

The Urgency of Law Enforcement of Illegal Medicine Distributions in Indonesia

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ABSTRACT

Background: Medicine plays an important role and is an irreplaceable component in health. World Health Organization (WHO) statistics in 2015 stated that illegal medicine distributions in Indonesia is not less than 3 trillion rupiah per year, or 10 percent of all existing medicine distributions. These findings indicate that law enforcement against criminal acts of illegal medicines distribution is still not adequate. The distribution of illegal medicines including counterfeit medicines, is a serious threat to the health of all Indonesian people. This study aimed to analyze the urgency of law enforcement of illegal medicine distribution in Indonesia.

Subjects and Method: This was a qualitative study (descriptive non-doctrinal legal research) conducted in Sragen, Central Java. Five informants consist of the head of Loka BPOM Surakarta, the head of Sragendistrict health office, a hospital director, a pharmacist in a community health center, and a pharmacy owner. Data collected by interview, observation, and documentary review. Data were analyzed by data reduction, presentation, and verification.

Results: The investigations of distribution of illegal medicines are carried out by PPNS from BPOM and accompanied by the police as supervisory coordinators. BPOM has a mapping of facilities and cases, as well as information from the community. If there is sufficient evidence, BPOM applies administrative sanctions, and if there is criminal sanction, it will continue to other law enforcement officers. The regulations in the field of medicine are adequate, starting from Law number 36 of 2009 concerning Health, government regulations, the minister of health regulations, and BPOM regulations. The distribution of illegal medicines still occur because there is demands from community and online medicine sales that have not been regulated by the government.

Conclusion: Based on Lawrence M. Friedman's theory, legal substance, legal structure and legal culture are a unity in carrying out law enforcement efforts, meaning that no matter how good a law is if it is not accompanied by a good implementing structure and a supportive culture it will be difficult to enforce the law. The society's trust in the law enforcement officers in Indonesia that considered low should be restored with some improvement in structural and substance aspects of law along with the presence of legal culture.

Keywords: medicine, pharmacy, distribution, illegal,

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BACKGROUND

The government is obliged to guarantee health services for all its citizen and establish legal rules relating to the protection of its citizens in health sector. Every effort to improve the highest degree of community's health is carried out based on the principle of non-discrimination, participation, protection, and sustainability. One of the

health effort mentioned in Law Number 36 of 2009 Article 48 paragraph (1) concerning Health is the security and use of pharmaceutical preparations and medical devices.

Pharmaceutical preparations consist of medicines, medicine ingredients, traditional medicines, and cosmetics. The definition of medicine is material or alloy

material, including biological products that are used to influence or investigate the system of physiology or pathological conditions in the framework of establishing diagnosis, prevention, healing, recovery, improving health and contraception, for humans (Minister of Health Regulation Number 1010 of 2008 concerning Drug Registration Article 1). Medicine plays a very important role and is an irreplaceable component in health services. Development in the field of medicine aims to ensure the availability and affordability of medicines that are safe, efficacious, and quality for the community with the type and amount that is appropriate to the needs as stated in national medicine policy.

There are many kinds of medicine at the market, ranging from pharmacies, hospital pharmacies, drug stores, supermarket, etc. Globalization in the economic field also has an impact on the rise amounts of imported products into Indonesia, including imported medicines. Considerations in choosing the medicines consumed are not only influenced by the level of need, but often economic value considerations are also decisive. As a commodity that is always needed in everyday life, it cannot be denied that medicines are included in commodity traded, both freely and in accordance with statutory provisions. Competition in trade often results in wide difference of prices on the same type of commodity. Low economic status affecting people to override quality, legality, and how to get these commodities just to fulfil their needs for a moment without realizing that medicines they consume can greatly affect their current health and later.

Medicines in the community must have marketing permits issued by the Head of National Agency of Drug and Food Control (NS-DFC) or *Badan Pengawas Obat dan Makanan* (BPOM), as stated in

Law Number 36 of 2009 concerning Health Article 106 paragraph (1) that pharmaceutical preparations and medical devices can only be circulated after obtaining marketing authorization. With the distribution permit from BPOM, it shows that the medicine is suitable for consumption and meets the requirement of safety, efficacy or benefit, and quality. However, not all medicines in the community have marketing authorizations. Medicines that do not meet the above requirements are referred to as illegal medicines, which include counterfeit medicines, medicines that have no production and distribution permit, and the usage not accordance with the permit (BPOM, 2017).

The distribution of illegal medicines is one of crime in the field of pharmacy and is a serious problem currently faced by every country in the world including Indonesia. World Health Organization (WHO) statistics in 2015 stated that illegal medicine distributions in Indonesia is not less than 3 trillion rupiah per year, or 10 percent of all existing medicine distributions. In 2016, 52 cases of pharmaceutical crime were identified in the operations carried out by BPOM. From 2013 to 2016, there was an increase number of illegal medicine distributions. Based on BPOM data, in 2013 there were 71 illegal medicines findings with a finding value of 5.67 billion rupiah. In 2014 there were 3,656 medicines with a value of 31.6 billion rupiah, in 2015 there were 3,671 medicines with a value of 20.8 billion rupiah, and in 2016 as many as 6,228 medicines with a value of 19.7 billion rupiah.

These findings indicate that law enforcement against criminal acts of illegal medicines distribution is still not adequate. While in Law Number 36 of 2009 concerning Health Article 98 paragraph (2) states that "Every person who does not have the expertise and authority is prohibited from organizing, storing, processing, promoting,

and distributing medicines and medicine ingredients". The criminal provisions in the distribution of illegal medicines are regulated in Law Number 36 of 2009 concerning Health Article 196 which states that "Every person who intentionally produces or distributes pharmaceutical preparations and/or medical devices that do not meet security, standards and/or requirements, efficacy or benefit, and quality, as referred to in Article 98 paragraph (2) and (3) shall be subject to a maximum imprisonment of a maximum of 15 (fifteen) years and fines at most Rp. 1,500,000,000.00 (one billion five hundred million rupiah)".

The criminal provisions are regulated to prevent the procurement, misuse, or storage of pharmaceutical preparations and/or medical devices that can endanger the community by irresponsible parties. The distribution of illegal medicines including counterfeit medicines, is a serious threat to the health of all Indonesian people. The potential threat of crime in the medicine field besides having a negative impact on health, also has an impact on the country's economy due to reduced income from taxes and import duties, and suppresses the competitiveness of the business field. Furthermore, this potential can threaten public security and order including the resilience of the nation if there is no anticipation. The low economic status reason and weak sanctions are used by perpetrators to find loopholes in order to seek maximum profits. Distribution of illegal medicines is a global problem which requires the right acts to overcome, by increasing law enforcement consistently and continuously.

SUBJECTS AND METHOD

1. Study Design

This was a qualitative study and descriptive non-doctrinal legal research. The study was

conducted in Sragen, Central Java. This study aimed to analyzed the influencing factors of law enforcement using Lawrence M. Friedman theory based on legal substance, legal structure, and legal culture.

2. Study Informants

Informants of this study were people who work in institutions related to drugs distributions and government policies. The informants include of the head of Loka BPOM Surakarta, the head of Sragen District Health Office, a hospital director, a pharmacist in a community health center, and a pharmacy owner.

3. Data Collection and Data Analysis

The data collected by interviews, observation, and document review. The data were analyzed by data reduction, presentation, and verification.

RESULTS

1. Legal Structure

Law enforcement officers consist of polices, lawyers, prosecutors, and judges. Other than that there are officials called civil servant investigators or *Penyidik Pegawai Negeri Sipil* (PPNS). The investigations of distribution of illegal medicines are carried out by PPNS from BPOM and accompanied by the police as supervisory coordinators. PPNS do the investigations not only based on community reports. BPOM has a mapping of facilities and cases, as well as information from the community. If there is sufficient evidence, BPOM applies administrative sanctions, which consist of guidance to the closure of the facilities. If there is criminal sanction, it will continue to other law enforcement officials. Health offices are also involved in open cases of distribution of illegal medicines. As the role and functions of health offices are guidance, supervision, and control in the health sector. The strengthening of law enforcement officials is also carried out with a change in the structure of BPOM in accordance with

Presidential Regulation Number 80 of 2017 on BPOM, that the institutional structure at BPOM is strengthened by the presence of new deputies namely deputy prosecution. The deputy prosecution consists of police, prosecutors, and state intelligence agencies (*Badan Intelijen Negara/BIN*). There are three fields in deputy prosecution, namely the fields of intelligence, investigation, and security.

2. Legal Substance

The regulations in the field of medicine are adequate, starting from Law number 36 of 2009 concerning Health, also the regulations below such as government regulations and regulations of the minister of health including regulation of medicine registration, pharmaceutical service in hospital, pharmaceutical service in community health center, and pharmaceutical service in pharmacy, etc. BPOM also issued regulations regarding the implementation instructions of the regulations issued by The Minister of Health to be performed by medicine producers, distributor, and users. The Sragen District Health Office has duties and functions based on Law Number 23 of 2014 concerning Local Government relating to government affair in the health sector are to provide guidance, supervision, and control over the security of pharmaceutical preparations and medical devices. Health institutions such as hospital and community health center are mandatory to be accredited according to the law, so that both institutions should be performed the regulations. As well as pharmacy, all procedures in pharmacy should be performed according to the regulations. The regulations include selection, planning, procurement, storage, and distribution of medicine.

3. Legal Culture

The distribution of illegal medicines will always be available as long as there is demand from community and a lack of

enforcement by law enforcement officials. Today most of people want something instant, cheap, and easy to get. The illegal medicines are commonly sold by freelance sales and sellers in the traditional markets and stalls that people can buy very easily with cheap price. The consumers are commonly people from the lower economic groups. In addition, illegal medicines can also be purchased via online media. Technological advancement and the change of lifestyle make many people prefer to buy medicines via online media rather than go to pharmacies or health facilities. Also by buying medicines via online, people feel free and can stay anonymous. Most of people do not realize that the medicines they buy are illegals and some of people do not care as long as the medicines can cure their symptoms or diseases.

DISCUSSIONS

Lawrence M. Friedman argued that effective and successful law enforcement depend on three elements of the legal system, namely the legal structure (structure of the law), legal substance (substance of the law), and legal culture. The legal structure concerning law enforcement officials, legal substance including legislation and legal culture is the living law that was adopted in a society (Friedman, 1987). Law enforcement was an effort made to make the law, both in narrow formal sense and in a broad material sense, as a code of conduct in every legal act, both by the legal subjects concerned and by law enforcement officials who were officially given the task and authority by law to guarantee the functioning of legal norms that applied in public and state life (Raharjo, 1980). Law enforcement as part of a legal system that cannot be separated from the three elements mentioned above.

1. Legal Structure

Structure was one basic and obvious element of the legal system. The structure of a system was a skeletal framework; it was in the permanent shape, the institutional body of the system, the tough, rigid bones that keep the process flowing within bounds (Friedman, 1987). Legal structure include the executive, legislative, judicial bodies, and related institutions, such as the Prosecutor's Office, police, courts, judicial commission, and others.

The process of investigating criminal acts of illegal medicines distribution was carried out by BPOM and police. Civil Servant Investigators (PPNS) BPOM has main tasks and functions. The main task of PPNS BPOM was to carry out investigation against illegal acts in the field of therapeutic products, narcotics, psychotropic substances and addictive substances, traditional medicines, cosmetics, and food, and other similar products (Head of the Republic of Indonesia Drug and Food Supervisory Agency Decree Number 02001/I/SK/KBPOM dated February 26, 2001 concerning the Organization and Work Procedure of the Drug and Food Supervisory Agency Article 341).

As its function, BPOM can deal directly with criminal cases of illegal medicine distributions, while investigators from the police as a supervision coordinator (in the case of findings of irregularities in drug and food product supervision). The police would accompany BPOM and at certain points would take over actions such as detention of suspects, which cannot be carried out by BPOM. The assistance process would be carried out until the case files were transferred to the Public Prosecutor. Before the file is submitted to the Public Prosecutor, the file would go through a checking process which was then accompanied by an introduction from the police

investigator so that the file can enter the prosecutor's office.

To strengthen the role and function of PPNS BPOM and the synergy of supervision, BPOM has increased cooperation with related sectors within the framework of the Criminal Justice System (CJS) as outlined in the form of Joint Decrees, including police, customs, attorney general, minister of health, and minister of law and human right.

Presidential Regulation Number 80 of 2017 concerning BPOM Organization issued to strengthen the institution's capacity, capability, and authorities of BPOM through the establishment of the Deputy for Enforcement Sector, especially in the security and preventive functions. Organizational restructuring made by filling in positions in the Deputy for Enforcement from high leaders in the State Intelligence Agency, the Attorney General's Office, and the competent and experienced police to accelerate the handling of drug and food crime cases at BPOM. The three directors, namely the Director of Intelligence and the Director of Security, will strengthen the performance of the Deputy for Enforcement, which included three simultaneous strategies, namely prediction and prevention, detection, and response (BPOM, 2018).

Prediction and prevention carried out the function of analyzing trends or intelligence data, assessing crime risk, analyzing potential crimes, impacting crimes, analyzing global situations, and monitoring law enforcement. Detection carried out tactical intelligence functions, joint operations and analysis of tactical intelligence or data trends. While the response strategy performed the functions of prosecution and investigation, joint operations, and information distribution and cooperation with law enforcement. Strengthening PPNS as

the spearhead of law enforcement against crime in the field of medicine was also ongoing. Optimizing the effectiveness and efficacy of the investigation process was carried out to detect illegal medicine crimes (BPOM, 2018). Various efforts have been made by BPOM to improve law enforcement against illegal medicine crimes. It was expected to accelerate the law enforcement process in an effort to provide a deterrent effect for perpetrators of illegal medicine crimes.

Friedman emphasized that law has the first element of legal system, was the legal structure, institutional order, and institutional performance. Legal structure concerning law enforcement officers that would implement the law, the extent to which law enforcement officers felt bound to the existing regulations, the extent to which synchronization of assignments given to officers can carry out their authority appropriately and contextually, and the kind of example that must be demonstrated by the authorities to the community so that they can be trusted (Friedman, 1975).

Indonesia is a state of law, therefore, the law should be enforced. The rules of law were made to be obeyed and implemented in the life of the community, nation, and state. But in reality, the rules of law were often violated, even by law enforcement officers and the law makers themselves. There were a lot of law enforcement officers (police, judges, prosecutors, advocates) in handling case of committing disgraceful acts such as bribery, case brokers, case transactions, buying and selling decisions, etc.

Many cases of violations of the law were not processed in accordance with statutory provisions or the application of legal sanctions was too light. The same problem also occurred in the law enforcement of illegal medicine distribution. Data

BPOM stated that only 11.27 % of illegal medicine cases entered to court, 52.11 % of cases entered the investigation stage, and 32.39 % of cases were in the prosecution stage. This showed that law enforcement was still weak for producers and distributors of illegal medicines. Court decisions also often did not fulfill justice due to sanctions that were considered not suitable with the loss due to illegal medicines that can cross generations.

2. Legal Substance

Another aspect of the legal system was its substance. This was meant the actual rules, norms, and behavioral patterns of people inside the system. The stress here was on living law, not just rules books. The substance was composed of substantive rules and rules about how institutions should behave (Friedman, 1987). In Indonesia, it was said that law was written regulations, while unwritten regulations were not declared as law. In Article 1 of The Criminal Code it was stated "There is no criminal act that can be punished if there are no rules governing it". So that whether an action was subject to legal sanctions or not, if the acts have been regulated in law and regulations.

Legal arrangements regarding the criminal offenses of illegal medicines distribution in Indonesia were regulated in Law number 36 of 2009 concerning Health, including the criminal acts of producing or distributing medicines that were not in accordance with medicine standard (Article 196); the criminal acts of producing or distributing medicines that did not have distribution permits (Article 197); the criminal acts of producing or distributing medicines without expertise and authority (Article 198); and the criminal acts of producing or distributing medicines carried out by a corporation (Article 201). Referring to Law number 36 of 2009 concerning

Health, a number of regulations were issued in the framework of regulating medicines in the form of government regulations, minister of health regulations and regulations issued by BPOM.

From the regulation of criminal acts in Article 196, it can be concluded that a person was prohibited from producing or distributing pharmaceutical preparations in the form of medicines that did not fulfill the standards. The standard used was the Indonesia Pharmacopoeia, which was a standard medicine book issued by the government official body that issues medicinal substances, chemicals in their properties, medicinal properties, and dosages that were approved, and must be produced in accordance with standard operating procedures or manufacturing methods applicable good medication.

From the regulations of criminal acts in Article 197, it can be concluded that a person prohibited from producing or distributing pharmaceutical preparations in the form of medicines that did not have distribution permits. Distribution permit was a form of drug registration agreement to be distributed in the territory of Indonesia. Medicines that would be distributed in the territory of Indonesia must have marketing licenses issued by BPOM. To obtain a distribution permit, medicines registration must be done. Medicines registration was a registration and evaluation procedure to obtain marketing authorization.

From the regulations of criminal acts in Article 198, it can be concluded that a person who did not have the expertise and authority was prohibited from practicing pharmacy. Pharmaceutical work in the production of pharmaceutical preparations must have a responsible pharmacist, who can be assisted by a companion pharmacist and/or pharmaceutical technical staff.

The criminal acts of producing or distributing illegal medicines can be found through online media. The problems occurred when selling the medicines through online media have not been regulated in Indonesia's law and regulations. Currently, there was no regulation related to medicine sales through online media in Indonesia. Every online pharmacy, online drug store or individual was free to sell medicines through online media without any requirements or restrictions. In this digital era, business people who generally did not know and have no authority in selling medicines made an innovative online sales system, which only tried to capture the pharmaceutical business opportunities.

There were many legal issues regarding medicine sales through online media, such as the health risks of illegal medicines including wrong medicines or fake medicines and consumers may experience allergies that were unknown to pharmacists and/or medicines sales when offering medicines through online. Regulations on online medicine supervision and distribution were needed as a legal basis for online medicines supervision and distribution, and contain rules as aspects of prevention and enforcement. This legal aspect was a priority as an effort to protect consumers from the risks of medicines in online that were increasingly prevalent (Ariyulinda, 2018).

Juridically, there have been several regulations related to drug sales and drug classification, including:

- a. Minister of Health Regulation Number 917 of 1993 concerning Compulsory Medicines. Based on this regulation Article 1 number 3 classifies medicines consisting of over-the-counter medicines, limited over-the-counter medicines, hard medicines, narcotics and psychotropics. Medicines, narcotics, and psy-

chotropic medicines can only be purchased at pharmacies or healthcare facilities with doctor's prescription. Whereas for over-the-counter medicines, limited over-the-counter medicines, traditional medicines, herbal medicines, and health supplements can be purchased and sold at retail, drug stores or pharmacies.

- b. Minister of Health Regulation Number 9 of 2017 concerning Pharmacy Article 12 paragraph (1). This regulation states that the establishment of a pharmacy must have a permit from the Minister of Health. In this case the Minister of Health can delegate the authority to grant a pharmacy permit to the district or city government.
- c. Minister of Health Decree Number 1331 of 2002 concerning Amendments to the regulation of the Minister of Health No. 167 of 1972 concerning Medicines Retailers. It states that drug stores or medicine retailers in selling over-the-counter medicines and limited over-the-counter medicines must have permits from the district or city government after fulfilled all the requirements.
- d. Letter of the Minister of Communication and Information of the Republic of Indonesia Number 5 of 2016 concerning Limitation and Responsibility of Platform Providers and Trade Merchants Through Electronic (Electronic Commerce) Systems in the Form of User Generated Content. This letter regulates goods and/or services that are not permitted to be traded in a platform include goods and/or services that contain content of certain medicines, foods and drinks. Included in this category are medicines that require a doctor's prescription, anaesthesias, as well as drugs or ingredients that contain prohibited substances. This letter are not included in laws and regulations regarding to the

type and hierarchy of laws and regulations of Article 7 and 8 of Act Number 12 of 2011 concerning the Establishment of Legislation.

- e. Presidential Instruction Number 3 of 2017 concerning Increasing the Effectiveness of Drug and Food Control. It instructed the Minister of Communication and Information to block sites that promote and/or sell illegal medicines and foods online based on recommendations from relevant agencies. This regulation only sees the side of pharmaceutical products being sold, namely illegal or licensed medicines, not include the site (online pharmacy, online drug store, or individual).

The weaknesses of the above rules can be used as legal loopholes for every person who sell medicines through online media. Therefore, a regulation was needed that comprehensively regulated the sale of medicines through online media.

3. Legal Culture

Legal culture was all factors that determine the legal system to get its place in society culture logically; at this level, the term culture was defined as a whole social value related to the law itself (Soekanto, 1977). Lawrence M. Friedman explained that the concept of legal culture was human attitude to the law and legal system – trust, value, thinking, and expectation. In other word, legal culture was a social thinking circumstance and social power which determine how the law was used, avoided or misused, so that without legal culture, the legal system would be helpless (Ali, 2002).

Lawrence M. Friedman (1975) used the term legal culture to describe a number of interrelated phenomena. Legal culture as intended by Lawrence M. Friedman was the whole of the general public attitudes and values in society that would determine opinions about the law, thus the existence

of a legal culture became very strategic in determining the choice to behave in accepting the law or rejecting the law. In other words, a law would be a law that was truly accepted and obeyed by the community, largely determined by the legal culture of the community concerned. Legal culture according to Raharjo (1983) was the values and attitudes of the people that can affect the operation of the law.

Indonesian legal culture was changed according to the changes that occurred in Indonesia society itself. A crucial problem was the emergence of degradation of legal culture in the community. The decline in legal awareness and community legal compliance was one of the problems in law enforcement of criminal acts of illegal medicines. This was indicated by the many occurrences of legal violations and legal non-compliance in the field of medicine. Illegal medicines in Indonesia came from domestic and foreign industries, either through smuggling or illegal imports. The development of the internet in Indonesia has also encouraged an increase in violations in the field of medicine. Recorded in 2014, internet users in Indonesia ranked fourth in Asia at around 71,200,000. With the increase in internet users in Indonesia, the vulnerable Indonesian people would be the danger of illegal medicines, because according to WHO, 50% of medicines sold online were counterfeit medicines.

In Indonesia, there were still many people who were fooled by offering medicines online. The development of e-commerce was currently increased rapidly. While the community has not been protected in online purchasing and the difficulty of controlling illegal products because the buying and selling process was not done directly. Communities especially with low levels of education made it difficult for people to distinguish legal medicines

illegally. In addition, the low level of community economic capacity made the people did not want to think before buying the drugs with the consideration of lower prices. As for the perpetrators, the lure of obtaining large economic benefits made a person determined to commit a crime. People tend to look for loopholes in each regulation. Today's society was more courageous to disobey the law for personal gain, because the law in its enforcement was deemed to have no more authority. Existing law enforcement was perceived as discriminatory. The lack of reporting culture from the community also hampers law enforcement.

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