International Journal of Social Science Research and Review

http://ijssrr.com
editor@ijssrr.com
Volume 6, Issue 7
July, 2023
Pages: 617-627

Drug Distribution Monitoring System in Health Law Policy in the Context of Dignificant Legal Justice

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http://dx.doi.org/10.47814/ijssrr.v6i7.1499

Abstract

The importance of government intervention is inseparable from the government's duties as a regulator, which is obliged to control the behavior of its citizens to achieve the desired goal of realizing the welfare and happiness of the whole community. BPOM in this case as a state formation has an important role in drug and food control with the applicable statutory provisions, every drug and food before being distributed to be marketed must be tested for the feasibility of drugs before finally being declared fit for distribution to the wider community. BPOM's obligation to carry out due diligence is regulated in Article 98 paragraph (4) of the Health Law, which stipulates that the Government is obliged to foster, regulate, control and supervise the procurement, storage, promotion and distribution as referred to in paragraph (3) which states as follows: Provisions regarding procurement, storage, processing, promotion, distribution of pharmaceutical preparations and medical devices must meet the quality standards of pharmaceutical services stipulated by Government Regulations. Obstacles that often occur in the implementation of the legal responsibility of pharmaceutical business actors for distribution permits are not necessarily only errors and negligence on the part of one party. However, it is the fault of all parties involved. Supervision of pharmaceutical preparations certainly cannot be borne by the government (BPOM) or the Health Service alone, but all levels of society should also take part in the oversight function of drug distribution. This requires cooperation from various parties and new breakthroughs so that the solution to this problem becomes even better. Guidance and outreach must also be given to the general public so that the public's knowledge and concern for pharmaceutical or medicinal preparations is getting better. BPOM conducts thorough supervision of drugs circulating in the community. If there is a dispute over the loss felt by consumers after consuming certain drugs, after reporting to the Information and Complaint Service Unit (ULPK) at BPOM, the combined supervisory team and enforcement team from BPOM will follow up. However, the settlement of disputes between business actors and consumers will be resolved by both parties in accordance with the operational standards (SOP) owned by the business actor industry. The rest of the dispute resolution steps are carried out in accordance with the Consumer Protection Act. According to the Minister of Industry and Trade Decree Number

350/MPP/Kep/12/2001 dated December 10, 2001, what is meant by disputes between business actors and consumers who demand compensation for damage, pollution and or suffering losses as a result of consuming drugs or utilizing services. The Consumer Protection Law provides for consumer dispute resolution facilities through court and out of court

Keywords: *Drug Distribution Control; Dignified Legal Justice; Health Law Politics*

Introduction

Along with the times, the demand for human needs for medicines will continue to grow. Based on technological developments, the marketing process in the drug trade, the drug distribution process, drug distribution or drug sales, as well as the process to obtain drugs are experiencing technological developments. Drug purchases do not have to bring consumers and sellers together directly. Online sales do not have consumers come to health service units such as pharmacies, health centers, hospitals or drug stores. The drug distribution process is facilitated directly into the hands of consumers through the internet. Business actors provide convenience and innovation so that consumers can easily make transactions through internet media.

Medicines are the most important aspect in supporting one's health. In health services starting from prevention, diagnosis, treatment and recovery. Medicine is a health product that is useful in supporting consumer health. In this case, consumers need treatment needs so that patients as consumers have the right to know and know clear information about the drugs they are consuming, both in terms of the drug content, the benefits of the drug and the effectiveness of the drug's benefits. (Masputra et al., 2020).

In everyday life, drugs have a very important role for humans. The role of drugs is to maintain survival, protect and maintain health, therefore drug safety really needs to be considered by the community. Consumption of drugs must be adjusted to the needs of each individual. BPOM supervision is limited to products and supervision in pharmaceutical facilities by the Ministry of Health through the Health Office. The Health Office does not have oversight resources. Violations committed pharmaceutically include not having a license, not having pharmacists and improper drug storage. There are also those who sell drugs without a distribution permit, do not destroy expired drugs or sell hard drugs without a doctor's prescription. Weak oversight is an irony considering that Indonesia has many pharmaceutical regulations. With complete regulations, it remains only to implement them (Wulandari & Mustarichie, 2017).

Drug and food control is a program related to many sectors, both government and non-government. For this reason, it is necessary to establish good cooperation, communication, information and education. Supervision by business actors should be carried out from upstream to downstream, starting from inspection of raw materials, production processes, distribution until the product is consumed by the community. Business actors have a role in providing guarantees for medicinal and food products that meet the requirements (safe, efficacious and useful and of good quality) through a production process that complies with the provisions. BPOM seeks to provide support to business actors to obtain convenience in their business by providing incentives, clearing houses and regulatory assistance (Suriangka, 2017).

Legal protection guarantees can be carried out through government intervention in drug manufacturers, up to distribution to the public through statutory regulatory products. The importance of government intervention is inseparable from the government's duties as a regulator, which is obliged to

control the behavior of its citizens to achieve the desired goal of realizing the welfare and happiness of the whole community. BPOM in this case as a state formation has an important role in drug and food control with the applicable statutory provisions, every drug and food before being distributed to be marketed must be tested for the feasibility of drugs before finally being declared fit for distribution to the wider community. BPOM's obligation to carry out due diligence is regulated in Article 98 paragraph (4) of the Health Law, which determines as follows:

The government is obliged to guide, regulate, control and supervise the procurement, storage, promotion and distribution as referred to in paragraph (3) which states as follows: Provisions regarding the procurement, storage, processing, promotion, distribution of pharmaceutical preparations and medical devices must comply with quality standards for pharmaceutical services stipulated by Government Regulations.

Based on Article 98 paragraph (2) of the Health Law, states as follows:

> "Any person who does not have the expertise and authority is prohibited from procuring, storing, processing, promoting and distributing drugs and substances with medicinal properties".

Factors that influence the need for medicines for individuals that must be considered include age factors, health status such as medical history, certain physiological factors (pregnancy, breastfeeding), and the individual's economic factors. The level of public consumption of medicines in Indonesia for products offered by well-known brands is an opportunity for distributors of these products to carry out various types of strategies so that products that are sold can be marketed at low prices without separating from the safety of these products such as distribution permits from BPOM. This is supported by the ignorance of the public which is a factor in the widespread circulation of illegal drug products without a permit. The sale of illegal drugs online is increasingly common, especially in Indonesia. Some examples of illegal drugs that are sold online are tonic, weight loss drugs and weight gain drugs (Handoko, 2021).

One example of illegal drugs that are widely sold online is slimming drugs and weight gainers. Of the many types of weight gain drugs sold on the internet. The researcher took one example, namely a weight gain drug with the Gingseng Kianpi Pil brand. Gingseng Kianpi is a weight gain drug in the form of pills sold in bottles which according to information can increase weight by up to several kilos, but unfortunately this Gingseng Kianpi Pil drug is not registered or registered with the Food and Drug Monitoring Agency, so this Gingseng Kianpi pill can be classified as an illegal drug. Clarity of information on medicines sold online is very important for the public or consumers, because it is very influential for their health and safety.

Distribution of drugs in the community must be accompanied by supervision carried out by BPOM. This supervision aims to provide consumer protection. According to Presidential Regulation Number 80 of 2017 concerning the Food and Drug Supervisory Agency (hereinafter referred to as Presidential Regulation Number 80 of 2017), Article 2 states (Utami & Herwastoeti, 2022) :

(1) BPOM has the task of carrying out governmental tasks in the field of drug and food control in accordance with the provisions of laws and regulations;
(2) Drugs and food as referred to in paragraph (1) consist of drugs, medicinal ingredients, narcotics, psychotropics, precursors, addictive substances, traditional medicines, health supplements, cosmetics and processed food.

BPOM's authority is regulated in Article 4 Prepres Number 80 of 2017, which states: In carrying out drug and food control duties, BPOM has the authority to:

a. *Issuing product distribution permits and certificates in accordance with standards and requirements for safety, efficacy/benefits and quality as well as drug and food testing in accordance with statutory provisions;*
b. *Carry out intelligence and investigations in the field of drug and food control in accordance with statutory regulations; And*
c. *Administrative sanctions in accordance with the provisions of the legislation.*

By looking at some of the explanations above, the researcher emphasizes issues including: (1) how is the drug distribution control system in the political context of health law and (2) how is the health law in imposing sanctions on illegal drug dealers in imposing sanctions in an order of dignified justice.

Research Method

The research used in this research process uses a type of normative legal research (Soekanto & Mamudji, 2015). By using library materials or secondary materials that have been collected. Legal research is also a process to determine legal rules, legal principles, and legal doctrines in order to answer the legal issues faced. Critical law school is a critique of legal theory which demands that the doctrinal approach was flawed, with abstract principles such as independence, freedom of contract and property rights can contradict each other in many ways. They use sociological, anthropological, and ideological techniques in order law. They try to delineate the tension between normative ideas and social structures.

Result and Discussion

(1) Drug Distribution Control System in the Political Context of Health Law

In the world of health in Indonesia, there is a fact that the economic level of the majority of Indonesian people is at the lower level. On the one hand, they needed medicine to treat illnesses, but on the other hand, the prices of the medicines were beyond their means to afford. This condition makes people in Indonesia look for cheaper drugs with the same properties that are circulating in small shops, without sufficient knowledge to distinguish between genuine drugs and fake drugs. The high demand from this community group, sometimes cannot be covered by supply. Until finally this opportunity was used to facilitate the production and distribution of drugs without a distribution permit in the market.

Whereas regarding the regulation of the responsibility of pharmaceutical business actors in producing and distributing drugs that comply with drug standards is contained in Article 196 of Law Number 36 of 2009 Concerning Health, which reads: Everyone who deliberately produces or distributes pharmaceutical preparations and/or medical devices that do not meet the standards and/or requirements for safety, efficacy or efficacy, and quality as referred to in Article 98 paragraph (2) and paragraph (3) shall be subject to imprisonment for a maximum of 10 (ten) years and a fine of a maximum Rp. 1,000 000,000.00 (one billion rupiah).

Referring to the definition of counterfeit drugs according to the Regulation of the Minister of Health Number 1010/Menkes/Per/XI/2008 concerning Drug Registration, counterfeit drugs are "drugs produced by unauthorized parties based on applicable laws and regulations or production of drugs with markings that imitate the identity of other drugs that already have distribution permits". Indonesia Drugs that have a distribution permit must meet the following criteria (Mudrikah & Salomo, 2021):

a) Conclusive efficacy and adequate safety demonstrated by animal trials and clinical trials;
b) Quality that meets the requirements as assessed from the production process according to Good Drug Manufacturing Practices (GMP);
c) The marking contains complete and objective information that can guarantee the proper, rational and safe use of the drug;
d) In accordance with the needs of society.

So drugs that are produced or distributed that do not have a distribution permit or imitate drugs that already have a distribution permit are counterfeit drugs and the regulation is contained in Article 197 of Law Number 36 of 2009 concerning Health, which reads:

> "Anyone who deliberately produces or distributes pharmaceutical preparations and/or medical devices that do not have a distribution permit as referred to in Article 106 paragraph (1) shall be subject to imprisonment for a maximum of 15 (fifteen) years and a fine of a maximum of Rp. 1,500,000,000.00 (one billion five hundred million rupiah)".

Responsibilities of Pharmaceutical Business Actors in Producing Drugs According to Standards As stipulated in the laws and regulations in Chapter IV of Law Number 8 of 1999 concerning Consumer Protection, it is regulated regarding actions that are prohibited for consumer actors, regarding the responsibilities of business actors in distributing drugs with distribution licenses stipulated in Article 8 Paragraph (1) point a of Law Number 8 of 1999 concerning Consumer Protection, which stipulates that business actors are prohibited from producing and/or distributing drugs that do not meet standards according to laws and regulations. Drugs that do not meet the standards are one of the criteria for counterfeit drugs. Article 8 Paragraph (1) point a reads as follows (Setiawan, 2018): "Business actors are prohibited from producing and/or trading goods and/or services that do not meet or do not comply with the required standards and provisions of laws and regulations".

Health efforts are related to promotive, preventive, curative and rehabilitative efforts. In relation to drugs, according to the definition of drugs themselves, namely as agents for diagnosing, preventing and curing diseases. Therefore efforts to cure with drugs are closely related to curative health services, namely an activity and/or a series of treatment activities aimed at curing disease, reducing suffering from disease, controlling disease, or controlling disability so that the quality of sufferers can be maintained as optimally as possible.

By having an official distribution permit for each drug preparation, it can be ensured that the drug will go through the correct stages in the flow of securing pharmaceutical preparations. It is important to know that every drug in circulation must first go through a registration process which in its implementation requires strong cooperation and commitment from various parties. With the cooperation and commitment of various parties, namely drug manufacturers, distributors, and the government as the regulator, the safety of drug preparations can be ensured properly until they reach consumers or the public.

Drug manufacturers, namely the pharmaceutical industry, after conducting drug safety and quality tests in accordance with regulations, are required to always register with the Food and Drug Supervisory Agency (BPOM) to obtain an official distribution permit. BPOM as the evaluator will evaluate and re-examine the safety of each drug preparation. With the existence of a system of checks and balances from manufacturers and the government, it is hoped that the output of these drugs will have validity and good quality and be guaranteed in terms of safety. After obtaining an official distribution permit for medicinal preparations, producers have the right to distribute medicinal preparations to distributors as well as the public (Syakbani & Suprayitno, 2013).

The government through BPOM and Health Office has an important role in creating security for pharmaceutical or drug preparations in Indonesia. The government as the regulator of regulations regarding the safety of pharmaceutical preparations also plays a role in the monitoring and evaluation function of pharmaceutical or drug preparations. With the lack of performance in the monitoring and evaluation function of drug distribution in Indonesia, many gaps have arisen, especially in terms of fulfilling drugs that have a distribution permit. As previously known, the monitoring and evaluation function of drug distribution cannot be fully maximized due to the massive distribution of drugs without a distribution permit in Indonesia and the lack of authority that exists from the Food and Drug Supervisory Agency (BPOM). Often it is also very difficult for BPOM and the Health Office to find distribution of drugs without a distribution permit in plain view because the modes of perpetrators of violations are increasingly varied and spread across all circles. Therefore, the government's not optimal monitoring and evaluation function is still a problem that continues to arise day after day (Permatha et al., 2020).

Another thing that is highlighted in the obstacles to the implementation of legal responsibility for pharmaceutical business actors is that the sanctions given by violators are seen as not having a deterrent effect commensurate with the results of the actions of the offenders. According to research on the literature on Supreme Court rulings from 2001, perpetrators who violate laws and regulations regarding distribution permits and counterfeit drugs are on average only given prison sentences of less than 1 year. The average fine ranges from IDR 1,000,000.00 to IDR 3,000,000.00. In fact, the total loss to the state due to counterfeit drug preparations continues to increase every year. Either due to taxes, violations of brand rights, to losses in the health sector caused to patients. This is certainly not in accordance with Article 197 of Law Number 36 of 2009 concerning Health which provides for a maximum imprisonment of 15 years and a maximum fine of IDR 1,500,000,000.00.

The lack of guidance for pharmaceutical business actors also contributes greatly to the ignorance of pharmaceutical business actors regarding drug distribution permits. This is coupled with the lack of outreach to the public regarding the importance of safe and quality pharmaceutical preparations. This of course also has an impact on the indifference of the public and pharmaceutical business actors regarding safe and quality pharmaceutical preparations. This seems to be a common and natural thing because people are aware of this phenomenon and only consider it normal. If an extraordinary incident occurs, such as a "fake vaccine" which has spread to several private hospitals in Tangerang and its surroundings, then this will become a serious concern for the community. Changing the mindset that prevention is better than cure has its own difficulties in securing these pharmaceutical preparations.

Obstacles that often occur in the implementation of the legal responsibility of pharmaceutical business actors for distribution permits are not necessarily only errors and negligence on the part of one party. However, it is the fault of all parties involved. Supervision of pharmaceutical preparations certainly cannot be borne by the government (BPOM) or the Health Service alone, but all levels of society should also take part in the oversight function of drug distribution. This requires cooperation from various parties and new breakthroughs so that the solution to this problem becomes even better. Guidance and outreach must also be given to the general public so that the public's knowledge and concern for pharmaceutical or medicinal preparations is getting better.

The lack of supervision and evaluation by the government and the health department, as previously stated, is a problem that will continue to arise. This cannot be separated from the broad scope of society who are consumers of pharmaceutical or drug preparations. Increasing and strengthening the elements of oversight within the government cannot be separated from the increasing need for oversight in society. This is of course relevant to the goal of increasing the safety of pharmaceutical or drug preparations. Increasing authority by the Food and Drug Supervisory Agency is one of the solutions that can be taken to improve the monitoring and evaluation function of drug distribution in Indonesia. With an

increase in authority, such as expanding the scope of drug control by BPOM in hospitals, clinics or pharmacies, it is hoped that this will reduce the incidence of drug distribution without a distribution permit in the community. Improving the work tools of the Food and Drug Supervisory Agency is also a way that can be taken to further expand the area of drug control. With the strengthening that was first initiated by the regulators, namely the government and the DPR, the oversight and evaluation function of BPOM can also be increased.

The sanctions given to violators are also highlighted by some groups as not having the maximum deterrent effect. This is because court decisions often impose sanctions that do not consider the effects of drug counterfeiting. The existing sanctions are seen as only creating a momentary deterrent effect on perpetrators, but do not teach the public about the importance of law-abiding behavior. In addition to the weighting of criminal sanctions, of course, what can create a deterrent effect is maximum administrative sanctions. Pharmaceutical business actors can be given sanctions such as closing business licenses and closing opportunities to open new pharmaceutical business licenses. This can make offenders think twice before committing the crime. With strict action and strict sanctions, counterfeiting of drugs and circulation of drugs without a distribution permit can be minimized.

(2) The Health Law in Imposing Sanctions for Illegal Drug Dealers in Imposing Sanctions in an Order of Dignified Justice

BPOM as the drug and food control system has an important role in detecting, preventing and supervising the distribution of drug and food products both from within and outside the country with the aim of protecting the security, safety and health of the public as consumers both inside and outside the country effectively and efficiently. BPOM has the task of supervising drug and food products that enter from within and outside the country and those circulating in the domestic market.

There are still many reports from the public regarding the distribution of medicines and food that do not have an official distribution permit and whose circulation is doubtful, including reports regarding the distribution of imported medicines without a distribution permit. BPOM cooperates with the community by providing a consumer complaint service unit as a forum for reporting violations of drug and food products which later on consumer reports will be immediately followed up by BPOM as a form of monitoring efforts against the circulation of drug products without a distribution permit. (Panutan et al., 2019).

Another effort by BPOM is to cooperate with Customs and Excise in the process of importing medicinal and food products, imported medicinal products which are imported into Indonesia are sent directly from the producer of the country where the product was made, so that when it is distributed to the territory of Indonesia, it must be accompanied by a document certifying that the drugs concerned have passed testing in terms of quality, safety and efficacy from the competent authority in the country of origin of the drug. "Imported products must be inspected and passed inspection by customs and excise officers, inspection for imported goods includes checking documents for imported goods and physical inspection of imported goods whether they match what is in the import documents for the size, quantity and weight of goods".

Another form of supervision is taking action related to the distribution of imported drugs without a distribution permit. This action consists of 2 (two) types of action, namely administrative action and legal action (pro iustitia). Administrative measures against companies that do not follow the provisions in the distribution of drugs are given guidance, warnings, stern warnings, temporary suspension of business up to the revocation of the company's license as well as administrative actions on drug products whose imports do not comply with the provisions, then these products must be destroyed by the company that owns the product, if not destroyed then BPOM will confiscate the product. Legal action (pro iustitia)

against companies that do not follow the provisions in distributing imported medicines, namely by bringing them to court and including evidence in the form of drug products that have been confiscated by BPOM.

Other forms of supervision carried out by BPOM in an effort to suppress the circulation of medicines and food without a distribution permit are disseminating information about the circulation of imported drugs without a distribution permit and information regarding the findings of drugs that are proven not to have a distribution permit and conducting outreach through exhibitions, electronic media and print media, so as to educate the public in participating in supervising the circulation of imported drugs without a distribution permit.

BPOM in supervising the entry of medicines into the country is in 2 stages, namely the first stage is the pre-market supervision stage, namely before the drug products are distributed, registration must be carried out in advance and administrative technical requirements are carried out and laboratory tests are carried out on the product, so that later if it passes the process a distribution permit for the product will be issued and an official label from BPOM will be given and the second stage is post-market supervision, this supervision is carried out to the place of production of medicines whose raw materials are mostly imported directly from abroad and supervises distributors and lab tests and distribution permits for drug products circulating on the market . So that in the process of distributing imported medicines, before having to register these imported medicines with BPOM, they have to obtain a distribution permit for these imported medicines.

The drug and food control system administered by BPOM is a comprehensive process, including pre-market and post-market supervision. The monitoring system consists of:

a) Standardization. Is the function of setting standards, regulations and policies related to drug and food control. Standardization is done centrally, which is meant to avoid differences in standards that might occur as a result of each province making its own standards.
b) Assessment (pre market evaluation). This is a product evaluation before obtaining a distribution permit number and finally it can be produced and distributed to consumers. Assessment is carried out centrally so that products that have distribution permits apply nationally.
c) Supervision after circulation (post market control). In order to see the consistency of product quality, safety and product information carried out by sampling drug and food products in circulation as well as inspection of drug and food production and distribution facilities, monitoring of pharmacovigilance and supervision of labels/marking and advertisements. Post market supervision is carried out nationally and in an integrated, consistent and standardized manner.
d) Laboratory testing. Products that are sampled based on risk are then tested through a laboratory to determine whether the product meets safety, efficacy and quality requirements. Laboratory test results are the scientific basis used to determine products that do not meet the requirements to be withdrawn from circulation.
e) Law enforcement in the field of drug and food control. Law enforcement is based on evidence from testing, examination and initial investigations. The process of law enforcement up to pro justicia can end with the imposition of administrative sanctions, if the violation enters the realm of crime, then it can be processed criminally.

Article 8 of the Consumer Protection Law states, "Business actors are prohibited from producing and/or trading goods and/or services that do not include an expiry date or good use period for certain goods". The provisions of Article 79 paragraph 4 BPOM Regulation Number 27 of 2017 concerning Processed Food Registration state that Processed Food whose distribution permit validity period has expired is prohibited from being produced and/or distributed. Based on an interview with Wayan Eka

Ratnata as the Head of the BPOM Inspection and Investigation Division for the city of Denpasar, explained the efforts to resolve the RI POM against business actors if they are still selling expired products are:

> BPOM officers carry out regular field inspections and if there are findings of expired products, BPOM will ask the owner of the goods or business actors to destroy them. If it doesn't work, BPOM will confiscate the item to be destroyed. If these findings repeatedly occur to the same business actor, BPOM will provide more severe sanctions, such as by taking juridical actions in court. Consumers can also file lawsuits against business actors with the assistance of the Consumer Dispute Settlement Agency. Legal protection is a protection given to legal subjects in the form of legal instruments both preventive and repressive in nature, both written and unwritten. (Philipus M. Hadjon, 1987).

Based on the results of these interviews, consumer protection is all efforts that guarantee legal certainty to provide protection to consumers, consumer protection based on benefits, fairness, balance, consumer security and safety, as well as legal certainty. Consumer protection aims (Herlina, 2019) :

1. Increasing consumer awareness, ability and independence to protect themselves;
2. Raising the dignity of consumers by preventing them from negative excesses in the use of goods and/or services;
3. Improving consumer empowerment in selecting, determining, and demanding their rights as consumers;
4. Create a consumer protection system that includes elements of legal certainty and information disclosure as well as access to information;
5. Growing awareness of business actors regarding the importance of consumer protection so that honest and responsible attitudes develop in doing business;
6. Improving the quality of goods and/or services that guarantee the continuity of the business of producing goods and/or services, health, comfort, security and consumer safety.

Based on an interview with Wayan Eka Ratnata as the Head of the BPOM Inspection and Investigation Division for Denpasar City, explained that the legal sanctions that BPOM gives to business actors who sell expired products and the strategy of the POM to reduce business actors selling expired products are: There must be sanctions and prevention. Legal sanctions are contained in the Food Law. Prevention is carried out by the efforts of the BPOM team to provide socialization to business actors about the dangers of expired drugs. The socialization also explained legal sanctions for business actors who continue to sell expired products. This is done through outreach to the community, where it is hoped that both the community as consumers and business actors can be wiser in purchasing drugs by checking the expiration date.

The criminal threat for business actors who violate this prohibition based on Article 62 paragraph (1) of the Consumer Protection Law is a maximum imprisonment of 5 (five) years or a maximum fine of Rp. 2,000,000,000.00 (two billion rupiahs). In addition to these criminal threats, business actors can be subject to additional penalties, in accordance with Article 63 of the Consumer Protection Law, namely:

1. Confiscation of certain goods;
2. Announcement of the judge's decision;
3. Payment of compensation;
4. Orders to stop certain activities that cause consumer losses;
5. Obligation to withdraw goods from circulation; or
6. Revocation of business license.

BPOM has the authority to take these actions, such as ordering the termination of certain activities that cause consumer harm, withdrawing goods from circulation. The settlement of consumer disputes by BPOM through conciliation or mediation or arbitration is carried out on the basis of the choice and approval of the parties concerned.

In the Consumer Protection Law, especially Article 19 paragraph (1), it only states that the business actor is responsible. Not given a more detailed explanation of the business actor referred to. For legal certainty, it should be clear which business actor is responsible for consumer losses in the case of expired food products. Taking into account the substance of Article 19 paragraph (1) of the Consumer Protection Law, that the responsibilities of business actors include:

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

Based on this, the existence of goods and/or services in the form of expired food is not the only basis for the responsibility of business actors. This means that the responsibility of business actors includes all losses experienced related to the consumption and trading of goods and/or services in the community. Furthermore, paying attention to the form of compensation that can be given to consumers who are harmed, according to the provisions of Article 19 paragraph (2) it can be in the form of:

1. Return of goods;
2. Replacement of goods and/or services of equal value;
3. Health care;
4. Giving compensation.

Conclusion

The legal responsibility of pharmaceutical business actors for drug distribution permits in an effort to cure diseases is something that must be obeyed. Every distribution of drugs, medicinal ingredients, traditional medicines and cosmetics in Indonesia must obtain a distribution permit before the drugs can be distributed. This is in accordance with Article 106 paragraph (1) jo. Article 1 paragraph (4) of Law No. 36 of 2009 concerning Health. Obstacles in carrying out legal responsibilities of pharmaceutical business actors regarding drug distribution permits in efforts to cure diseases are still found. Among other things, the lack of performance in the oversight and evaluation function of drug distribution in Indonesia has led to many loopholes arising, especially in terms of fulfilling drugs that have distribution permits. The monitoring and evaluation function of drug distribution cannot be fully maximized due to the massive circulation of drugs without a distribution permit in Indonesia and the lack of authority that exists at the Food and Drug Supervisory Agency (BPOM). Another obstacle is the difficulty for the public to distinguish between packaging that has an official distribution permit and fakes. Drug preparations that do not have a distribution permit also sometimes have lower prices than official drug preparations.

References

Handoko, D. (2021). Perlindungan Hukum Terhadap Konsumen Dalam Penggunaan Obat-Obatan Kedaluarsa. *Journal of Law (Jurnal Ilmu Hukum)*, *6*(2).

Herlina, N. (2019). Penerapan Sanksi Administrasi dalam Hukum Perlindungan Konsumen. *Jurnal Ilmiah Galuh Justisi*, *7*(2), 13.

Masputra, M. H. C., Setiyono, J., & Irawati, I. (2020). KEADILAN TERHADAP DOKTER PADA KASUS PENGGUNAAN OBAT YANG BELUM TERDAFTAR DI BPOM REPUBLIK INDONESIA. *Jurnal Pembangunan Hukum Indonesia*, *2*(1). https://doi.org/10.14710/jphi.v2i1.102-116.

Mudrikah, E. D., & Salomo, R. V. (2021). Stakeholder Engagement Dalam Perancangan Indikator Kinerja Pengawasan Obat. *Sawala : Jurnal Administrasi Negara*, *9*(1). https://doi.org/10.30656/sawala.v9i2.3281.

Panutan, F. A. A., Fatimah, E., & Sugihartoyo, S. (2019). Upaya Pengembangan PKSN Jasa di Kawasan Perbatasan Negara Kabupaten Sintang. *Seminar Nasional Pembangunan Wilayah Dan Kota Berkelanjutan*, *1*(1). https://doi.org/10.25105/pwkb.v1i1.5263.

Permatha, A., Syafril, & Zarfinal. (2020). PENGAWASAN BPOM DALAM PEREDARAN OBAT TRADISIONAL ILEGAL DI KOTA PADANG. *Law Study Program, Faculty of Law, Bung Hatta University*, *21*(1).

Philipus M. Hadjon. (1987). *Perlindungan Hukum bagi Rakyat Indonesia*. Bina Ilmu.

Setiawan, A. (2018). ANALISIS PERAN BIDANG PROFESI DAN PENGAMANAN TERHADAP PENYALAHGUNAAN SENJATA API YANG DILAKUKAN OLEH ANGGOTA POLRI (Studi di Kepolisian Daerah Lampung). *Journal of Chemical Information and Modeling*, *53*(9), 1689–1699.

Suriangka, A. (2017). PERLINDUNGAN KONSUMEN TERHADAP PENYALURAN OBAT KERAS DAFTAR G OLEH BADAN POM DI MAKASSAR. *Jurisprudentie : Jurusan Ilmu Hukum Fakultas Syariah Dan Hukum*, *4*(2). https://doi.org/10.24252/jurisprudentie.v4i2.4044.

Syakbani, B., & Suprayitno, H. (2013). Cek dan balance sistem pemerintahan di indonesia. *Stie Amm Mataram*.

Utami, A., & Herwastoeti, H. (2022). PERLINDUNGAN HUKUM TERHADAP KONSUMEN ATAS PENJUALAN OBAT-OBATAN ILEGAL SECARA ONLINE. *Klausula (Jurnal Hukum Tata Negara, Hukum Adminitrasi, Pidana Dan Perdata)*, *1*(2), 93. https://doi.org/10.32503/klausula.v1i2.2727.

Wulandari, S., & Mustarichie, R. (2017). Upaya Pengawasan BPOM di Bandung Dalam Kejadian Potensi Penyalahgunaan Obat. *Jurnal Farmaka Unpad*, *15*(4).

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