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The execution of Minister of Agrarian Affairs Regulation No. 12 of 2017, which concerns the implementation of the Comprehensive Systematic Land Registration (PTSL) in Weragati Village, Majalengka Regency, is currently underway.

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Abstract. *The Complete Systematic Land Registration (PTSL) is a thorough procedure of registering all unregistered land parcels in every region of the Republic of Indonesia, inside a single village/sub-district or other administrative unit at the same level, conducted concurrently. The PTSL method is a government project spearheaded by the Ministry of ATR/BPN to cater to the basic needs of the community, such as clothing, food, and shelter. The research methodology used is juridical-empirical, which is a type of qualitative research. This study made use of both primary and secondary legal information. The potential obstacles in executing the Complete Systematic Land Registration (PTSL) program encompass unresolved PPH and BPHTB taxes, absentee land ownership concerns, surplus and neglected land, human resource constraints, insufficient facilities and infrastructure, and challenges in acquiring precise physical and legal data.*
Keywords: *Land Registration, Complete Systematic Land Registration (PTSL*)

A. Introduction

Health comprises an individual's physical, mental, spiritual, and social well-being, allowing them to live productive lives in both social and economic aspects. The accessibility of medications is an essential component of health services. Pharmacotherapy uses drugs to address and proactively mitigate a broad spectrum of illnesses effectively. In the current era of globalization, business entities are involved in fierce competition. Pharmaceutical companies in the sector compete to offer a diverse array of pharmaceutical products that are guaranteed superior quality. A thorough understanding of the Consumer Protection Law is essential for customers to prevent being deceived or disadvantaged in their future transactions.[1]

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1 DSLA, 2020. https://www.dslalawfirm.com/id/ protectonan-consumer/aimp/ diakses pada 9 January 2023

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Janus Sidabalok asserts that the protection law, consumer law, and regulation govern the rights and responsibilities of buyers and sellers to meet consumer requirements and establish rules to safeguard consumer interests—guidelines to ensure legal safeguards for the rights and welfare of consumers.

In order to comply with requirements, two medications need to go through a declaration process and be registered and certified by the Food and Drug Supervisory Agency (BPOM). Nevertheless, the distribution of medications does not guarantee the safety and well-being of users. An occurrence that took place was the emergence of acute renal failure in children in Indonesia in mid-2022. The Ministry of Health (Kemenkes) and the Indonesia Pediatricians Association (IDAI) have documented a rise in reported cases till the end of 2022, spanning 26 provinces in Indonesia, including one province of West Java. [3] Considering the patient's toxicological analysis and investigation into the drugs they consumed, along with references from the World Health Organization (WHO), it is probable that the case was caused by toxic chemical compounds present in children's syrups and vitamins that have been in circulation in the community.[4] This is questionable because the drugs in circulation should be registered according to the quality standards determined by the government.

Consumer Protection aims to safeguard consumers by ensuring the presence of legal certainty. This entails establishing a clear and defined framework that guarantees that all actions taken by businesses are not arbitrary and provide legal protection to consumers, thereby safeguarding their legal interests.[5] Relying solely on the government's involvement in creating rules and enforcing laws through product supervision operations is not sufficient for the effective implementation of consumer protection laws. Business entities are expected to actively comply with consumer protection legislation in cooperation with the government.Given the concerns raised by the author on the escalating problems in the community, it is imperative to prioritize safeguarding consumers in relation to the distribution of children's syrup medications that may include hazardous ingredients. How can we guarantee consumer legal protection in the case of distributing children's syrup drugs that contain hazardous ingredients? What are the responsibilities of firms in manufacturing children's syrup medications that contain dangerous ingredients?

[2]Sida Beam, 2014. Jainus. *Consumer Protection Laws in Indonesia*. Bandung: Citra Adityai Bakti, p. 39

[3]Secretary of the Republic of Indonesia, (2022), *Cases of Acute Kidney Failure in Children Increase, Ministry of Health Asks Parents to Be Vigilant,* Available from: https://setka ib.go.id/kaisus-gaigail-ginjalakut-pada-anak-meningkat-kemenkesminta-orang-tua-waspa idai/i. Accessed on May 18, 2023.

[4] Secretariat of the Republic of Indonesia, (2022), *Explanation of the Minister of Health on Cases of Acute Gastrointestinal Disorders in Children,* Availaible from:https://setkab.go.id/penjelasan-menkestentang-kasus-gangguan-ginjal-akut-padaanak/. Questioned on May 18, 2023.

[5]Ahmad Miru and Sutarman Yodo. 2004, *Protection Law in Consumers,* (Jakarta: PT. Raja Grafindo Persa da,) p. 1.

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B. Research Methods

The study utilizes normative legal research as its technique. This study defines the concept of law as either the written legislation and regulations (referred to as "law in the book") or as a guideline or norm. However, law can also be interpreted as the tangible execution of legal concepts (law in practice). There exist six distinct categories of research, with one of them being qualitative research. The way to realizing that the interior qualities of persons influence all the consequences of human-made environmental is to do qualitative study that focuses on humanism and human behavior impacts.[7] The focus of this research is to examine the legal protection provided to consumers against the distribution of drugs that include dangerous ingredients.

C.Literature Review

The Constitution of the Republic of Indonesia, Chapter 1, Paragraph (3), explicitly declares that Indonesia is a constitutional state. The theory underpinning this research is the theory of legal protection. The government enforces the legal safeguards for customers as stipulated in Law No. 8 of 1999, which pertains to consumer protection. Consumers endeavor to establish legal certainty to safeguard their rights and interests.

Health refers to the whole well-being of an individual, encompassing their physical, mental, spiritual, and social aspects, which enables them to lead a productive life. Medications are crucial in healthcare systems for illness management and control. Medicines that are produced and distributed must adhere to the necessary standards and undergo registration and certification by the Food and Drug Control Agency (BPOM), responsible for overseeing the circulation of all drugs and food in Indonesia.

Customer protection is a regulatory framework that ensures that every customer is entitled to safety, health, and security while purchasing goods and/or services. It establishes regulations that outline the responsibilities and forbidden actions of businesses. The regulations governing consumer protection in Indonesia are outlined in Law Number 8 of 1999, also known as the Consumer Protection Law (UUPK). This law covers various aspects such as consumer rights and obligations, the rights and obligations of businesses, prohibited actions for businesses, and the responsibilities of businesses. Additionally, the National Consumer Protection Agency (BPKN) plays a role in enforcing these regulations. Chapter 4 of the Law governing consumer rights states that consumers are entitled to receive products that are comfortable, safe, and provide protection. This means that consumers must be safeguarded from any potential risks to their health, life, or property that may arise from the use or consumption of purchased products.

6 Jonaiedi Efendi, Johny Ibrahim, 2018, *Research Methods* in *Norm Law* itif *da* inEmpiris, Jaikairtai : Kencainai, p. 124

7Anton Wibisono, 2019,https://www.djkn.kemenkeu.go.id/a irtikel/*ba ica i/12773/Meunderstand-Method-*

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C. Result and Discussion

Chapter 7 of the UUPK stipulates that business actors are obligated to provide precise, clear, and honest information regarding the composition of their products. In addition, they must ensure the quality of their merchandise and provide restitution in the event that their product causes financial harm to consumers. Chapter 8 of the UUPK delineates the actions that business actors are not allowed to engage in. The statement clearly prohibits corporate entities from manufacturing and selling products that fail to fulfill the prescribed criteria outlined in laws and regulations. Furthermore, they are forbidden from engaging in the exchange of tainted medicinal preparations without furnishing precise and thorough information. According to the aforementioned laws, it may be inferred that the manufacturers of syrup pharmaceuticals are not meeting their commitments in accordance with the legislation. Their production involves the use of hazardous substances above the specified limits and results in pharmaceuticals that fail to fulfill the necessary quality criteria. This lack of adherence to regulations not only infringes upon consumer rights but also presents potential health hazards. Furthermore, these corporate entities are involved in illicit practices by manufacturing and selling pharmaceutical items that fail to meet the necessary criteria and distributing tainted medicines without furnishing precise and comprehensive details.

Consumers have the right to receive compensation for any harm they suffer as a form of legal safeguard. Furthermore, it is imperative for corporate entities to assume accountability for their actions in compliance with the applicable legislation. The Indonesian government has enacted Law Number 36 of 2009 on Health to safeguard consumers in the country in their acquisition and utilization of medications. The law, particularly in chapter 98 paragraphs (1) and (3), requires that pharmaceutical compositions adhere to specific standards. The criteria encompass safety, efficacy, superior quality, and affordability. Furthermore, the legislation establishes criteria for the acquisition, retention, treatment, advertising, and dissemination of pharmaceutical products. These requirements must be in accordance with the quality standards for pharmaceutical services set by Government Regulations. As per Chapter 106, Paragraph (3) of Law Number 36 of 2009 on Health, the government is authorized to revoke distribution permits and require the withdrawal of pharmaceutical preparations and medical equipment from the market if they fail to fulfill the requirements of quality, safety, and efficacy. These products may be confiscated and annihilated in compliance with the applicable laws and regulations. The business entity has violated regulations by producing and distributing children's syrup drugs that do not meet the quality standards specified in the applicable regulations, resulting in excessive contamination of EG/DEG beyond the safe limit.

Thus, in accordance with the aforementioned requirements, the Indonesian government organization, BPOM, which is responsible for overseeing pharmaceuticals and food in the country, has responded by enforcing administrative penalties on the relevant businesses. This entails the revocation of the CPOB certificate and drug distribution permit certificate, discontinuation of medical syrup manufacturing, withdrawal of the drug syrup from circulation, and disposal of all current stockpiles of medicinal syrup.8 The author suggests that the government and allied agencies should give priority to and improve the effectiveness of drug supervision, for both drugs that have not yet been disseminated and those that have already

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been spread in the community. Furthermore, it is imperative to enforce severe sanctions on enterprises that breach regulations, with the aim of deterring them from participating in deceptive medicine manufacturing. This will guarantee that pharmaceuticals ingested by the public are considered safe for health and protect consumer safety.

Responsibility of Business Actors for the Production of Children's Syrup Drugs Containing

Hazardous Ingredients

Chapter 19 of Law Number 8 of 1999 on Consumer Protection, often known as UUPK, delineates the legal framework governing commercial entities' responsibility in safeguarding consumer rights. Under this legislation, commercial entities are required to compensate customers for any harm suffered as a consequence of consuming goods and/or services produced or traded by them. Compensation might be provided in the form of healthcare and/or remuneration, as mandated by applicable laws and regulations. Remuneration is given within a 7-day period of leniency after the transaction. Nevertheless, offering compensation does not absolve the potential for criminal prosecution in the event that more proof of wrongdoing is discovered. Moreover, compensation is not applicable if the business actor can provide evidence that the error was caused by the consumer.

As per Chapter 19 of the UUPK, if children's syrup drugs are discovered to contain excessive levels of EG/DEG contamination, resulting in acute kidney failure in children, the accountable business entities are obligated to offer compensation in the form of healthcare and/or financial restitution as specified in the applicable legislation. Consumers who have suffered injury from using these products have the legal entitlement to initiate criminal actions against the corporate organizations implicated.

The concept of liability, which is predicated on the assignment of fault, is a universally applicable principle in both civil and criminal law. This notion posits that an individual can be held legally accountable if they have participated in any type of wrongdoing. According to Chapter 1365 of the Civil Code, an unlawful conduct is defined as a behavior that must satisfy four key criteria: the presence of an action, the element of mistake, the occurrence of a loss, and the creation of a causal connection between the mistake and the loss. In the case of children's syrup drugs causing acute kidney failure in children, the pharmaceutical industry, as the entity responsible for manufacturing the drug, has made a mistake by using a combination of drug solvents that are not recommended and exceeding the safe limit established by regulations. This error has led to both monetary damages and a risk to the well-being of the general population. Therefore, the pharmaceutical industry is obligated to provide compensation for the medical expenses accrued by the individual and restitution to the individual's family if it is found liable for the consumer's demise.

The BPOM is taking measures to address the problem of children's syrup drugs that have excessive amounts of EG/DEG contamination, which is a violation of regulations. As a result, significant penalties are being imposed on the Pharmaceutical Industry responsible for this issue.

8 BPOM RI, 2023, Pocket *Book Series on Handling Cases of Ethylene Glycol and Diethylene Glycol (Eg/Deg)*

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.Administrative sanctions given by BPOM are in the form of warnings, stern warnings, the issuance of a certificate of Good Manufacturing Practices (CPOB) and a drug distribution permit certificate, as well as ordering the pharmaceutical industry that owns a distribution permit to stop the production of medicinal syrup, return the letter of intent for the distribution permit of all medicinal syrups, withdraw and ensure that all medicinal syrups have been withdrawn from circulation and destroy all stocks of medicinal syrups.[9]

The pharmaceutical business responsible for the infringement in the case of children's syrup pharmaceuticals causing acute kidney failure was found to have utilized Propylene Glycol solvent as raw materials, resulting in the creation of medical syrups containing excessive amounts of EG and DEG, which beyond the acceptable level.

According to Law Number 36 of 2009 on Health, there have been accusations of criminal acts by business entities involved in the production or distribution of pharmaceutical preparations that do not meet the required standards for safety, effectiveness, usefulness, and quality.

This element means violating the provisions of Chapter 98 paragraph (3) so that the pharmaceutical industry concerned can be criminally prosecuted in accordance with Chapter 196 which states that: "Any person who deliberately produces or distributes pharmaceutical preparations and/or medical devices that do not meet the standards and/or requirements for safety, efficacy or usefulness, and quality as referred to in Chapter 98 paragraph (2) and paragraph (3) shall be sentenced to imprisonment for a maximum of 10 (se ten) years and a maximum fine Rp1,000,000,000.00 (one billion rupiah)." The second allegation is a criminal act with elements of trading goods that do not meet or are not by the required standards and provisions.

Legislation and regulatory frameworks. This element indicates that it has complied with the regulations stated in Law No. 8 of 1999 on Consumer Protection, specifically in Chapter 8, which prohibits certain actions by business entities. Furthermore, according to Chapter 62, paragraph (1) of the same law, business actors who violate the provisions mentioned in Chapter 8, Chapter 9, Chapter 10, Chapter 13, paragraph (2), Chapter 15, Chapter 17, paragraph (1), sub-paragraphs a, b, c, and e, paragraph (2), and Chapter 18 may face a maximum prison sentence of 5 years or a maximum fine of Rp.2,000,000,000.00 (two billion rupiah). According to a press conference held by the Criminal Investigation Branch of the National Police regarding the case of children's syrup drugs containing harmful substances that lead to sudden kidney failure, it has been announced that 7 pharmaceutical companies and 4 individuals have been identified as suspects. The Offender

The Investigation Branch of the National Police has also arrested the suspects who are the President Director of the Pharmaceutical Industry concerned and are currently conducting further investigations and examinations.[10]

9 Communication with in Bapak Endang Yaya Selaiku Perwakilan Bagian Information and Communication Balai Besar Pomn Bandung City Pada Har Friday 7 July 2023 at 13.30

10 TribunGayo.com, (2023), *DPO of the Acute Kidney Failure Syrup Drug Case for Children, 2 Company*

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In the author's opinion, the existence of a case of circulation of children's syrup drugs that contain dangerous ingredients and cause acute kidney failure proves that there is still a lack of awareness of business actors in complying with laws and regulations on consumer protection in Indonesia.

Business entities responsible for manufacturing pharmaceuticals must ensure the production and maintenance of their products' quality, as well as their efficacy, in accordance with existing regulations. The government should enforce stringent penalties on business entities that violate regulations in the production and/or trade of products that pose a risk to consumers. This will serve as a deterrent for violators and prevent them from repeating their mistakes, ultimately ensuring consumer protection. Business entities that engage in misconduct should be subject to criminal, civil, and administrative liability according to relevant regulations in order to ensure that customers are granted the right to compensation for their incurred losses. Individuals who have ingested children's syrup medications contaminated with EG/DEG are eligible to hold business entities accountable and seek compensation and restitution from the relevant business entities. BPOM takes action by imposing administrative sanctions on business actors who have committed infractions as a means of holding them accountable. Business entities that have been demonstrated to have committed violations and satisfy the criteria of a criminal act must bear criminal liability in accordance with the relevant regulations.

E.Conclusion

1. In Indonesia, consumer protection is ensured through the implementation of regulations outlined in Law No. 8 of 1999 on Consumer Protection. These regulations cover various aspects, including the rights and obligations of consumers and businesses, as well as prohibited acts for businesses. Additionally, Law Number 36 of 2009 on Health ensures that pharmaceutical products meet quality standards set by existing regulations, guaranteeing their safety and effectiveness for consumers.
2. Business actors who are found to have caused losses to customers are required to fulfill their responsibilities by being held accountable criminally, civilly, and administratively in accordance with relevant rules. According to the relevant legislation, individuals who have experienced financial losses

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