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The Role of Self-Contained Consumer Protection Services (*LPKSM*) in Providing Protection to Consumers on The Circulation of Hazardous Drugs

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Abstract

The acute kidney injury cases that occurred recently highlight the urgency of consumer protection issues in Indonesia. The Consumer Protection Law in Indonesia is a preventive effort by the government to provide legal certainty for consumers. LPKSM is mandated by the Consumer Protection Law to provide legal protection to consumers. This research aims to examine the extent of the role of LPKSM in providing protection to consumers. The research method used in this research is normative juridical research. The approach used is a statute approach and a legal concept analysis approach. The technique of collecting legal materials by conducting document studies related to the problems studied and also primary, secondary and tertiary legal materials, then interpreting and reviewing related laws and regulations. Based on the results of the research that has been conducted, consumer protection is an issue that should receive attention from all parties, including the government, society, and business actors. LPKSM is a non-profit institution that, undoubtedly, requires operational costs, which often become a hindering factor in fulfilling its mandate according to the Consumer Protection Law. The government's role is crucial in this regard, specifically in providing financial support to LPKSM to fulfill its duties effectively. In addition to monitoring the circulation of goods and/or services in the market, LPKSM also provides consumer education and has the authority to file lawsuits against businesses that harm consumers.

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Introduction

The rapid development of the globalization era has led to intense business competition today. The healthcare industry that produces medical supplies and medicines competes competitively in the market. Various choices of similar drugs from various brands are circulating in the market. This situation is very beneficial for consumers, because they can choose products that are in accordance with their preferences and economic capabilities. In this quite competitive industry, it must be followed by an increase in product quality from business entrepreneurs. However, business entrepreneurs tend to be product centric, only focusing on producing profitable products by overemphasizing whether they are helpful and ensure the safety of consumers to achieve as many advantages as possible. Minimizing production costs to be able to gain profits. In 2022 to early 2023, the ministry of health recorded cases of acute kidney injury that occurred in children, as a total of 157 (58%) were reported to have died. Based on the results of biopsies done on the bodies of patients with acute kidney injury, damage to the kidneys is caused by ethylene glycol (EG) compounds. This compound is suspected to originate from a liquid or syrup drug (cnnindonesia.com, 2022). From this situation, it can be seen how consumers are the weaknesses and victims of the mischievous drug manufacturers who combine materials that are

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dangerous to health and even threaten a person's life. In this case, the consumer is in a vulnerable role, as a layperson based on a sense of trust that the medicines on the market are products that are guaranteed to be safety.

The responsibility of business actors is directly tied to products, both goods and services, especially if they harm consumers in accordance with Law Number 8 Year 1999. Business entrepreneurs must be responsible for all goods and services sold or used by consumers, because in principle consumers always demand the right to comfort and safety in enjoying the goods or services provided by business entrepreneurs. Thus, any loss of goods and services must be borne by the entrepreneur absolutely by providing compensation otherwise criminal responsibility will be prosecuted in accordance with Law Number 8 of 1999. (Pauth, 2018).

According to Rohman, et al, pharmaceutical companies have followed the stages of drug registration regulated by BPOM in accordance with the process from start to finish as evidenced by the existence of a distribution permit on the product owned by the syrup drug being circulated. However, the occurrence of problems such as this shows that there is a fatal negligence by BPOM in conducting continuous monitoring in ensuring consumer safety, especially in consuming types of syrup containing hazardous substances that can have fatal side effects as evidenced by the emergence of cases of acute kidney failure experienced by children in consumers after consuming the drug. (Rohman, 2023)

To protect consumers, a special institution is needed that can protect consumers, both those formed by non-governmental organizations and those formed by the government, where the institution functions to protect consumers from the actions of business actors who are not in good faith. Over time, to facilitate consumers so that they are not harmed by business actors in consuming goods or services and to be able to assist consumers in resolving disputes with business actors, an institution called LPKSM (Lembaga Perlindungan Konsumen Swadaya Masyarakat) has emerged, which was formed by the community itself (Suryadi, Rahmatiar & Abas, 2023).

The protection of consumers is the combined responsibility of the government and society. The Non-Governmental Consumer Protection Organization (*Lembaga Perlindungan Konsumen Swadaya Masyarakat*) is a tangible manifestation of community participation in consumer protection issues. The mandate given by the Consumer Protection Law (UUPK) to *LPKSM* is a challenge for business entrepreneurs. The good intentions of business entrepreneurs are seen from the delivery of correct, transparent and truthful information to consumers. This is a good behavior and ethics that must be maintained by business entrepreneurs. In light of this, it is necessary to determine the importance of *LPKSM's* role in providing legal protection to consumers in relation to the circulation of drugs containing dangerous materials in the market.

The prior research related to this study, which was carried out by (Nadhira, Hermawan & Candrakirana, 2021) explained that evaluation and improvement must continue to be carried out, revision of the substance of laws that are still unbalanced and still favorable to business actors and improving the quality of human resources of *LPKSM* administrators must be a priority program to solve the problem of providing protection programs for consumers in Indonesia.

Method

The research method used in this research is normative juridical research. The approach used is a regulatory approach and a legal concept analysis approach. The technique of collecting legal materials by conducting document studies related to the issues discussed and also primary, secondary and tertiary legal materials, further interpreting and reviewing related laws and regulations.

Discussion

Consumer Protections

Nowadays, along with the rapid advancement of science and technology, it increases the productivity and efficiency of producers of goods and services that they produce to meet business objectives. (Endipraja, 2016) However, amidst this progress, ensuring consumer protection has emerged as a matter of paramount importance. The term consumer protection is related to legal protection. Therefore, consumer protection also includes legal aspects. The protected material includes not only

physical rights but also abstract rights. In other words, consumer protection is tantamount to the protection of consumer rights granted by law. (Azizah, 2018)

Referring to research conducted by (Uloma, et al, 2022), product safety is related to product strategy in pharmaceutical companies. Consumer protection relates to consumer awareness to get education related to the rights owned by consumers, as well as consumer involvement in the struggle for their rights. Many consumers do not realize and know their rights due to insensitivity, poverty and illiteracy. In addition to laws governing consumer protection, there is a need for collaboration between legal entities to increase awareness and sensitization regarding consumer education (Uloma, et al, 2022).

Oranusi, et al in their research mentioned that the media has a very important role to protect and educate the public with accurate information against misleading practices carried out by producers and distributors. The role of the media to educate consumers is still a big challenge in the developing countries. Studies have shown that consumers tend to be careless, skeptical and have poor knowledge and perceptions. Therefore, the government and media must work together intensively to educate consumers about their rights and what efforts can be made to enforce these rights. The government must be serious about consumer protection (Oranusi, et al, 2021)

The research by Sarmistha Agasti et al. states that marketing has shifted from product-centric to buyer-centric. Consumers in general do not know about their rights and responsibilities, therefore it is important to include consumer protection material in the education curriculum. With consumers having an awareness of the importance of their rights and responsibilities, it is expected that they will be safer from the bad behavior of rogue manufacturers.

According to Utum et al, consumer protection laws have a major impact on the country, which can shape ethical marketing practices in the pharmaceutical industry. The importance of collaboration between stakeholders (academics and industry) regarding monitoring and enforcement in the preparation of legislation in the pharmaceutical sector (Utum, et al, 2020). Pharmaceutical companies have done a lot of damage to their reputation, and the only way to regain the trust of the public is to implement ethics at every level of business operations (Ganesan & Thambusamy, 2020).

Discussing the issue of consumer protection, of course, the rule of law that can provide protection is needed. Indonesia already has laws governing consumer protection, namely Law No. 8 of 1999 on Consumer Protection (UUPK). After 24 years of UUPK being enacted, problems related to consumer protection continue to increase and develop along with the rapid advancement of science and technology. Based on data from the bpkn.go.id page, the total receipt of consumer complaints from 2017 to June 1, 2023 was 8607 complaints. (bpkn.go.id)

Based on article 1 paragraph of UUPK:

Consumer protection refers to all efforts that guarantee legal certainty to provide protection for consumers.

Consumers are defined as any individuals who utilize goods and/or services available in society, whether for their own interests, the interests of their families, other individuals, or other living beings, and not for commercial purposes.

The objectives of consumer protection are set out in Article 3 of the UUPK:

- a. Increase awareness, ability and independence of consumers to protect themselves;
- b. Raise the dignity of consumers by preventing them from the negative excesses of the use of goods and / or services;
 - c. To empower consumers in choosing, determining, and asserting their rights as consumers;
- d. To create a consumer protection system that contains elements of legal certainty, information transparency, and access to obtain information;
- e. To cultivate awareness among business entities regarding the importance of consumer protection, fostering honest and responsible conduct in business endeavors;
- f. To enhance the quality of goods and/or services that guarantee the continuity of production, consumer health, comfort, safety, and security.

Consumer rights, as stated in Article 4 of the Consumer Protection Law (UUPK), are:

the right to comfort, security, and safety in consuming goods and/or services;

the right to choose goods and/or services and to obtain those goods and/or services in accordance with the exchange rate and the promised conditions and guarantees;

the right to correct, clear, and honest information regarding the conditions and guarantees of goods and/or services;

the right to have their opinions and complaints about the goods and / or services used heard;

the right to obtain advocacy, protection, and efforts to resolve consumer protection disputes properly;

the right to receive guidance and consumer education;

the right to be treated or served correctly and honestly and non-discriminatory;

the right to compensation, compensation and/or replacement, if the goods and/or services received are not in accordance with the agreement or not as they should be;

rights stipulated in the provisions of other laws and regulations.

The obligations of business actors regulated in Article 7 of UUPK are:

Acting in good faith in conducting their business activities.

Providing accurate, clear, and honest information regarding the condition and guarantees of goods and/or services, as well as explaining their usage, repair, and maintenance.

Treating or serving consumers correctly, honestly, and without discrimination.

Ensuring the quality of goods and/or services produced and/or traded based on the applicable quality standards.

Providing consumers with the opportunity to test and/or try specific goods and/or services, as well as providing guarantees and/or warranties for the manufactured and/or traded goods.

Providing compensation, reimbursement, and/or replacement for losses resulting from the use, utilization, and exploitation of traded goods and/or services.

Providing compensation, reimbursement, and/or replacement if the received or utilized goods and/or services do not conform to the agreement.

The responsibilities of business entities are regulated in Article 19 of the Consumer Protection Law, which states:

- (1) Business entities are responsible for providing compensation for damages, pollution, and/or losses suffered by consumers as a result of consuming goods and/or services produced or traded by them.
- (2) Compensation as referred to in paragraph (1) may take the form of monetary refunds or replacement with goods and/or services of similar value, or healthcare and/or appropriate assistance in accordance with the provisions of the applicable laws and regulations.
 - (3) Compensation shall be provided within a period of 7 (seven) days from the transaction date.
- (4) The provision of compensation as stated in paragraphs (1) and (2) does not eliminate the possibility of criminal charges based on further evidence of wrongdoing.
- (5) The provisions as stated in paragraphs (1) and (2) do not apply if the business entity can prove that the fault lies with the consumer.

In criminal cases of consumer protection, the burden of proof regarding the presence or absence of fault follows a system of reversed burden of proof, where the business entity has the burden and responsibility to prove their innocence or provide negative proof against the prosecution's allegations, as regulated in Article 22 of the Consumer Protection Law (UUPK).

Article 23 of the UUPK states that "if a business entity refuses or fails to respond, or does not fulfil the obligation to provide compensation for consumer claims as stipulated in Article 19 paragraph (1), paragraph (2), paragraph (3), and paragraph (4), the consumer can file a lawsuit through a consumer dispute resolution body or bring the case to court at the consumer's domicile".

Based on Article 61 paragraph (3) of the UUPK, criminal prosecution can be conducted against

business entities for offences that result in serious injuries, severe illnesses, permanent disabilities, or death. Regarding the criminal sanctions referred to in Article 62, Article 63 regulates additional penalties, which include:

Confiscation of specific goods;

Announcement of the judge's decision;

Payment of compensation;

Issuance of orders to cease specific activities that cause consumer losses;

Obligation to withdraw goods from circulation; or

Revocation of business permits.

The existence of a balance in legal protection between consumers and business entities signifies that the business activities are in a healthy condition. The absence of balanced protection results in consumers having a significantly weak position. The losses experienced by consumers are, among other things, caused by unlawful actions committed by business entities (Yasa, Sudiatmaka & Ardhya, 2021).

The Role of Lembaga Perlindungan Konsumen Swadaya Masyarakat (LPKSM)

The role of national consumer organizations is crucial in the provision of consumer protection. The role of consumer organizations is so important that the world consumer congress held in Santiago discussed their role in facilitating legal remedies for consumers. To resolve this concern, the ideal form is that consumer protection will be effective if it is conducted simultaneously at two levels/streams, there are LPKSM that conduct socialization and accommodate consumer aspirations. On the other hand, from the government, there is a part of the power structure that specifically deals with consumer protection (Talumewo, 2018).

Based on the research conducted by Rosida & Sulistyowati it is expected that consumers can be more active in advocating for their rights, by visiting the LPKSM office for consultation. If the consumer authorizes LPKSM and makes a legal document signed and approved by the consumer, LPKSM will first take action with a family approach before taking legal action. (Rosida, & Sulistyowati, 2022). The same statement was also conveyed in research conducted by (Panggabean & Badriyah, 2023) previously LPKSM would first clarify to business entrepreneurs who were suspected of harming consumers based on reports that consumers made through LPKSM (Panggabean & Badriyah, 2023). In addition, LPKSM would also clarify to business entrepreneurs who were suspected of harming consumers based on reports that consumers made through LPKSM. (Samuel & Soemartono, 2022)

Based on Article 1, paragraph (9) of the Consumer Protection Law (UUPK), "Lembaga Perlindungan Konsumen Swadaya Masyarakat is a non-governmental organization registered and recognized by the government, engaged in consumer protection activities". LPKSM is a registered and recognized non-governmental institution owned by the government that deals with consumer protection. Based on UUPK, LPKSM has the opportunity to take an active role in realizing consumer protection (Rahmat, et al, 2019). As the implementing regulation of the UUPK, Government Regulation Number 89 of 2019 concerning Amendments to Government Regulation Number 59 of 2001 concerning Civil Society Consumer Protection Institutions, Article 2 stipulates that LPKSM must fulfil the following requirements:

Registered with the provincial local government;

Engaged in consumer protection activities as stated in its articles of association.

LPKSM which meets these requirements can carry out consumer protection activities throughout Indonesia. Furthermore, Article 9 states that LPKSM, in carrying out its duties, can collaborate with other organizations or institutions, both at the national and international levels. LPKSM reports on the implementation of its duties to the provincial local government annually.

Based on Government Regulation Number 59 of 2001 concerning Lembaga Perlindungan Konsumen Swadaya Masyarakat as amended by Government Regulation Number 89 of 2019 concerning Amendments to Government Regulation Number 59 of 2001 concerning Lembaga Perlindungan Konsumen Swadaya Masyarakat, Article 7 states, "In assisting consumers in fighting for their rights, LPKSM can engage in advocacy or empower consumers to independently fight for their rights, both individually and collectively." How to attribute statutory authority to LPKSM is the main issue in this study. If analyzed

based on the applicable laws and regulations, LPKSM only acts as an institution that receives consumer complaints and does not have the authority to conduct advocacy or legal assistance. According to (Marangga & Rahayu, 2023) the forms of advocacy carried out by LPKSM are through consultation, negotiation, mediation, and assistance outside and inside the court. (Marangga & Rahayu, 2023) Lack of knowledge about the role, function and authority of LPKSM requires wise understanding because LPKSM is generally not allowed to make legal service agreements like lawyers (Zulhidayat, 2023).

Article 8 regulates "supervision of consumer protection by *LPKSM*, the government, and the public, conducted on goods and/or services circulating in the market through research, testing, and/or surveys."

In Article 29, paragraph (4), letter b of the Consumer Protection Law (UUPK), it is regulated that "the government's supervision of consumer protection includes efforts to develop civil society consumer protection institutions."

Article 30 of the UUPK regulates supervision over the implementation of consumer protection and the enforcement of its statutory provisions. Supervision is carried out by the government, the public, and lembaga perlindungan konsumen swadaya masyarakat (LPKSM). The supervision conducted by the public lembaga perlindungan konsumen swadaya masyarakat (LPKSM) focuses on goods and/or services circulating in the market. The results of the supervision conducted by the public and lembaga perlindungan konsumen swadaya masyarakat (LPKSM) can be disseminated to the public and conveyed to the Minister of Trade and the responsible minister according to their technical duties.

In Article 34 of the Consumer Protection Law (UUPK), letters d and f mention the tasks of the National Consumer Protection Agency (BPKN):

Encouraging the development of civil society consumer protection institutions;

Receiving complaints about consumer protection from the public, civil society consumer protection institutions, or business entities;

The position of National Consumer Protection Agency (BPKN) is an institution established to assist in the development of consumer protection, especially in helping consumers who have been harmed by violations through the complaint mechanism, directly from the public and *Lembaga Perlindungan Konsumen Swadaya Masyarakat (LPKSM)* is of great importance in resolving disputes. BPKN must strengthen cooperation with other governmental and non-governmental institutions in monitoring, evaluating, and reporting progress in handling consumer protection cases. (Kairupan, 2013)

The tasks of *LPKSM* as regulated in Article 44, paragraph (3) of the Consumer Protection Law (UUPK), include:

Disseminating information to increase awareness of consumer rights, obligations, and caution in consuming goods and/or services;

Providing advice to consumers in need;

Collaborating with relevant agencies to achieve consumer protection;

Assisting consumers in advocating for their rights, including receiving consumer complaints or grievances;

Conducting supervision together with the government and the public on the implementation of consumer protection.

LPKSM that meet the requirements may file a lawsuit in general court against business entities for violations, as regulated in Article 46, paragraph (1), letter c," the qualified of Lembaga Perlindungan Konsumen Swadaya (LPKSM) include:

It is a legal entity or foundation;

Its articles of association explicitly state that the purpose of the organization is for consumer protection; and

It has carried out activities under its articles of association.

In addition to individuals as bearers of rights, in law, legal entities or associations are also considered legal subjects with rights and the ability to engage in legal acts. Legal entities (rechtpersoon) refer to entities person created by law (Kansil, 1989).

H.M.N. Purwosutjipto stated several requirements for an entity to be categorized as a legal entity, which are: (Purwosutjipt, 1982)

The existence of wealth (rights) with a specific purpose that is separate from the personal wealth of the founders of the entity;

The interest that serves as the objective is a collective interest;

The presence of several individuals as the administrators of the entity.

LPKSM that are legal entities are those that have been authorized by the Minister of Law and Human Rights.

In Article 46, letter d of the Consumer Protection Law (UUPK), it is mentioned that the government can file a lawsuit against business entities for violations. However, in reality, the government has not yet filed any lawsuits against businesses that have harmed consumers, as mandated by the UUPK. The government's seriousness in consumer protection is highly anticipated. The effectiveness of enforcing the UUPK undoubtedly requires support from all parties, both from the government and the public. The government has provided preventive legal protection by enacting the UUPK to ensure legal certainty. However, it should also be supported by repressive protection from the government by filing lawsuits against business entities that cause material losses and numerous fatalities. In the recent case of acute kidney failure, where a significant number of victims were affected, representative group lawsuits (class action) were filed by the families of the victims, as mandated in Article 46 of the UUPK, with the support of the Indonesian Consumer Institution Foundation.

The National Consumer Protection in Article 4 mentions that STRANAS-PK consists of strengthening three pillars, namely:

Strengthening the role of the government;

Empowering consumers;

Enhancing business compliance.

Based on Article 5 of Government Regulation No. 58 of 2001 on the Development and Supervision of Consumer Protection, "In efforts to develop *LPKSM*, the Minister coordinates the implementation of consumer protection with relevant technical ministries in terms of:

Socializing legislation and information related to consumer protection;

Capacity building and enhancing human resources of LPKSM administrators through education, training, and skills."

Furthermore, Article 7, it is regulated that "supervision of the implementation of consumer protection and the enforcement of its legal provisions are carried out by the government, the community, and *lembaga perlindungan konsumen swadaya masyarakat*".

In more detail, it is regulated in article 10

- (1) Monitoring by *LPKSM* is conducted on products and/or services circulating in the market.
- (2) Monitoring as referred to in paragraph (1) shall be conducted by means of research, testing and or surveys.
- (3) Aspects of monitoring include the posting of information about the risks of using the product if required, the installation of labels, advertising, and others required under the provisions of laws and regulations and customs in business practices.
- (4) Research, testing and/or surveys as referred to in paragraph (2) shall be conducted on products and/or services that are suspected of not fulfilling the requirements of safety, health, comfort and consumer safety.
- (5) The results of monitoring as referred to in paragraph (2) may be disseminated to the public and may be submitted to the minister and technical ministers.

In the explanation section of Government Regulation No. 58/2001, it is stated that the implementation of research, testing and/or surveys can be carried out either before or after things have occurred that endanger the security, health, comfort and safety of consumers.

Article 11 clearly states, "Testing of products and/or services in circulation is implemented

through testing laboratories that have been accredited in accordance with applicable laws and regulations". The appointment of testing only to accredited laboratories is intended to obtain test results that are objective and transparent and can be accounted for. The accreditation may be conducted either through national or international accreditation institutions.

According to Suherman, N.A. et al, the financing or funds received by LPKSM in carrying out operational obligations are obtained independently. This implies that the government is not responsible for funding to support LPKSM 's performance in providing consumer protection as stated in the applicable regulations (Suherman, et al, 2023). The same was stated by (Widyasari, 2020) the obstacles that have been experienced by LPKSM from the internal side are shortages and a small number of members. From the external side, the government is not proactive in consumer protection, and business entrepreneurs do not comply with laws and regulations, which makes it quite difficult for LPKSM to provide protection to consumers (Widyasari, 2020).

LPKSM has been established in all regions in Indonesia, but not all of them are currently active. Many are inactive due to funding difficulties for operations. LPKSM is a legal entity that is not profit-oriented, services to consumers are performed free of charge. The integrity of the management and members is needed to protect consumers. Preventive protection by educating the public on consumer protection issues creates empowered consumers.

Conclusion

Consumer protection is an area of concern that should be considered by all parties, including the government, the public and business entrepreneurs. *LPKSM* is a non-profit organization, which in carrying out its duties requires operational costs, which often become an inhibiting factor to be held accountable in accordance with the mandate of the UUPK Law. The role of the government is required in this case, how the government can provide funding support to *LPKSM* thus it can fulfill its duties appropriately. *LPKSM*, in addition to supervising the circulation of products and/or services in the market, providing education to consumers, can also conduct lawsuits against business entrepreneurs who are harmful to consumers.

The government should further increase its role in consumer protection issues in Indonesia, for example, the mandate of the law that has not been implemented is the government or related institutions can conduct lawsuits against business entrepreneurs who have caused material losses and a large number of deaths. Business entrepreneurs should prioritize honesty and good intentions in conducting their business to provide protection to consumers. Consumers should get more education about consumer protection.

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