



Volume 2, Issue 2, Maret 2024 (icrtlaw@ums.ac.id)

Analysis of Consumer Protection for Medicines and Foods That Are Not Registered with BPOM

Bayu Nugroho¹, Arief Budiono²

¹ Fakultas Hukum, Universitas Muhammadiyah Surakarta (<u>C100190255@student.ums.ac.id</u>) ² Fakultas Hukum, Universitas Muhammadiyah Surakarta (nn123@ums.ac.id)

ABSTRACT

The author writes a journal by analyzing and explaining BPOM's goals in enforcing and enforcing consumer protection regulations based on the Consumer Protection Administration Law No. 8 of 1999. In this case the Food and Drug Supervisory Agency (BPOM) has a role and responsibility for the circulation of each drug and food product in the framework of granting permits for each drug and food product circulating in the community. The Food and Drug Supervisory Agency (BPOM) is a government agency responsible for drug and food control. The Consumer Protection Law prohibits the manufacture of goods for the general public, namely the types of goods listed in Law Number 8 of the Republic of Indonesia concerning Consumer Protection for the purpose of increasing knowledge and skills (1999 Consumer Protection Law). violated because of the indiscriminate nature of the company's behavior. and independence of consumer self-defense. Protect the dignity of customers by protecting them from harmful use and oversupply of services. Empowering consumers by letting them choose the products they want to buy and asserting their legal rights.

Keywords: consumer protection; food and medicine; responsibility

INTRODUCTION

Indonesia is a country that puts itself forward as a country that bases itself on law (rechstaat) not on national economic strength (machstaat). This is in accordance with the statement of Article 1 Paragraph (3) of the 1945 Constitution of the Republic of Indonesia that "The State of Indonesia is a State of Law". The implication of this provision is that Indonesia is a country that has been forged with Pancasila and the Constitution of the National Government since 1945. Therefore, every provision must be obeyed and must not violate the principles of Pancasila and the 1945 Constitution of the Republic of Indonesia as foundation of the rule of law, as explained by Hans Kelsen in the theory known as the Legal Pyramid or Multi-Storied Building Theory.²

To ensure social progress for all Indonesian people, Indonesia regulates everything with strict rules known as laws and regulations. The only rules governing these transactions relate to consumers. If consumers are analyzed, it is impossible for the analysis to deviate from the legal implications of protection for consumers, both food and medicine. In this case, an agency is needed to deal with legal violations and protect victims of drug and food users, namely BPOM.

In the current era of globalization, information and access to new products are very easy to obtain. However, not all products sold on the market have valid permits and certification from BPOM. Medicines and foods that are not registered with BPOM have the potential to be dangerous to consumers' health. BPOM is an institution that supervises all distribution of medicines and food throughout Indonesia. The organization currently shares responsibility with the Food and Drug Administration (FDA) and the European Medicines Agency (EMA). The aim of this drug and food safety campaign is to ensure that every product is safe for consumption and does not harm consumers.

¹ Kansil C.S.T, 1989, *Pengantar Ilmu Hukum dan Tata Hukum Indonesia*, Cetakan ke-8, Jakarta: Balai Pustaka, Hal. 346.

² Asshiddiqie Jimly dan M. Ali Safa'at, 2006, *Teori Hans Kelsen Tentang Hukum*, Jakarta:Konpress, hal. 17.

³ Bahmid, Bahmid and Martua, Junindra and Arbiah, Arbiah (2020) Peranan Badan Pengawas Obat Dan Makanan Dalam Memberikan Perlindungan Studi Di Kantor Cabang Badan Pengawas Obat Dan Makanan Badan Pengawas Obat Makanan (BPOM) Tanjungbalai. DE LEGA LATA: Jurnal Ilmu Hukum, 5





Volume 2, Issue 2, Maret 2024 (icrtlaw@ums.ac.id)

However, the reality is that the vortex of food and medicine is getting bigger and more complex. Unfortunately, there have been no cases of unlicensed consumption of products proven to contain dangerous ingredients in such a wide range. Therefore, an active and efficient public distribution system is necessary to maintain consumption of public goods. This system is led by BPOM, the only Non-Ministerial Government Institution (LPNK) that has been determined to have "high professional credibility". BPOM has national and international connections, as well as expertise in human trafficking. As LPNK, BPOM's functions and duties were created by the nation in a straightforward manner. ⁴The mission of the Food and Drug Administration Agency is to promote government initiatives in the Food and Drug sector that are in line with applicable laws. These pharmaceutical and food products are defined in regulations and include pharmaceutical products, medicinal ingredients, prohibited substances, psychotropic drugs, precursors, addictive substances, traditional ingredients, health supplements, cosmetics and processed foods. (Article 2 Presidential Decree No. 80 of 2017).

This problem is a serious concern because medicines and foods that are not registered by BPOM have the potential to be dangerous to consumers' health. This product may contain dangerous chemicals that do not comply with the quality standards set by BPOM. Consumers who do not know this risk consuming products that are detrimental to their health. Therefore, it is important to carry out an analysis regarding consumer protection for medicines and foods that are not registered with BPOM. This article will discuss the importance of consumer protection against unregistered medicinal and food products, as well as provide solutions to overcome this problem.

Article 4 and Article 8 of Law Number 8 of 1999 concerning Consumer Protection which contains regulations regarding consumer rights and obligations as well as prohibitions that must be complied with in the manufacture or trade of a product, clearly regulates processed food products that have been registered and have a distribution permit. However, there are clear differences between the two, and when BPOM carries out its function as an inspection on the market, it is often found that several products have distribution permits; However, due to time constraints, the company cannot ensure that the quality and quantity of the product meets the requirements set at the beginning of the production process to obtain a distribution permit.

RESEARCH METHODS

The method used in this research is the normative legal method (juridical-normative), namely a research procedure that uses scientific logic from a normative perspective to find a legal truth by focusing on the analysis of statutory regulations which provide opportunities for environmental practices in the form of exploitation (Johnny Ibrahim, 2007). In studying the issues discussed, a legal approach and a conceptual approach were used by examining related cases that already had final decisions (Peter Ahmad Marzuki, 2005). This research also uses normative data analysis obtained from various sources such as books, scientific journals and articles. To collect data, the Library Research technique is used which involves reviewing archives or literature studies that are relevant to the research topic, then the data is recorded and processed as research material on the topic being researched.

The analysis technique used is Content Analysis, which is a method used to analyze and understand text with the aim of extracting relevant and significant information. This method can also be interpreted as a research technique that aims to analyze data objectively. (John Fiske, 2005). The interpretation in this research is based on data obtained from secondary legal material sources. Secondary legal materials used in this research include articles, scientific journals, books, news in the mass media, and case decisions related to the topic being researched. The analysis technique used is Content Analysis, which is a method used to analyze and understand text with the aim of extracting relevant and significant information. This method can also be interpreted as a research technique that aims to analyze data objectively. (John Fiske,

⁴ Cut Desi Wanda Sari, (2020) Peran BBPOM Terhadap Pengawasan Peredaran Kosmetik Illegal Dalam Perlindungan Hukum Di Kota Banda Aceh. Skripsi thesis, UIN AR-RANIRY.





Volume 2, Issue 2, Maret 2024 (icrtlaw@ums.ac.id)

2005).

GENERAL REVIEW

a. Consumer Overview

Understanding Consumers

Consumers are users of commercial and non-commercial goods and services accessible in society, as well as themselves, their families, other people, and other living things. Consumer protection means making every effort to provide legal clarity to protect consumers.⁵

Likewise, Indonesian scholars use some or one of the above terms to indicate their respective references and even the meaning of these terms. Below, the author presents the opinions of scientists regarding the concept of consumer protection, namely:

• Mochtar Kusumaatmadja.

Consumer Protection is the comprehensive principles and laws and regulations that regulate relationships and issues between various entities regarding consumer products or services in the context of human existence.

Az. Nasution.

Consumer protection falls within the realm of law, which includes regulations and guidelines designed to protect consumer interests. Consumer protection law is primarily concerned with the legal framework that regulates interactions and conflicts between parties involved in the delivery of consumer products or services. The government needs a legal framework that supports Indonesia's consumer protection laws.

Consumer protection is an important component of consumer regulation, which consists of regulatory guidelines or regulations with features that protect consumer welfare, while consumer law is the legal framework that regulates associations and disputes among various entities related to consumer commodities or facilities. ⁶The Indonesian government has established the legal basis for consumer protection laws.

II. Consumer Rights

Guarantees of legal certainty are very important in protecting consumers. This is primarily achieved through the implementation of laws that specifically protect consumer rights. This law functions as a deterrent for business entities from carrying out all forms of arbitrary behavior that have the potential to violate consumer rights.⁷

Unreasonable actions can cause uncertainty in the legal system. To ensure legal certainty, the Consumer Protection Law and other related laws and regulations aim to protect consumer rights both through civil and criminal law. This includes the application of various scientific fields to clarify the relationship between Consumer Protection Law and Economic Law. This effort serves to maintain the validity of consumer protection measures.8

Consumer rights are regulated in the Consumer Protection Law no. 8 of 1999 concerning Consumer Protection in Indonesia, which is based on Article 5 paragraph (1), Article 21 paragraph (1), Article 27, and Article 33 of the 1945 Constitution:

• The right to choose products

Customers have complete rights in choosing the products to be used or consumed. Even the manufacturer concerned does not have the authority to regulate. Likewise, the right to check the quality of goods to be purchased or consumed in the future.

Compensation and right to compensation

⁵ Pasal 1 Undang-Undang Republik Indonesia Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen

⁶ Shidarta, Hukum Perlindungan Konsumen Indonesia edisi Revisi 2006, Gramedia Widiasarana, Jakarta, 2006, hlm. 3

⁷ Happy Susanto, Hak-hak Konsumen Jika Dirugikan, (Jakarta: Visimedia, 2008). Hal 4.

Ahmadi Miru dan Sutarman Yodo, Hukum Perlindungan Konsumen, (Jakarta: PT. Raja Grafindo Persada, 2004), 1





Volume 2, Issue 2, Maret 2024 (icrtlaw@ums.ac.id)

Consumers have the right to receive compensation or compensation for losses they suffer as a result of their purchases. Consumers have the right to file a complaint against the manufacturer if there is a mismatch in image or quality.

• The right to obtain related products and services

Consumers have the right to receive products and services based on a written contract. For example, if your online deal offers free shipping, you should implement it. If this is unreasonable, consumers have the right to exercise this right.

• The right to receive the truth of all information

The most important thing for consumers is to find out what information is relevant to the product they are buying. Manufacturers are not allowed to hide or reduce information about their products or services. For example, if goods are defective or faulty, the manufacturer must inform consumers of this.

• The right to receive services without discrimination

Actions that discriminate against consumers constitute a violation of consumer rights. There should be no differences between consumers in the services offered by manufacturers.

b. Overview of Legal Protection

I. Understanding Law

The definition of law according to JCT Simorangkiri quoted by CST cancel Law is coercive regulations that determine the behavior of people in a social environment, which the authorities have the power to carry out, violations of these regulations give rise to actions, namely sanctions certain.9

Definition of law According to Sudikno Martokusumo, law is a set of general and prescriptive rules or regulations. The law is general because it applies to everyone, to determine what must be done, what must not be done or what must be done, and how it must be done normatively, namely respecting the rules.¹⁰

II. Understanding Legal Protection

The purpose of legal protection is to protect individual basic rights that have been violated by others. This protection is provided to people to ensure that they can exercise all their legal rights. In other words, legal protection comes from various judicial sources. The role of law enforcement is to provide a sense of physical and psychological security against harassment and intimidation by any party.

- a. Satjito Rahardjo stated that legal protection aims to protect the interests of individuals by giving them fundamental rights and authority to behave in accordance with their interests. 11
- b. According to Muchsini, protection through legal channels is an effort to safeguard people by harmonizing the principles and regulations included in behavior and actions, so as to create a structured environment for interpersonal relationships between individuals. 12
- c. According to Setiono, legal protection is a system designed to protect society from actions by those in power that are not in accordance with the principles of the legal system, which aims to create stability and calm that allows individuals to enjoy their true value. or business. 13

Legal protection is a priority protection effort, based on the idea that law is a means that gives full attention to the interests and rights of consumers.

⁹ C.S.T. Kansil, Pengantar Ilmu Hukum dan Tata Hukum Indonesia, Cet Ke-8, Balai Pustaka, Jakarta, 1989, hlm. 38.

¹⁰ Sudikno Martokusumo, Mengenal Hukum Satu Pengantar, Liberty, Yogyakarta, 2005, hlm. 4.

¹¹ Satjipro Rahardjo, Sisi-Sisi Lain dari Hukum di Indonesia, Kompas, Jakarta, 2003, hlm. 121

¹² Muchsin, Disertasi: "Perlindungan dan Kepastian Hukum bagi Investor di Indonesia", Fakultas Hukum, Universitas Sebelas Maret, Surakarta, 2003, hlm. 14.

¹³ Setiono, Supremasi Hukum, (Surakarta: UNS, 2004), hlm. 3.





Volume 2, Issue 2, Maret 2024 (icrtlaw@ums.ac.id)

RESULTS AND DISCUSSION

BPOM's Responsibilities and Causes of Consumer Protection Violations

In this case, the Food and Drug Supervisory Agency (BPOM) has a role and responsibility for the distribution of every drug and food, so every drug and food is given permission to circulate in the community, because the Food and Drug Supervisory Agency is a body that has government duties in the field of supervision. medicine and food.

The Food and Drug Supervisory Agency (BPOM) is the first institution trusted by the government to provide permits for consumption of products and food to the public. The food regulatory agency must be diligent, thorough and professional in issuing permits and preparing medicines and food for distribution to the public so that there are no problems or complaints about the medicines and food.

Violations of consumer protection are caused by the arbitrariness of companies that produce products for general consumption, medicines and food whose product types are listed in the Consumer Protection Law of the Republic of Indonesia number 8 of 1999.

Consumer protection efforts in Indonesia are in accordance with the provisions of Law no. 8 of 1999 concerning Consumer Protection.

According to Law Number 8 of 1999 concerning Consumer Protection Article 2. There are 5 principles of consumer protection, namely:14

1. Principle of Benefits

This principle implies that the implementation of UUPK must provide optimal benefits for both parties, namely customers and commercial entities, without any party being superior to the other. It is vital that both parties receive their legal rights.

2. Principles of Justice

The use of this principle can be seen in the provisions of Article 4-7 UUPK which contains the rights and responsibilities of customers and entrepreneurs. This principle aims to ensure that customers and entrepreneurs can obtain their rights and fulfill their obligations fairly and evenly.

3. Principle of Balance

By applying this principle, it is hoped that the interests of customers, entrepreneurs and authorities can be handled equally, without any one party being favored.

4. Principles of Consumer Safety and Security

The implementation of the UUPK is expected to ensure that consumers are safe and comfortable in using the goods and/or services they consume or utilize.

5. Principle of Legal Certainty

This aims to ensure that customers and commercial entities comply with regulations and receive fair treatment in enforcing consumer protection, while the government ensures legal guarantees.

The aim of consumer protection in accordance with Law Number 8 of 1999 is to:15

- 1. Increase customer awareness, skills and autonomy to protect themselves, raise respect for customers.
- 2. Safeguarding against unfavorable access to the use of commodities and/or facilities.
- 3. Increase consumer choice.
- 4. Determine and assert their consumer rights.
- 5. Develop a consumer protection framework that includes legal certainty, information disclosure and fast access to information.
- 6. Increase business actors' understanding of the need for consumer protection in order to foster an honest and responsible business attitude.
- 7. Improving the quality of products and/or services to ensure continuity of production, as well as consumer comfort and safety.

¹⁴ Sudikno Mertokusumo, Mengenal Hukum Suatu Pengantar, Cet. Kedua, (Yogyakarta: Liberty, 1999), hal. 33

¹⁵ Janus Sidabalok, Hukum Perlindungan Konsumen di Indonesia, (Bandung: PT. Citra Aditya Bakti, 2006), hal. 44





Volume 2, Issue 2, Maret 2024 (icrtlaw@ums.ac.id)

CONCLUSION AND SUGGESTION

Conclusion

a) BPOM's Responsibilities and Causes of Consumer Protection Violations

Because the Food and Drug Supervisory Agency (BPOM) is tasked with supervising the distribution of every drug and food and providing distribution permits to the public, the Food and Drug Supervisory Agency (BPOM) is tasked with supervising the distribution of every drug and food. food. The careless behavior of corporate actors who create public consumption goods, especially those regulated in Law of the Republic of Indonesia Number 8 of 1999 concerning Consumer Protection, has resulted in violations of consumer rights.

b) Consumer protection efforts in Indonesia are based on Law Number 8 of 1999 concerning Consumer

People who purchase goods and services and those who produce them are equally entitled to the benefits provided. It is very important that neither party feels disadvantaged or has an unfair advantage. By obtaining rights and obligations fairly and impartially, consumers and producers/business entities can behave fairly. Laws on consumer protection seek to create a balance between the rights and obligations of producers and consumers. Legal warranties ensure that consumers enjoy the products they use and that the products do not harm their lives or property. Legal clarity is provided to producers and consumers in implementing and complying with legal regulations regarding their rights and obligations. The government guarantees legal certainty without blaming any party.

Suggestion

The application of consumer protection law is not only for sellers, but also for consumers, which is expected to increase knowledge, skills and self-defense independence among consumers. maintain the dignity of customers by protecting them from harmful uses and/or excesses of services. increasing consumer empowerment by deciding for themselves what products to buy and demanding their legal rights.

REFERENCES

- 1. Undang-Undang No 8 Tahun 1999 Tentang Perlindungan Konsumen
- 2. KANSIL, Christine ST. Pengantar ilmu hukum dan tata hukum Indonesia. (No Title), 1979. Asshiddiqie Jimly dan M. Ali Safa'at, 2006, Teori Hans Kelsen Tentang Hukum, Jakarta: Konpress, hal. 17.
- 3. BAHMID, Bahmid; MARTUA, Junindra; ARBIAH, Arbiah. Peranan Badan Pengawas Obat Dan Makanan Dalam Memberikan Perlindungan Studi Di Kantor Cabang Badan Pengawas Obat Dan Makanan Badan Pengawas Obat Makanan (BPOM) Tanjungbalai. DE LEGA LATA: Jurnal Ilmu Hukum, 2020, 5.2: 183-192.
- 4. SARI, Cut Desi Wanda, et al. Peran BBPOM Terhadap Pengawasan Peredaran Kosmetik Illegal Dalam Perlindungan Hukum Di Kota Banda Aceh. 2020. PhD Thesis. UIN AR-RANIRY.
- 5. NASTIANDI, Gilang; KURNIAWAN, Kurniawan; HIRSANUDDIN, Hirsanuddin. PERLINDUNGAN HUKUM KONSUMEN TERHADAP PENGGUNAAN KOSMETIK ILEGAL (STUDI KASUS DI BPOM MATARAM). Jurnal Justitia: Jurnal Ilmu Hukum dan Humaniora, 2022, 9.4: 2130-2140.
- 6. SUSANTO, Happy. Hak-hak konsumen jika dirugikan. Visimedia, 2008.
- 7. MIRU, Ahmadi. Hukum perlindungan konsumen. 2004.
- 8. CST, Kansil. Pengantar Ilmu Hukum dan Tata Hukum Indonesia. *Jakarta: Balai Pustaka*, 1989.
- 9. MERTOKUSUMO, Sudikno. Mengenal Hukum Suatu Pengantar, liberty. 2005.
- 10. RAHARDJO, Satjipto. Sisi-sisi lain dari Hukum di Indonesia. Penerbit Buku Kompas, 2003.





Volume 2, Issue 2, Maret 2024 (icrtlaw@ums.ac.id)

- 11. MUCHSIN, Muchsin. Perlindungan dan Kepastian Hukum bagi Investor di Indonesia. Universitas Sebelas Maret, 2003.
- 12. Setiono, Supremasi Hukum, (Surakarta: UNS, 2004), hlm. 3.
- 13. MERTOKUSUMO, Sudikno. Mengenal Hukum Suatu Pengantar (cetakan keempat). Liberty, Yogyakarta. hlm, 2008, 41.
- 14. Janus Sidabalok, Hukum Perlindungan Konsumen di Indonesia, (Bandung: PT. Citra Aditya Bakti, 2006), ha/l. 44