), registration. However, in the market there are drug packages that are not labeled or the information on the label is inadequate, which makes them take it for granted when they find a product that is actually not suitable for their consumption. This is clearly very detrimental to consumers.

In general, it is known that there are four basic consumer rights, namely:

- 1. The right to safety.
- 2. The right to obtain information (the right to be informed)
- 3. The right to choose (the right to choose).
- 4. The right to be heard.

Medicines circulating in the market can also be damaged due to defects in processing, for example defects in packaging or damage due to incorrect storage methods so that the drugs are damaged due to the influence of air, heat or cold. It is feared that damaged drugs have undergone chemical changes that might endanger the health and life of the wearer, making these drugs unfit for consumption. Counterfeiting of pharmaceutical drugs in Indonesia is mostly carried out on packaging, composition of ingredients and brands. Even though it is only packaging, it has a very important function in pharmaceutical drugs (Rusmini, 2017). One of the easiest ways to acquaint the public with the authenticity of drugs is through their packaging. The criteria for good safety packaging must represent five elements, namely high technology, easy to detect without the need for tools, difficult to imitate in its originality, has multiple levels of security, and is produced specifically in one unit and is not sold freely.

There are so many bad consequences from the wrong or inappropriate use of over-the-counter drugs and limited over-the-counter drugs. Therefore, it is natural that protection is needed for drug consumers due to errors or inappropriate use of drugs. Especially if the error or negligence is not on the part of the consumer, limited free drugs have the right to demand accountability from the parties who produce and sell the drug, and receive compensation for the losses they have suffered (Modina, 2018).

Currently, Indonesia already has a regulation that protects consumers, namely Law Number 8 of 1999 concerning Consumer Protection which was ratified and promulgated on April 20, 1999 in Jakarta and contained in the State Gazette of the Republic of Indonesia of 1999



YURISDIKSI

Jurnal Wacana Hukum dan Sains Universitas Merdeka Surabaya

This work is licensed under a Creative Commons Attribution-ShareAlike 4.0 International ISSN print 2086-6852 and ISSN Online 2598-5892

Number 42 (hereinafter referred to as the Consumer Protection Act). Consumer). It is hoped that the presence of this law can create a balance between the protection of consumers and business actors.

2. RESEARCH METHOD

The method used in conducting this research is to use normative juridical methods. The normative juridical method is to describe based on legal provisions and legal facts that apply in the wider community and the issues discussed are based on the facts that occur in society. While from its nature, this research is a descriptive analysis research. The descriptive method can be interpreted as a problem solving process that is investigated by describing or describing the condition of the subject or object of research, namely a person, institution, community and others and at present based on visible facts or as they are.

3. RESULTS AND DISCUSSION

Legal Remedies That Can Be Taken by Consumers Experiencing Losses Due to Drug Use

Repressive legal protection for drug consumers means a legal system that protects the interests of consumers who have suffered a loss from the bad consequences of drug use. Losses that may be suffered by drug consumers are disease not cured, disease getting worse, emergence of new diseases, disability or death.

Drug consumers or patients are people who are forced to need drugs to get the healing process. Meanwhile, consumers' knowledge about medicines, such as whether they are suitable for the disease they are suffering from or if they cause side effects that are harmful to health, can even cause death is still lacking.

The emergence of this view is due to a number of professional deviations in the field, such as the absence of drug information services at pharmacies due to the pharmacist's absence. This condition then causes no socialization regarding drugs, their types and functions, both in the form of communication, information and drug education. This situation is certainly very detrimental to consumers (society). Because it means that there has been a reduction in guarantees regarding the accuracy, safety and rationality of the drugs that consumers will consume.

Antibiotic-type drugs are often used incorrectly. According to regulations, this class of drugs used to treat various kinds of infectious diseases, should be obtained with a doctor's prescription. If used arbitrarily, without a doctor's prescription, for example, side effects are not



YURISDIKSI

Jurnal Wacana Hukum dan Sains Universitas Merdeka Surabaya

This work is licensed under a Creative Commons Attribution-ShareAlike 4.0 International ISSN print 2086-6852 and ISSN Online 2598-5892

impossible for consumers. Allergic reactions, for example, can be skin redness and itching. In severe shock occurs which can result in death.

Other effects, can cause disorders of the nervous system and decrease or increase in blood pressure, shortness of breath, deafness and disturbance of body balance, eye vision abnormalities, blood urine, and jaundice. It is also important to know, the use of antibiotics in pregnant and lactating women is better avoided. If you drink it, there will be death in the fetus, it can also have negative effects on babies who are breastfed. Apart from antibiotics, this type of analgesicantipyretic drug is also often used incorrectly by consumers. Analgesic is an anti-pain drug (anti-pain) while antipyretic is a medicine to reduce body heat.

Use that is not according to the rules will result in bleeding or inflammation in the stomach, burning or pain in the pit of the stomach. Likewise, it can eliminate white blood cells, disturbance of the body's electrolyte balance, profuse sweating, decreased consciousness and can cause death. If used for a long time or excessive doses can lead to dependence or addiction to these drugs.

Other types that are also used incorrectly are types of sleeping pills, tranquilizers and antihistamines. The use of these drugs carelessly without a doctor's supervision can cause adverse side effects, even resulting in death. This type of group is usually used by teenagers to fly or teller as a substitute for marijuana or morphine.

Many errors can be prevented if consumers carefully read drug labels before taking them. There was an incident where medication for a child suffering from an ear infection was given in the wrong way. Antibiotic drops that should be taken are dripped into the ear that hurts. As a result, the child's mother was worried about the condition of the child's ear, which after a week of treatment the infection had not healed. Apparently, the mother paid little attention to what the doctor ordered and did not read the label on the package.

That is, the nutritious ingredients that we drink, we need to know first what the contents are on the label. An honest manufacturer will list all the ingredients of a drug. The authorities (BPOM) certainly do not give permission for drug circulation if it contains ingredients that are harmful to health, both because of the nature of the type and type of substance as well as the reason for the dosage. So the consumer's right to always see whether the drug has been listed includes BPOM permits.

Consumer rights include the right to comfort, security and safety in consuming goods and/or services, the right to correct, clear and honest information regarding the conditions and warranties of the goods and/or services and the right to receive compensation, compensation or



YURISDIKSI

Jurnal Wacana Hukum dan Sains Universitas Merdeka Surabaya

This work is licensed under a Creative Commons Attribution-ShareAlike 4.0 International ISSN print 2086-6852 and ISSN Online 2598-5892

reimbursement, if the goods or the services received in a sale and purchase transaction with business actors are not in accordance with the agreement or not as it should be. Consumer rights are guaranteed by law to demand replacement of goods or services of similar or equivalent value, refund of health care costs and/or provision of compensation.

To increase awareness, ability and independence of consumers to protect themselves by demanding their rights as consumers, as well as to raise awareness of business actors regarding the importance of consumer protection so that honest and responsible attitudes grow in doing business.

Consumers also have obligations, including the obligation to read carefully and comply with labels, descriptions, instructions for use and after-sales guarantees for the goods purchased. Other consumer obligations must read carefully the terms of use. Before buying, consumers must pay close attention to the label on an item. For example the composition and also the expiration date.

Even though the Consumer Protection Law (UUPK) Number 8 of 1999 has been in force since 2000, there are still many consumers who do not know their rights and obligations. Likewise, business actors or producers have not fully fulfilled their obligations. Conditions like this encourage the birth of various forms of violations against consumers but do not receive legal sanctions.

Wise tips that can be used to choose drugs that are beneficial to the health of the body, safe and of good quality and to avoid drugs that are of poor quality or counterfeit:

- 1. Pay attention to the registration number as a sign that you have obtained a permit to be sold in Indonesia.
- 2. If you buy drugs with a doctor's prescription, pay attention to whether the brand of the drug is in accordance with the doctor's prescription.
- 3. Check the quality of the packaging and the physical quality of the drug product.
- 4. Check the name and address of the manufacturer, are they clearly stated.
- 5. Read the indications, rules for use, warnings, contraindications, side effects, how to store, and all the information listed on the packaging.
- 6. Check and see the expiration date.
- 7. For ethical medicines, buy drugs only at the pharmacy based on a doctor's prescription.
- 8. If in doubt, you can contact the Balai POM Consumer Complaint Service Unit (ULPK).

Liability of Drug Business Actors for Consumer Losses

Drug consumers who feel aggrieved by drug business actors can file a lawsuit in court. Every consumer has the right to receive legal protection for actions committed by business actors.



YURISDIKSI

Jurnal Wacana Hukum dan Sains Universitas Merdeka Surabaya

This work is licensed under a Creative Commons Attribution-ShareAlike 4.0 International ISSN print 2086-6852 and ISSN Online 2598-5892

Law Number 8 of 1999 concerning Consumer Protection makes it easy for drug consumers to claim responsibility as well as ask for compensation for all losses suffered by drug consumers (Grady, 2020).

Business actors can be sued if they do not fulfill their obligations as regulated in Article 7 of Law Number 8 of 1999 concerning Consumer Protection as follows:

- a. Have good faith in carrying out its business activities.
- b. Provide correct, clear and honest information regarding the condition of the guarantee of goods and/or services and provide an explanation of use, repair and maintenance.
- c. Treating or serving consumers properly and honestly and not discriminatory.
- d. Guarantee the quality of goods and/or services produced and/or traded based on the provisions of the applicable standards for the quality of goods and/or services.
- e. Providing opportunities for consumers to test and/or try certain goods and/or services and provide guarantees and/or guarantees for goods made and/or traded.
- f. Providing compensation, compensation and/or reimbursement for losses resulting from the use, use and utilization of traded goods and/or services.
- g. Providing compensation for damages and/or reimbursement if the goods and/or services received or used are not in accordance with the agreement.

The form of compensation that will be received by consumers who suffer losses as a result of consuming drugs is as stated in Article 19 of the Consumer Protection Act which states:

- 1. Business actors are responsible for providing compensation for damage, pollution and/or consumer losses as a result of consuming goods and / or services produced or traded.
- 2. Compensation as referred to in paragraph (1) can be in the form of a refund or replacement of goods and/or services of the same or equivalent value, or health care and/or compensation in accordance with the provisions of the applicable laws and regulations.
- 3. Compensation is made within 7 (seven) days after the transaction date.
- 4. The provision of compensation as referred to in paragraph (1) and paragraph (2) does not eliminate the possibility of a criminal charge based on further evidence regarding the existence of an element of guilt.
- 5. The provisions referred to in paragraphs (1) and (2) do not apply if the business actor can prove that the mistake is the fault of the consumer.

Copyright (c) 2024 Author(s)

© 0 0 BY SA

YURISDIKSI

Jurnal Wacana Hukum dan Sains Universitas Merdeka Surabaya

This work is licensed under a Creative Commons Attribution-ShareAlike 4.0 International ISSN print 2086-6852 and ISSN Online 2598-5892

The purpose of the above article can be concluded that business actors are responsible for providing compensation for consumer losses due to consuming goods produced or traded by business actors. The compensation given can be in the form of money or health care.

Meanwhile Article 43 of Government Regulation Number 72 of 1998 concerning Security of Pharmaceutical Preparations and Medical Devices states:

- Everyone has the right to receive compensation if the pharmaceutical preparations and medical devices used cause health problems, disability or death that occurs due to pharmaceutical preparations and medical devices that do not meet the requirements for quality, safety and efficacy.
- 2. Compensation as referred to in paragraph (1) is carried out in accordance with the provisions of the applicable laws and regulations. It can be concluded from this article that everyone has the right to receive compensation if the pharmaceutical preparations and medical devices used cause health problems, disability or death because they do not meet the requirements for quality, safety and efficacy. Compensation is carried out in accordance with the applicable laws and regulations.

From the above arrangements it can be seen that consumers can submit claims or demands for compensation to drug business actors if consumers feel disadvantaged as a result of drug use. The basis for lawsuits in court that can be filed by consumers can be through the default route based on Article 1243 BW or using the basis for lawsuits against the law based on Article 1365 BW.

Dispute Settlement of Consumers and Drug Business Actors for Losses Arise

Settlement of disputes in Law Number 8 of 1999 concerning Consumer Protection is regulated in Chapter X. Dispute settlement is carried out in two ways, namely through the courts (litigation) and outside the court (non-litigation). The consumer voluntarily chooses which effort he will take (Pelealu, 2016).

Out of Court Settlement (Non Litigation)

In Article 47 of Law Number 8 of 1999 concerning Consumer Protection it states that "Dispute settlement outside the court is held to reach an agreement regarding certain actions to guarantee that losses will not occur again or will not be repeated losses suffered by consumers".

In the elucidation of Article 45 paragraph (2) of the Consumer Protection Law it states that "Consumer dispute resolution as referred to in this paragraph does not rule out the possibility of an amicable settlement by the parties to the dispute. At every stage efforts are made to use a peaceful settlement by both parties to the dispute.



YURISDIKSI

Jurnal Wacana Hukum dan Sains Universitas Merdeka Surabaya

This work is licensed under a Creative Commons Attribution-ShareAlike 4.0 International ISSN print 2086-6852 and ISSN Online 2598-5892

By looking at the provisions of the article, dispute resolution outside the court can be done in several ways, namely:

1. Through peaceful means.

Amicable dispute resolution is a settlement carried out by both parties to the dispute (business actors and consumers) without going through a court or consumer dispute resolution agency and does not conflict with the Consumer Protection Act, this is explained in the elucidation of Article 45 paragraph (2) of the Law -Consumer Protection Law. Settlement of disputes peacefully can be done with or without a power of attorney or companion by deliberation to reach a consensus. In peaceful dispute resolution, the parties are required to have the will and ability to negotiate. Dispute resolution in this way is also called dispute resolution in a family way (Ariani, 2012).

Through the Consumer Dispute Settlement Agency (BPSK).

The Consumer Protection Act introduces the existence of a special agency to resolve consumer disputes, this body is named the Consumer Dispute Settlement Agency (BPSK), which is tasked with resolving disputes outside the court, where this body is formed by the Government in each Level II Region (Article 49 paragraph 1). Article 23 of the Consumer Protection Law states that "Business actors who refuse and/or do not respond and/or do not fulfill compensation for consumer demands as referred to in Article 19 paragraph (1), paragraph (2), paragraph (3), and paragraph (4), can be sued through the Consumer Dispute Settlement Agency or submit it to the judiciary at the consumer's domicile (Astuti, 2017).

Law Enforcement Against Distribution of Drugs That Do Not Have Permits

is a one-sided state administration legal action that applies regulations in concrete terms based on the requirements and procedures as stipulated by the provisions of laws and regulations. Licensing is a form of implementation of the regulatory function and is in the nature of control owned by the Government over activities carried out by the community. Licensing can take the form of registration, recommendation, certification, determination of quotas and permits to carry out a business which usually must be owned or obtained by a corporate organization or person before the person concerned can carry out an activity or action. Denial of permits occurs when the criteria set by the authorities are not met. For example, the prohibition of constructing a building, unless there is written permission from an authorized official (JULIANTO et al., 2018).

Law enforcement is an activity of harmonizing the relationship of values that is spelled out in solid and embodied principles and attitudes as a series of final stages of value elaboration to create, maintain and maintain peace in social life in society. Meanwhile, a criminal act is an act



YURISDIKSI

Jurnal Wacana Hukum dan Sains Universitas Merdeka Surabaya

This work is licensed under a <u>Creative Commons Attribution-ShareAlike 4.0 International</u>

ISSN print 2086-6852 and ISSN Online 2598-5892

<u>License</u>

that is prohibited by law and is punishable by punishment, where the meaning of an act here is in addition to an active legal action (doing something that is actually prohibited by law) as well as a passive action (not doing something that is actually required by law). law).

Distribution is any activity or series of activities for the distribution or delivery of drugs, whether in the context of trading, non-trading, or transfer. Distribution Permit is a form of drug registration approval to be distributed in the territory of Indonesia.

The Food and Drug Supervisory Agency (Badan POM) is an institution in Indonesia that is tasked with overseeing the distribution of medicines and food in Indonesia. The functions and duties of this agency resemble those of the Food and Drug Administration (FDA) in the United States.

Article 3 paragraph (5) Regulation of the Head of the POM Agency Number 14 of 2014 concerning the Organization and Work Procedure of the Technical Implementation Unit within the Food and Drug Supervisory Agency gives authority to the Balai Besar POM to carry out investigations and investigations into cases of law violations in the drug and food sector.

The Food and Drug Monitoring Agency (BPOM) of the Republic of Indonesia is implementing policies in the field of supervision of therapeutic products, narcotics, psychotropic and addictive substances, traditional medicines, cosmetics, complementary products as well as food products and hazardous substances. Article 1 point (1) Law Number 8 of 1999 concerning Consumer Protection states that consumer protection is all efforts that guarantee legal certainty to provide legal protection to consumers. Talking about consumer protection means questioning guarantees or certainty about the fulfillment of consumer rights.

One of the efforts made by the government to ensure the availability of quality, safe and efficacious drugs is by implementing Good Medicine Manufacturing Practices (GMP). Good Medicine Manufacturing Practice (GMP) aims to ensure that medicines are made consistently, meet the set requirements and are in accordance with their intended use. GMP covers all aspects of production and quality control.

4. CONCLUSION

Preventive legal protection efforts for drug consumers in Indonesia is a legal system that protects consumers to avoid various bad consequences of drug use. This effort is realized through laws and regulations on drug safety. The device is intended to ensure safety in the use of drugs. Various administrative or criminal sanctions are also regulated by the regulation. This is an effort to prevent the bad faith of business actors in the pharmaceutical sector.



YURISDIKSI

Jurnal Wacana Hukum dan Sains Universitas Merdeka Surabaya

This work is licensed under a Creative Commons Attribution-ShareAlike 4.0 International ISSN print 2086-6852 and ISSN Online 2598-5892

Drug entrepreneurs are liable for consumer losses. Lawsuits can be filed based on default or unlawful acts. Lawsuits based on defaults are very weak because they require a contractual relationship between the parties so that only parties bound by a contract can sue each other. Thus, the producer can refuse responsibility on the grounds that there is no contractual relationship between the parties. However, the producer cannot simply escape responsibility because there are still other legal remedies, namely lawsuits for unlawful acts that do not require a contractual relationship between consumers and business actors. The proof system used in this business actor's liability is regulated in Article 28 of Law Number 8 of 1999, namely using a reverse proof system. Consequently, it is the business actor who proves whether there is a mistake in him or not.

REFERENCES

Ariani, NV (2012). Alternative business dispute resolution out of court. *Journal Rechts Vinding:* National Law Development Media, 1(2), 277–294.

Astuti, HD (2017). Obstacles to Consumer Dispute Resolution through the Consumer Dispute Settlement Agency (Bpsk). *Justitia Pulpit Law Journal*, 1(2), 572–591.

Barkatullah, AH (2019). Consumer rights. Nusamedia.

Cahyaningtiyas, N., Amaniyah, LR, & Widodo, HS (2022). Juridical Analysis of Supervision of Drug Preparations That Do Not Have a Distribution Permit during the Covid-19 Pandemic in Indonesia. *Journal of Collaborative Science*, *5*(8), 586–602.

Faesrahman, DG (2021). Supervision of Imported Traditional Chinese Medicines Without a Distribution Permit by the Food and Drug Supervisory Agency in the City of Surabaya. *Al Qodiri: Journal of Education, Social and Religion*, 18(3), 632–646.

Grady, N. (2020). Liability of Automotive Entrepreneurs for Consumer Losses Due to Design Defects. *Jurisdiction*, *3*(2), 559–586.

Hairunnisa, H. (2019). The Difficulty of Finding New Drugs in Indonesia. *Pharmaceutical Magazine*, 4(1), 16–21.



YURISDIKSI

lurnal Wacana Hukum dan Sains Universitas Merdeka Surabaya

This work is licensed under a Creative Commons Attribution-ShareAlike 4.0 International ISSN print 2086-6852 and ISSN Online 2598-5892

- JULIANTO, A., Pettanasse, S., & Nashriana, N. (2018). *ENFORCEMENT OF CRIMINAL LAW AGAINST THE DISTRIBUTION OF DRUG THAT DOES NOT HAVE A DISTRIBUTION PERMIT (STUDY OF SOMADRIL BRAND PILLS IN TEMPILANG DISTRICT)*. Srivijaya University.
- Modina, A. (2018). Legal Protection for Consumers Against Imported Snacks Without Distribution Permits Circulating Online. Hasanuddin University Faculty of Law.
- Nurhayati, I. (2009). The Effectiveness of the Supervision of the Food and Drug Supervisory Agency on the Circulation of Imported Processed Food Products in Realizing Consumer Protection. *Law Platform-Faculty of Law, Gadjah Mada University*, 21(2), 203–222.
- Pelealu, WC (2016). Legal Protection for Consumers for the Distribution of Illegal Drugs According to Law Number 8 of 1999 concerning Consumer Protection. *Lex Et Societatis*, 4(7).
- Prahardika, RA (2021). Description of the level of knowledge on the use of halal drugs in Merjosari Village, Lowokwaru District, Malang City. Maulana Malik Ibrahim State Islamic University.
- Rusmini, A. (2017). The Crime of Distribution and Misuse of Pharmaceutical Drugs Without a Distribution Permit According to Law Number 36 of 2009 concerning Health. *Al-Adl: Journal of Law*, 8(3).
- Susanto, H. (2008). Consumer rights if harmed. Visimedia.
- ZIA, KC (n.d.). LEVEL OF KNOWLEDGE, PERCEPTION, AND ATTITUDE OF PHARMACY WORKERS ON THE USE OF HALAL MEDICINE IN.
- Zuhaid, MAN, Turisno, BE, & Suharto, R. (2016). Consumer protection against the distribution of drugs without a distribution permit that are sold online in Indonesia. *Diponegoro Law Journal*, 5(3), 1–12.

