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Legal and Ethical Protection in Drug Distribution: Examining Health Efforts and Drug Supervision in Indonesia

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Abstract

The National Agency of Drug and Food Control (BPOM) has regulations regarding the Good Drug Distribution Method (CDOB), which is a guideline for distributing drugs properly. Community Health Centres (Puskesmas) are one of the legitimate institutions in distributing antibiotics. However, there is misuse of antibiotic distribution from community health centres to unofficial channels. This research uses normative juridical method by using secondary data from literature study and interviews with resource persons at the community health centre. The purpose of this study is to analyse the legal protection for drug users and consumers as well as the effectiveness of the legal responsibility of pharmaceutical facilities in overcoming pharmacist malpractice. The results show that legal protection for drug users is inadequate and the legal responsibility of pharmaceutical facilities is not yet effective in overcoming pharmacist malpractice, due to the lack of regulations governing pharmacist practices and firm handling of malpractice.

INTRODUCTION

In Article 28 H paragraph (1) of the 1945 Constitution, it is explained that every individual has the right to live in physical and mental prosperity, and has the right to a good and healthy environment. This right also involves the right to obtain health services. The government is obliged to provide health services to all Indonesian citizens and has the responsibility to make this happen. This concept is also reflected in the development of ideas about basic human rights in the health sector, including the right to health care and the right to determine the course of one's own life (*self determination*) (Siswati, 2013).

To keep people healthy, the government must provide services. Health care facilities are access to health efforts. In order for health to be expensive beyond the ability of the government. In addition, the government is required that the public can make various policies and work plans that lead to available and affordable means of service for public health (Indar et al., 2019).

The rapid development and advancement of technology and science has led to changes in individual needs. Each of these individuals always strives to keep their body and soul in good health. This is one of the topics in the Healthy Indonesia Programme with a Family Approach, which focuses on individual health efforts. In connection with individual health efforts that are identical to curative (treatment), the fulfilment of medicines in this part of health efforts is a vital factor in order to run well and smoothly.

One factor that is often perceived by the general public as a cause of high healthcare costs is the price of drugs. Because drugs are a major element in the treatment and healing process for patients, and are often the most effective therapeutic option for various diseases. Public complaints and aspirations for unaffordable drug prices have been widely expressed, especially through media such as newspapers, magazines, and daily news. There are many reports indicating that some patients even find it difficult to fulfil prescriptions due to financial constraints (Pujiastoeti et al., 2006).

Fulfilment of drug consumption with an illegal distribution system is still easily obtained due to the role of unscrupulous people, which ultimately causes drugs not to be properly distributed according to regulations and it damages the vital role of pharmaceutical workers in carrying out their professional functions. Until now, the system of drug distribution in Indonesia is still not in accordance with the regulations (Hartini & Sulasmono, 2010).. The Food and Drug Supervisory Agency (BPOM) launched a regulation on the distribution of good medicines, abbreviated as CDOB. CDOB is an acronym for Good Drug Distribution Methods, which is a regulation that lists various methods of distributing medicines to the market according to the rules. In addition to launching CDOB regulations, the application of the functions and roles of pharmacy personnel in the process of monitoring the circulation of medicines in the community is also needed and provides legal certainty for patients, the public and pharmaceutical personnel (Hartini & Sulasmono, 2010)Therefore, there is a need for government intervention, which will make the supervision of the circulation of medicines more controlled.

Phenomena related to the title of this journal writing, the author focuses more on the pharmaceutical facilities of Puskesmas. There are several Puskesmas in Sukabumi District that have misused the authority to manage antibiotic drugs. After the distribution process is carried out to pharmaceutical facilities, it turns out that these drugs are then misused. The potential for antibiotic resistance is great in the absence of supervision of the distribution of these drugs if it is not carried out in an official pharmaceutical facility according to applicable regulations.

The case of bacterial resistance to antibiotics is a serious problem in the health sector. According to data from the *Cancer for Disease Prevention*, 13,300 patients have died from bacterial infections that are not responsive to antibiotics. The increase in the number of cases of bacterial resistance is not in line with the discovery of new antibiotics. A concrete example of the increase in infections is due to the opportunistic pathogen *Staphylococcus aureus* (*S. aureus*), which can cause various serious infectious diseases such as septicaemia, pneumonia, endocarditis, osteomyelitis, gastroenteritis and abscesses. The number of infections caused by *S. aureus* has continued to increase over the past decade, further complicating the issue of antibiotic resistance in the treatment of *S. aureus* infections (Setiawati, 2015). The application of the concept of rational medicine is to determine the use of drugs that include the right patient, the right indication, the right drug, the right dose, and alert side effects (4 T and 1 W).

Article 51 of Law No. 29/2004 on Medical Practice outlines that doctors or dentists, when practising medicine, have responsibilities including providing medical services in accordance with professional norms, established operational procedures, and the medical needs of patients. (Is, 2017). But sometimes there is a lack of knowledge regarding the selection of antibiotics based on empirical data, namely the use in cases of infection that has not been known to the

type of bacteria that causes it, it has the aim of only inhibiting the growth of bacteria that are suspected of causing infection (Pusporini, 2019).

In principle, the ease of access in buying and selling drugs and food has contributed significantly to society. This is because such access has facilitated the availability of drugs and foods that play an important role as a source of health recovery, strengthening the body's immunity, and providing nutrition and energy for humans. However, it should be noted that this ease of access must be accompanied by a high level of professionalism from the officers responsible for food and drug supervision. They are expected to carry out their supervisory duties with full responsibility, through the implementation of a comprehensive, targeted, integrated and sustainable supervisory system for all types of drugs and food traded in the market.

In addition, it is necessary to strengthen regulations and cross-sectoral cooperation, as well as active participation from the public, to ensure that the quality and safety of drugs and food remain guaranteed. The ultimate goal is to achieve optimal health standards. This is all the more important given that there are still many actors who routinely sell drugs and food without complying with applicable regulations. Sub-optimal supervision of distribution and use for antibiotic drugs has long-term effects on the state of resistance of the body's immune system in accepting antibiotic drugs if used carelessly without monitoring. This should be a concern because if someone easily consumes antibiotics without getting clear information in using them, then the long-term effects will cause the body to become resistant to antibiotics or in other words do not provide treatment effects until they have to use higher levels of antibiotics.

It is necessary to conduct further review of legal protection for citizens who use strong antibiotic drugs, given the increasing circulation of these drugs in the community every year. This protection aims to provide a sense of security to the public from unlawful acts that may be committed by irresponsible parties. Professional ethics in the field of pharmacy, especially the role of pharmacists, must also be emphasised as a guide to ensure that pharmaceutical practices run according to the rules and avoid violations of the law (Dumadi, 2016). As in the case of abuse of the antibiotic class drug distribution system due to abuse of professional authority.

The purpose of this study is to examine health efforts in the context of community development, in line with the mandate of the 1945 Constitution Article 28 H paragraph (1) which affirms the right of every individual to live in prosperity, both physically and psychologically, and to obtain a healthy environment and health services. This research also aims to analyse health issues related to the distribution of drugs and food, with a focus on pharmaceutical facilities at community health centres. One of the main innovations of this research is a detailed exploration of the illegal distribution of drugs, especially antibiotics, which can contribute to the potential for bacterial resistance and its impact on public health. In addition, this research also pays attention to aspects of legal protection for drug consumers and the ethics of the pharmaceutical profession in the context of monitoring the distribution of medicines. The novelty of this research lies in the holistic approach to the issue of drug and food distribution that includes aspects of law, regulation, professional ethics, and consumer

protection, and focuses on the contribution of drug distribution fraud in increasing antibiotic resistance.

METHODOLOGY

This research adopts a normative juridical method with a legal research analysis approach (Soekanto & Mamudji, 2015). The legal materials used are legal regulations relating to the distribution and use of medicines, including the 1945 Constitution Article 28 H paragraph (1), Law Number 29 of 2004 on Medical Practice, as well as regulations of the Food and Drug Monitoring Agency (BPOM) related to Good Drug Distribution Methods (CDOB). The method of collecting legal materials is carried out through literature studies from various relevant sources, including legal literature and laws and regulations. The method of analysing legal materials used is comprehensive and directed analysis (Sugiyono, 2014). This research focuses on the concept of legal protection for people who use antibiotic drugs, as well as the responsibilities and roles of pharmaceutical workers in the supervision and distribution of medicines. This research also emphasises the need to strengthen regulations and cross-sectoral cooperation, as well as public awareness in maintaining the quality and safety of medicines in order to achieve optimal health standards. In this context, legal protection for drug consumers and the ethical role of the pharmaceutical profession are important elements in maintaining the proper and appropriate distribution and use of medicines.

RESULTS AND DISCUSSION

A Good Drug Distribution Method (CDOB) is a set of routine procedures that have been normalised, aimed at ensuring that the quality, safety, and effectiveness of pharmaceutical products are maintained from inception to expiry. The all-encompassing nature of CDOB can open up opportunities for greater efficiency in the operations of pharmaceutical wholesalers (PBFs). However, due to the comprehensive nature of CDOB, there is a potential vulnerability to loopholes that could be exploited to introduce illegal products (Cvetanovski et al., 2020).

Factors that influence the circulation of adulterated drugs or illegal products are large economic profits, lack of regulations and laws, diverse drug supply channels, weak drug safety systems, and misunderstanding of consumers and health workers. To prevent the distribution of poor quality pharmaceutical preparations, CDOB implementation must be of high quality in both government-owned and privately-owned Pharmaceutical Wholesalers (PBFs) (Jeong & Ji, 2018).

Pharmacy wholesalers are required to document the procurement, storage and distribution of pharmaceutical preparations in an orderly manner. Ninety-seven per cent (97%) of PBFs have implemented documentation. The type of documentation regarding receipt of orders from customers is carried out by PBF either manually or by computer. Other types of documentation include drug destruction, drug returns to manufacturers, stock items, reduction of goods from sales stock, delivery of drugs to customers, release from warehouses, drug storage, receipt and ordering of pharmaceutical preparations (Ade et al., 2012). Procurement and release procedures must be officially issued, to ensure that pharmaceutical products to be distributed are sourced from legal suppliers (Mudin, 2018).

Pharmaceutical wholesalers as companies and management organisations must have SOPs for the storage process of pharmaceutical preparations. The role of the SOP is very important because the compliance of personnel in implementing the SOP will ensure that the quality of pharmaceutical preparations remains in good quality. It is also explained in Chapter II of the Regulation of the Head of the Food and Drug Administration on Good Drug Distribution Methods Number 6 of 2020 concerning the Person in Charge of drug distribution to official health facilities.

Below is a flow chart of irregularities in the distribution of medicines, one of which is antibiotics. It is clear that the person in the pharmaceutical facility is the decision maker for the entry and exit of the distribution of this antibiotic class of drugs.

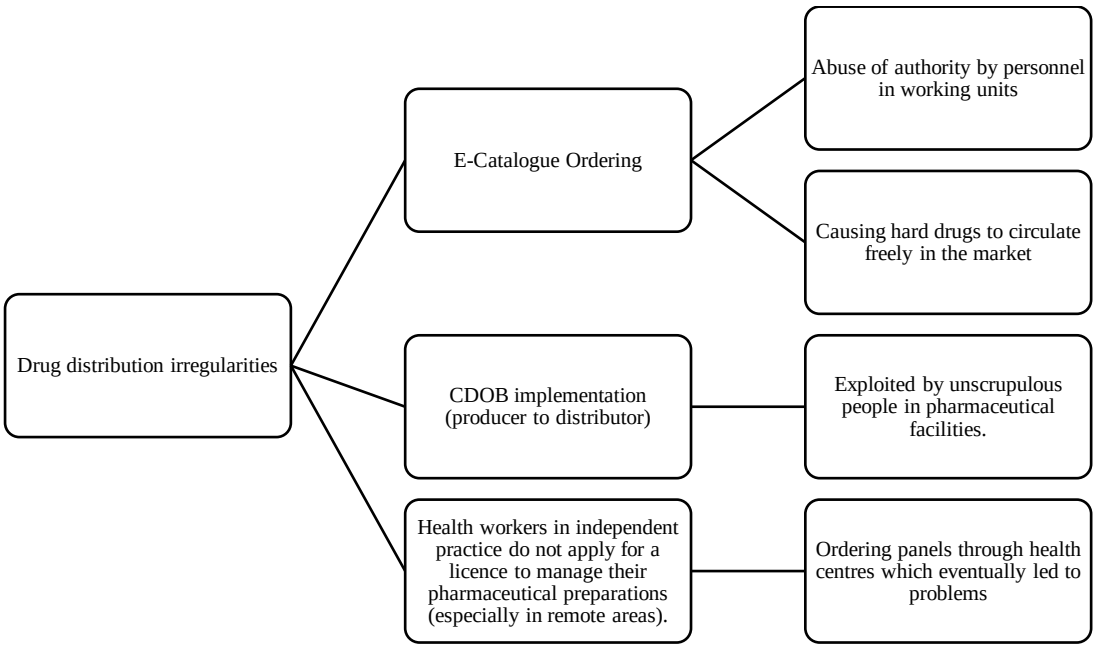

Figure 1: *Drug distribution irregularities scheme*

The description of the picture above can explain the misuse of the drug distribution flow by the parties. The existence of the electronic catalogue system (E-Catalogue) of the National Public Procurement Agency (LKPP) in the pharmaceutical facilities of community health centres (puskesmas), provides a loophole for every person in it to misuse the distribution of this antibiotic class of drugs. In the LKPP E-Catalogue system, drug pricing is made as cheap as possible because it is also a generic drug. Each manufacturer or pharmaceutical producer must be able to determine a price reduction of up to 50% of the regular price on the market.

In the Regulation of the Head of the Food and Drug Supervisory Agency Number 24 of 2021 concerning Supervision of the Management of Drugs, Medicinal Materials, Narcotics, Psychotropic Drugs, Pharmaceutical Precursors in Pharmaceutical Service Facilities, point 13 explains the definition of a Drug Store is a facility that has a licence to store over-the-counter drugs and limited over-the-counter drugs for retail sale. Here it can be seen that it is not the function of drug stores and stalls to sell antibiotic hard drugs.

In addition to the LKPP *E-Catalogue* system, the process of obtaining medicines can also be done through a direct purchase scheme to distributors. Medicines produced by the manufacturer as a result of previous requests from pharmaceutical facilities at the Puskesmas are then distributed through

distributors. After these medicines are received by the pharmaceutical facility at the Puskesmas, they are then, as in the case of the *E-Catalogue* purchase/procurement system, easily distributed to the black-market including grocery stalls and drug stores.

Furthermore, the last one in the author's observation regarding the misuse of the distribution system of antibiotic drugs is through the independent practice of every health worker other than doctors and dentists. Often what the author notices is when health workers such as nurses and midwives serve the treatment of people who come to their place of practice is that they do not hesitate to always give antibiotic class drugs in every treating their patients. The process of obtaining antibiotic drugs is what the author is more concerned about. Because in the flow of obtaining it, these paramedics can also obtain it through pharmaceutical personnel at the Puskesmas. Even worse, they have not upgraded their knowledge for a long time. In addition, sometimes these paramedics, especially in remote areas including around the southern part of Sukabumi District, do not extend their professional practice permits first because they are more concerned with personal gain.

Some examples of cases that have occurred in the author's neighbourhood include: Sale of antibiotic drugs in grocery stalls (Sagaranten District, Sukabumi); and Sale of antibiotic drugs in drug stores (Sagaranten District, Sukabumi).

The researcher in this case felt interested in the phenomena that occurred in the field. Therefore, the researcher finally decided to conduct a series of interviews after previously observing one of the individuals whose identity was kept confidential. Regarding the criteria for the quality of medicines that circulate well and have an adequate level of safety for individuals, a response was obtained from one of the interview subjects, who revealed that each class of medicine has specific therapeutic characteristics. Furthermore, from each class of drugs, there are potential side effects, both tolerable and intolerable. One phenomenon that has emerged is the possibility of intolerable side effects, especially in the use of antibiotics. This can lead to drug resistance if not used with full consideration.

Furthermore, related to the above statement, the researcher then asked again about the place where drugs were found that should not be circulated in authorised health facilities. One of the perpetrators explained that some business places that sell products of daily necessities can also be found selling drugs ranging from free, limited free, to hard drugs (antibiotics). Business places such as grocery stalls that sell daily necessities can also sell antibiotic drugs, in addition to drug stores that by regulation only sell over-the-counter and restricted drugs, apparently sell antibiotic drugs.

Furthermore, the question developed again with what types of drug classes that often exist not in authorised health facilities are forms of antibiotic hard drugs. One of the perpetrators explained that antibiotic drugs include those sold in grocery stalls and drug stores. In relation to the answer of one of the perpetrators about whether there had been unannounced inspections by BPOM officials or the Sukabumi District Health Office, the answer was that the Sukabumi District Health Office rarely and tended to never conduct monitoring in stalls and drug stores. Due to the vast area of Sukabumi District, and the lack of personnel who can be assigned to monitor, this is a factor that has never been done.

The author conducted an interview with one of the actors and obtained an answer that so far, the Sukabumi District Health Office has begun intensively monitoring activities, especially during the Covid-19 pandemic, where many medical devices do not have an official distribution permit from the Ministry of Health. In addition, the need for multivitamins to boost

the body's immunity is very large, so the Health Office must be more extra in monitoring its circulation, including hard drugs as well.

Information from one of the individuals involved indicated that inappropriate use of antibiotics could lead to drug resistance in the future. The individual had previously explained that he had a clear understanding of the risks of resistance that might occur due to unwise use of antibiotics. However, due to the pressure of urgent material needs, especially in the midst of a pandemic, this individual felt the need to find ways to benefit quickly. Therefore, he took the initiative to sell these antibiotic drugs over the counter, as he thought it could generate significant profits. The form of supervision of the Health Office on the circulation of medicines in the working area of Sukabumi District that has been carried out so far is through the sub-coordinator of the supervision of pharmaceutical facilities directly monitoring the supervision of each intended facility continuously every 3 months with a random area system. This is done because their official travel budget cannot be sufficient if they have to conduct supervision every 1 to 4 weeks.

In terms of the role of the Sukabumi District Health Office in carrying out its duties, functions and authorities optimally, he said that so far, the Health Office has not optimally conducted monitoring, especially to every stall and drug store. Due to the vast area of Sukabumi District, as well as the lack of personnel who can be assigned to monitor, this has not been a factor.

Regarding the practices of selling antibiotic drugs in the market that do not fulfil the regulations for good distribution based on the results of the interview. The informant was very aware. This is also what the informants do to increase their financial benefits, namely by selling antibiotic drugs at low prices because there are many enthusiasts.

Further information obtained from one of the perpetrators regarding whether (sellers) business actors who continue to sell antibiotic class drugs have legal consequences up to criminal action, is that there is no, but for cases of selling drugs by facilities that have not or have a distribution permit, then criminal action has been taken.

Antibiotics are hard drugs. Its use must be considered carefully. Regarding legal protection for consumers, Article 4 point (h) of Law Number 8 Year 1999 on Consumer Protection explains the right to obtain compensation, compensation and/or replacement, if the goods and/or services received are not in accordance with the agreement or not as they should be.

According to (Anief, 2018) the emergence of drug resistance can be explained in the following five ways:

a. Resistance arises due to exclusion by the agent. For example, elimination of the accumulation mechanism of Tetracycline resulted in the bacteria *Staphylococcus aureus* becoming resistant to Tetracycline.
b. Resistance arises because the organism carries a destructive enzyme. For example, the enzyme penicillinase is present which decomposes Penicillin into Penicillinic acid which is unable to kill the *Staphylococcus aureus* strain.
c. Resistance arises because the organism uses enzymes that convert the drug. Many purine and pyrimidine analogue compounds do not react with cancer before enzymes in the cell convert them into *ribonucleotides*.

d. Resistance in the form of overproduction of a substance by the organism that functions as a drug antagonist. For example, Pneumococcal bacteria become resistant to sulfonamides because they produce many additives such as *paraaminobenzoic* acid.
e. Resistance arises from changes in genetic material between bacteria. Gram-negative bacteria in the gut often transfer DNA to other bacteria, thereby conferring drug resistance. These types of bacteria include those that cause dysentery, cholera, typhoid and plaque disease. The drugs affected include Tetracycline and *Chloramphenicol* which are converted into inactive substances.

There are several variations of resistance to bacteria that are recognised, namely:

a. Primary or innate resistance, which is the natural resistance present in microorganisms, such as *Staphylococci* that contain penicillinase capable of breaking down Penicillin and Cephalonidin.
b. Secondary or acquired resistance, which is resistance that arises due to contact between microorganisms and chemotherapy that produces new bacteria with different characteristics. These mutants evolve and form new populations that are resistant to chemotherapy. Sometimes these mutations occur quickly, such as in contact with Streptomycin, INH, and Rifampicin. Sometimes resistance builds slowly, with varying degrees of resistance as with Penicillin, Erythromycin, and Tetracycline.
c. Episomal resistance, which is resistance that carries genetic factors from outside the main chromosome (DNA carrying genetic traits). Episomes or plasmids, which consist of DNA, can be transferred to other bacteria through fusion or contact between cells.
d. Cross-resistance is the resistance of a bacterium to certain antibiotics and their derivatives. For example, cross-resistance between Penicillin and Ampicillin, Amoxicillin; Rifampicin and Rifampicin; and various sulfonamides.

To avoid the occurrence of resistance, relatively high doses of antibiotics are used compared to the minimum effective dose in a short time (Anief, 2018).

Then, regarding protection for consumers for irregularities in the good drug distribution chain at pharmaceutical facilities at community health centres, it is linked to the Regulation of the Head of the Food and Drug Supervisory Agency Number 6 of 2022 concerning Good Drug Distribution Methods. The availability of drugs, medical devices, and consumable medical materials in the implementation of the Health Insurance programme is the responsibility of the Government, Regional Governments, and Health Facilities in accordance with the authority stipulated in the applicable laws and regulations. The principles adhered to in the provision of drugs are as follows: (Handayany, 2022) "Provision of medicines at the First Level Health Facility (FKTP). Provision at FKTP is in accordance with the drugs listed in the National Formulary at level 1 health facilities (Faskes TK 1). FKTP consists of Puskesmas or equivalent, Doctor's practice, Dentist Practice, Primary Service Doctor Practice (DLP), Primary Clinic or equivalent, Primary Class D Hospital or equivalent."

Taking into account the above statement, the Health Insurance programme requires medicines including the availability of antibiotics. But the phenomenon that occurs is even the opposite, namely the massive use of antibiotics not wisely which ultimately causes resistance.

From the information gathered, it becomes clear that a legal protection system is needed for every community or consumer. Thus, it can be formulated that there are at least four main reasons why consumer protection is necessary: (Meliala, 1993)

a. Saving the rights of consumers is also saving the whole nation, as stated in the national development goals in the Preamble of the 1945 Constitution of the Republic of Indonesia;
b. Consumer protection is needed to avoid the negative impact of using technology that can harm consumers;
c. Consumer protection plays a role in producing physically and mentally healthy individuals as the drivers of development;
d. Consumer protection is needed to ensure that development resources derived from the consumer community are maintained.

In carrying out law enforcement, there are three elements that must always be taken into account: legal certainty, benefits, and justice. (Mertokusumo, 2010). Law enforcement in concrete terms is the enactment of positive law in practice as it should be obeyed. Therefore, providing justice in a case means deciding the law in concreto in defending and ensuring the adherence to material law by using procedural means established by formal law.

This means that the role of cross-sectors is very important. Starting from the role of pharmaceutical personnel (Pharmacists and Pharmacist Assistants), State Civil Apparatus (ASN) within the City/Regency Health Office and the scope of BPOM, as well as coordination with Law Enforcement Officials (APH) if something undesirable happens when monitoring and evaluation activities are carried out to the environment of pharmaceutical facilities including at Puskesmas and to stalls and drug stores.

The issuance of the Law on Consumer Protection enables sellers (such as pharmacists who provide services at pharmaceutical facilities in community health centres) and buyers (patients) to understand the limits of the rights and responsibilities of each party. In the Consumer Protection Law, there are explanations on various issues related to buying and selling. However, in reality, many buying and selling transactions do not follow the regulations governing the rights and obligations in such transactions. This is evident in this study where the practice of misuse of antibiotic hard drugs in pharmacies is not in accordance with applicable law, as stipulated in Article 8 paragraph 1 (f) of the Consumer Protection Law which states that "Business actors are prohibited from producing and/or trading goods and/or services that are not in accordance with what is stated on the label, etiquette, description, advertisement, or sales promotion of such goods and/or services".

Preventive protection in the pharmaceutical sector is only regulated through government regulations and their derivative regulations, without a specific law that regulates the role of pharmaceutical workers in carrying out their duties. For example, Law No. 36/2014 on Health regulates pharmaceutical workers in general. Repressive protection against cases of abuse of the antibiotic hard drug distribution system can be done by providing free treatment to consumers by pharmacists so that antibiotic drugs are used wisely.

The Food and Drug Administration (BPOM) has a Food and Drug Surveillance System that monitors products through three layers: producer surveillance, consumer surveillance, and government surveillance (BPOM). Findings from this surveillance system prompt BPOM to take administrative measures and pro justisia actions. Administrative measures include verbal or written warnings, product security at the place of production or distribution, withdrawal of products from the market, revocation of registration numbers, revocation of production and distribution licences, and temporary suspension of production and distribution activities. Pro justisia action involves BPOM's civil servant investigators (PPNS) who can confiscate

unqualified products and bring suspects to court in accordance with applicable criminal procedural laws.

In carrying out consumer protection law enforcement, especially in terms of the circulation of antibiotic class medicinal products that are not in accordance with the provisions, a state tool is needed to carry it out. Article 59 of the Consumer Protection Law authorises investigations by Indonesian National Police Officers and Civil Servant Officers who have duties and responsibilities in consumer protection. This means that investigations related to the distribution of antibiotic class drugs are not only the authority of the police, but can also be carried out by investigators from among civil servants. Then, regarding the legal responsibility of pharmaceutical facilities at Puskesmas from the distribution of hard drugs that result in antibiotic resistance in consumers connected to the Regulation of the Head of the Food and Drug Supervisory Agency Number 6 of 2020 concerning Good Drug Distribution Methods, there is a relationship between pharmaceutical officers (Pharmacists) at Puskesmas in the distribution of antibiotic hard drugs when given to patients. In addition, there is also a relationship when these antibiotic drugs are not only distributed legally, but can also be done illegally. The desire for profit without having to try to comply with the rules, makes this unscrupulous pharmaceutical worker able to distribute these antibiotic class drugs to any means of business that does not have a licence to distribute antibiotic class drugs in accordance with applicable regulations. Finally, a pattern of legal relations will be formed between the person and the community which can be said to be an unbalanced relationship, in the sense that the community is a sick person who is lay and unscrupulous pharmaceutical personnel who are healthy and know more about the side effects of antibiotic class drugs without informing about information about this class of drugs. Thus, it can be said that both are legal subjects that must receive attention.

Based on the research described above, it turns out that the use of antibiotics that are not in accordance with the rules can cause the formation of resistance to antibiotics. Therefore, the law will provide protection to consumers in accordance with Law Number 8 of 1999 concerning Consumer Protection, which includes the right to obtain compensation, compensation, or replacement if the goods or services received are not in accordance with the agreement or expectations. In the principle of equality before the law, every individual has the same status in the eyes of the law, where everyone is subject to a uniform legal process.

The rules confirmed in the Head of the Food and Drug Administration Regulation Number 6 of 2020 in Section III point C regarding the Person in Charge indicate that the purchase or acquisition of antibiotic drugs should be done through an authorised health facility. It is important to avoid situations where the consumer community can freely obtain this class of antibiotic drugs. Accountability for actions taken by unscrupulous pharmacists should be in accordance with the type of offence that occurred. This includes ethical, disciplinary and legal offences. In providing health services, every health worker must adhere to a code of ethics in accordance with their profession. Therefore, it is imperative to have an Indonesian Pharmacist Code of Ethics that outlines the principles to be followed in pharmaceutical practice.

A breach of a professional code of ethics occurs when a person violates the norms that have been established and accepted by the professional group. A professional code of ethics guides its members on the behaviour that should be followed and also protects the public from

unprofessional behaviour. A breach of ethics does not necessarily mean a breach of the law. In the event of an ethical breach by a pharmacist, MEDAI (Majelis Etik dan Disiplin Apoteker Indonesia) will determine the administrative sanctions that can be given, such as a reprimand, and not a prison sentence. MEDAI's decision is based on the Indonesian Pharmacist Code of Ethics and the pharmacist's oath/pledge. The Professional Discipline aspect involves how a professional applies his or her knowledge in accordance with applicable standards. Forms of disciplinary violations or disciplinary malpractice of pharmacists include performing pharmaceutical practice without adequate competence.(Decree of the Central Board of the Indonesian Pharmacists Association on the Indonesian Pharmacist Discipline Guidelines, n.d.).

This phenomenon should be of concern to all *stakeholders.* This is because the lack of public knowledge about health in general, especially related to pharmaceutical services, as well as high trust in health services, has caused ordinary people to not understand the actions of pharmacists that may be considered as pharmacist malpractice. Therefore, efforts are needed to socialise to the public regarding their rights and obligations in receiving pharmaceutical services from pharmacists or pharmaceutical service facilities. In addition, the community also needs to have legal assistance when facing alleged cases of pharmacist malpractice that could have a negative or detrimental impact on the community.

The lack of understanding regarding the criteria for pharmacist malpractice on the part of both the pharmacist providing the health service and the patient receiving the health service leads to uncertainty in dealing with the situation. As a result, in the event of harm to both parties, legal protection is not always available.

When claiming the liability of a pharmacist, there are two legal bases that can be used. First, based on the concept of default (contractual liability) as stipulated in Article 1239 of the Civil Code. Second, based on tort (onrechtmatige daad) in accordance with Article 1365 of the Civil Code. (Setia, 2015).

CONCLUSION AND SUGGESTION

Effective drug distribution plays a crucial role in ensuring the quality, safety and efficacy of pharmaceutical products. The Good Drug Distribution Practices (CDOB) approach has become the standard in maintaining product quality throughout the time span until expiry, despite the potential risk of illegal circulation. The phenomenon of illegal circulation tends to be influenced by economic factors, regulatory vulnerability, inadequate security systems, and lack of understanding among consumers and health workers. In this context, a central role belongs to Pharmaceutical Wholesalers (PBFs) who oversee the procurement, storage, and distribution processes regularly, in order to reduce the possibility of illegal products circulating. The implementation of Standard Operating Procedures (SOPs) is a key factor in maintaining the quality of stored medicines. In addition, the text also highlights the issue of illegal distribution, especially in the antibiotic category, which has the potential to harm the public. This kind of illegal practice involves various elements, including pharmaceutical facilities, distributors, and health workers. In this context, protection against illegal practices should be guaranteed by regulations such as the Consumer Protection Law. The Food and Drug Supervisory Agency (BPOM) has a vital role in monitoring, detecting and taking action against illegal products, in line with the principles of the Professional Code of Ethics. To deal with this

problem, cross-sectoral synergy between the government, BPOM, health workers, and the community is needed with a holistic approach through education, law enforcement, and strict supervision for the distribution of safe and quality medicines.

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